Exhibit 1
Paul Solis: Speaking is Paul Solis with the Office of Congressional Ethics. I'm joined by my colleague, Jeff Brown. We're here for an interview of Representative Chris Collins on June 5th, 2017. Representative Collins is joined by his attorneys, Mark Braden and Maggie Abernathy. I have provided Representative Collins a copy of 18 U.S.C. 1001. He has signed the acknowledgement form, acknowledging that I did give him a copy of the statute. So with that, we can begin. Representative Collins, just a little bit of background, very generally – what is Innate Immunotherapeutics?

Rep. Collins: Okay, got two hours? I think I would take you back to a company called Virionyx. Virionyx has its roots back in the late 1980's, early 90's, as a company that was a private public entity in New Zealand, focused on a cure for HIV. The scientist, Dr. Frank Gelder, was the head of transplant at LSU and had an autoimmune disease. As part of that, he developed as an MD/PhD, a drug that would hopefully save his life and allow him to survive what was considered a deadly autoimmune disease. That in fact is the drug that we are now using in the secondary progressive MS trial.

Paul Solis: And that is MIS416?

Rep. Collins: Correct. So it's an adjuvant. An adjuvant is a basic stimulant to the innate immune system. You've seen it in vaccines all the time. It's a way to stimulate the immune system. So if you get a vaccine, the body accepts the pathogen, the virus if you will, and then the antibodies, that'll help you ward off future attacks, whether it's influenza or could be any number of things. So, the company goes back to Frank Gelder, head of transplant at LSU, came up with this adjuvant to basically cure himself. And as an MD/PhD, you're allowed to do that. You can experiment on yourself – can't experiment on anyone else. And it turns out, you know, to have had qualities that had never been seen before. So, Frank Gelder, who thinks out of the box – we'll leave it, go with that – one day was asking himself the question – many people think like this – why doesn't a woman abort her fetus? A fetus is a foreign object to self. So he didn't because he was working on transplant and rejection of organs, his mind went there and he studied fetus. He studied why the immune system doesn't attack and he found proteins that surround the fetus and hide it from the immune system so it's not attacked. It's just nature's way of doing what it does. And the more he studied it, he discovered these are the same proteins that hide HIV within the human body. Hence, the human body doesn't fight HIV. Pretty straightforward stuff. So in the way Frank Gelder thinks, you have to know him to appreciate this; very unique guy. He said to himself, "Hm, I wonder if there's some lessons here." And he thought, maybe he could – now that he understood how HIV was hidden – he could attack HIV the way we attack snake bites. And some other things where you grow antibodies in a foreign species and inject them into a human being and end up with a cure for rattle snakebite. So the more he thought about it, he said, "well why don't I relocate to –", in fact, he was actually one of the folks early involved in – because back in that point age was a deadly...
disease. There were no treatments and we didn’t know about what went in on in Mexico. He was part of that. So he went to New Zealand. New Zealand’s the only animal disease free state in the world. And he said, “I’m going to work on developing a cure for AIDS.” Actually HIV, Aid’s is just HIV – you know the aftermath. And he said, “If I’m going to have a drug it better be produced and I’m going to grow it in animals.” Much like you do rattlesnake venom. He said, "I'm going to inject goats with HIV, I'm going to use my adjuvant to produce mass of a quantity. I'm going to stimulate the hell out of these goats. I'm going to produce massive amounts of antibodies. We will purify them and inject them into human beings and cure HIV." That’s his thought process. So, he relocates to New Zealand. He does everything he says he’s going to do. Probably through the 90’s, my company – the involvement was, we grew the HIV. So I have a business called ZeptoMetrix and prior life was called, Cellular Products as in your bodies, not your cell phone. That’s why it’s no longer called Cellular Products. And they have level three enhanced and level four biocontainment labs that grow any and all viruses, including HIV. They were the first company in the country to have a test for HIV. So these things are going hand in hand – Frank Gelder contacts the business I own now, ZeptoMetrix, or half of and –

Paul Solis: Do you still own that business?

Rep. Collins: My wife does. And my family – my wife, my daughter and then there’s a 50/50 partner Dr. Hengst. So long and short of it is, Virionyx and then Cellular Products, now ZeptoMetrix, relationship began as the HIV supplier to Virionyx, which to raise money, went to 1,800 private individuals, but because the number was so massive under New Zealand’s security law, they became called a private public company. They would adhere to all public reporting, all disclosures, everything you would do as a public company, but they didn’t trade out in exchange. So, he moved right along through phase 1 trials, the drug works; people couldn’t understand totally how it works, but – and it doesn’t kill people. The idea of an immunotherapeutic like this, injecting polyclonal antibodies from another species, it works once, but it’ll kill you the second time. You’ll go into anaphylactic shock and die. So, that’s why it works with rattlesnake bite. Just don’t ever get bit a second time, but if they treat you in a hospital –

Mark Braden: Don’t get bit once.

Rep. Collins: Yeah, but they got a treatment much like what we were doing with HIV, but don’t get bit a second time. But if you’re in a hospital setting and you go into anaphylactic shock, that’s actually fairly easy. You won’t die in a hospital setting, but you would die at home. So, he said to himself, again, thinking out of the box, he goes, “what is AIDS?” You don’t have an immune system. HIV has destroyed your CD4, your white blood cells to where you can’t fight off any disease. So, AIDS, the auto-immune deficiency syndrome, you end up dying of a flu. You end up dying of something because you don’t have an immune system anymore to fight it off. You don’t die of AIDS, you die of
things because AIDS has destroyed your immune system. So Frank Gelder said, “Well you can’t go in anaphylactic shock with the second treatment when your body doesn’t recognize – doesn’t have an immune system.” Okay, that’s thinking out of the box. So long and short of it, he did what no one ever thought to do. Which was grow polyclonal antibodies in goats, using his adjuvant as the super charger so the goats would produce massive amounts of antibodies to harvest. He went into a phase 1A and a phase 2A trial at Harvard, raised – kept raising money as you could imagine was before I was involved. And lo and behold, it works. To this day, I’ll tell you, it’s the only drug that will kill HIV. Everything else treats HIV. And there’s a story there.

So, my company, I didn’t own it at the time, that was the relationship. I got involved with the company – basically it’d gone bankrupt. It’s what I do, one way or another. Back in February of ’99, Jim Hengst, now my partner, he and I acquired the business out of basically bankruptcy and you know, decided what we would do with it. Well we had these labs growing HIV, small business selling them to Frank down in New Zealand. Again, that’s how I got to know the folks. I ran for Congress in 1998. A lot of people don’t realize that. And I lost. So, come the year 2000, I was dutifully working in ZeptoMetrix. We had renamed it from Cellular Products to ZeptoMetrix. Now I got a call from Hillary Clinton and she says, “Would you host me in western New York? I’m the new Senator for New York. I don’t know anyone in western New York. Would you host me? I want a high-tech company and you got it. Could I use the background of ZeptoMetrix to introduce myself to western New York?” And I said, “Well Senator, of course I would. We may not have the same politics, but hey, never hurts to get to know your new U.S. senator.” So I hosted Hillary in like February or March of 2001 after her election and as a result of that, at least got to know her and got to know some of her staff. So, now you go four years later and it’s...well, Virionyx and ZeptoMetrix starting working on other things. If you can make polyclonal antibodies to treat HIV, we could treat SARS, we could treat Ebola, we can treat the bird flu, heck, we can treat anything; anything that’s a virus, we can inject that virus into another species, a neutralized version of it; it’s not live HIV. And using the adjuvant, grow massive quantities of antibodies, purify them, inject them in humans. So we started doing a lot of work together, we formed a company called Buckler Biodefense. We came up with treatments for things like SARS, West Nile, and people were fascinated with anthrax back then. We had the anthrax attack Albany, the Wadsworth Center in Albany was the research institution focused on anthrax and we got to know a fellow named Nick Serono. Nick was the key researcher at the Wadsworth Center. And we started doing joint work, ZeptoMetrix, Virionyx, department of health/Wadsworth Center and we started working on antidotes for anthrax, which is a deadly disease. We split the three toxins into three separate things, injected them into three goats, purifies them all, mixed them together, we called it tri-thrax. We felt as though we had the first post symptomatic treatment for anthrax toxemia in the nation. Nick, being a bit crazy, did some animal studies and he said to himself, and that would be
with Cipro the prophylactic, so somebody’s exposed, you treat them with Cipro, you know post office kind of stuff, they survive because you caught it before it grew in the lungs. Well, if you don’t know about it, you don’t treat it with Cipro. You know in a shopping center, they weaponized anthrax, put it through the heating systems, you know, fill the room up, people don’t realize what happened so they don’t get treated with the prophylactic ahead of time. And next thing you know, it’s like the flu. Well you’re dead 72 hours later. So we had to come up with something post symptomatic. You look like you got the flu, you’re going to be dead in 72 hours and, and, and. So, Nick started playing around with using our drug in combination with Cipro with mice, post symptomatic and found that pretty much 90% of them survived. We really had something there that no one else had. So then he said, “I wonder if I inject the mice with that adjuvant that was used to grow the polyclonal antibody.” You know that really stimulates the hell out of mice or out on goats. I wonder what it would do. So he took a control group of mice and this was deadly anthrax that killed everything in the control room. And lo and behold with just the adjuvant, which is now MIS416, on its own, half the mice survived. Control group, they were all dead. And the mice that died, all went 96 hours instead of 24 hours. Which was a bit of a voila moment. Holy moly, this adjuvant which is just used to – better production of polyclonal antibodies with any virus there is, has some magical things on its own. And yeah, that’s right, that’s what Frank’s been injecting with, by that point, 15 years keeping himself alive. So, we felt we had something. So we – this was now mid-2005. We wanted to get in front of the U.S. military, DARPA and so forth to get some government funding. They were desperate to get something for anthrax. They wouldn’t’ take our phone calls, we couldn’t get together. I called Hilary Clinton, her New York Company or her office. She said, “Let me make an arrangement.” At this point, I wasn’t an investor yet, but because Zepto was linked in with then-still Virionyx, we all decided we would go to this meeting in D.C. with the defense department. Hilary did a great job; she filled the room with 20 of the smartest PhD’s that have ever walked the face of the earth and not one of them wanted to be there. They were there for only one and one reason, the junior senator from New York had insisted they come and so come they did. So Frank Gelder was there, Simon Wilkinson, now CEO of Innate, couple of other scientists, I was there, can’t remember if my partner was or not, Jim Hengst, and then we started the presentation and they just couldn’t wait to get out of the room and they were yawning and they were you know, “we’re not interested. We’re working with five other companies on anthrax; we think we got a solution – by the way, they all failed. We think we got the solution, and from what you’re telling us, you’re too far along anyway, but it doesn’t matter. You could never produce enough product by just injecting – we understand polyclonal antibodies, but you know, you’ll never be able to inject enough goats that make the quantities you need.” And Frank goes, “we have a special adjuvant to boost production.” They said, “Really? Tell us about your adjuvant.” And while I’m not a PhD, he explained it to them and they went,
“doesn’t work. Can’t work. We all know about that.” Basic, for the last fifty years, everyone knows about that particular combination of chemicals that would be an adjuvant, but it’s deadly so you can’t use it. He goes, “well, it’s not deadly anymore.” And all of a sudden, everyone sitting back in the chairs and – and I’m watching this, is leaning forward like this. And one after another, they started jibber-jabbing and they said, “Alright, so tell me what you did. You actually blah-blah,” – their talk. And he goes, ”yes, I did.” And they were looking at each other, they said, “that’s just incredible.” And one says to another, ”What if we injected that into a person? Could you imagine injecting that into a person? We would create like a super-being with this adjuvant to stimulate their immune system. That would be nuts.” And somebody said, “Well we have.” And they went, "you've done what? You've injected human beings with this? You can’t do that. That's – you don’t’ have a trial for that.” And Frank says, ”No, I've been injecting myself and I'm an MD/PhD and I can do that. And I developed it.” And they went, “you’re right. You can. Why have you been doing that?” He told that story and I’ll call it – the excitement in the room, the body language was like nothing I’d ever seen. From people slouching back, couldn’t get ready to get out of the room, to leaning forward, leaning in with a level of excitement that was palatable. So we ended the meeting, we ultimately got no funding. They said we were too far along. They only – this is the federal government – they only invest in early stage companies. We were way too far along. And then they all failed. And we never got the drug in. So I’m chatting with Simon afterwards and he’s going to catch a plane back to New Zealand and – actually no, he was flying into New York City. He says, “Yeah.” I said, “Where are you headed?” and he said, “I’m flying into New York City to raise some more money. We’re out of money again. Virionyx needs some money again. We’re going to see what we can do. I got a broker and an investor that thinks he can raise some bucks.” And I said, “Oh, how much are you trying to raise?” And he goes, “well, about 6 million –“, or it may have been 8, “6 to 8 million dollars.” This was like December 12th or something, whatever the day of the week was, mid-December of ’05. And I said, “Would you have any interest in maybe looking at a proposal from me? If I could get some investors together in Buffalo. What I just saw in this meeting suggests to me you’re onto a real thing here. And you’ve got something that will cure HIV. There’s no two ways about it. And you’ve got other potential applications so, how are you pricing it? What’s the market cap of the company?” And the long and short of it is, he said – so I made – let me make about four phone calls. I made four phone calls and I found people willing to listen. So, I said, “Simon, could you alter the meeting in New York, push it off for a couple of days, fly back to me in Buffalo and we’ll have a meeting with some friends of mine. Let’s see where it goes?” He said, “Well yeah. I’d rather have a small group like yours then some broker out of New York City. There’s no if, ands or buts that would be a preferred way to doing something.” So long and short, he came in, I called a meeting. I brought 20 of my neighbors in, including as you know, coach of the Buffalo Sabres, who’s now the coach of the Dallas Stars. You saw
his name in the paper. I live in an upscale neighborhood with people that have means. And, I consider the slam-dunk. I’ve seen it, it works, it would be the first drug ever to cure HIV, oh my God, oh my God, oh my God, they need 6 million bucks, but they got to have it two weeks’ time. Everyone heard the presentation, they probably should’ve asked more questions than they did. Because ultimately, it failed, so obviously they should’ve asked more questions than they did. So should have I, but I raised 6 million dollars in 96 hours and so over a period of four days, everybody signed up. Priced at a $1.15 a share. We raised 8 million dollars, 6-8 million bucks out of maybe 20 people. I put maybe not quite a million dollars in myself. Maybe 6-7-8 hundred thousand. My kids, minors, but I invested on their behalf and so away we went. Most of the people where they connect the dots, and they see these are all connected to Collins one way or another, of course they are. They were my friends. They were the folks I called the December of ’05. Simon Wilkinson, now CEO, then-president of Virionyx, flew to Buffalo, we made the pitch; we put together a private placement offer; we had – I forget the law firm, but put that together. Everyone was accredited and away we went. Thinking, boy we’re really onto something. We’re going to get to 2B trial going, which would’ve been – FDA would’ve been done at Harvard. And so over the next you know three, four, five, six years, there’s no other product making money. We would run out of money, we would do another placement and I explained to Mark, under New Zealand and Australia law, they have something you don’t have in the U.S. The public company can’t go bankrupt without bankrupting the directors. They have a solvency provision that you have to dissolve a company the day you are no longer solvent to pay all of your vendors, all of your creditors, all of your payroll – including separation fees for employees who will now not be. That’s how they do things over there. Hence, if you’re director of – and you see, Virionyx was considered a public company because they had 1,800 investors back from the 90’s, you take no chances. Unlike in the U.S., take it to bankruptcy, you’re covered with a corporate shield and away you go. So they were very, very – and they’ve always been, the directors were never running out of money because we’re not dipping into my pocket. But so, we kept raising money and raising money and thought all was good until two new drugs came – we got approval around the 2B phase trial. The FDA’s big worry was, “are we killing cells in the body other than HIV?” They said, “We know you have a cure. We know how polyclonal antibodies work. We accept that this will work and our only worry is are you going to kill other cells. You have to prove to us you’re not going to kill the healthy cells. It should kill HIV cells, which we then did. We had full approval to kick off to phase 2B trial. We had enough money to do it and two new drugs came into the market. Unbeknownst us. They continued – they don’t cure it, but no one’s died of AIDS in the last 10+ years because they’re so effective that the treatment keeps the immune system active enough that AIDS is no longer – if you’re on all these cocktails, anti-retro viral drugs, Magic Johnson, you’re just going to keep on living. So bad day for us. A doctor cannot encourage a patient to go
onto a new experimental drug if there’s a current therapy that works. Even
though yours may be a cure and that’s nothing more than a therapy. It then
appeared the company was gone. We had enough – because we never kicked
off the 2B trial, we had enough money to continue to limp on and think
about what else we might do. Was there anything else we can do? We knew
MIS416 had been magical and the mice with anthrax, we knew with Frank
treating himself for deadly autoimmune disease, we saw what it did in the
goats, so... with some research it was decided as an autoimmune treatment,
what would be the disease you would pick? Would you pick ALS? Would you
pick multiple sclerosis to the most foreign known autoimmune diseases?
Well, the bigger markets, multiple sclerosis and lo and behold, there’s a
segment that has no treatment. Secondary progressive, most debilitating,
deadly, awful disease to die from in the world today. 75% women, 25% men,
all European decent, it’s a European genetic autoimmune disorder; so it’s
Europe, Australia, New Zealand, big, big, big in the Northeast United States,
in fact, the biggest in Buffalo, New York. In the family, the folks that
own Delaware North and, and, and, one of their family members died of
secondary progressive MS. So, well known in Buffalo, New York. Again, we’re
inhabited by Germans, eastern Europeans and Irish, deaths with genetic
disorder. So, we decided we’d see if we could do some animal studies and do
some other things and it became something that we thought would actually
work. In Australia especially, you’re allowed to treat deadly untreatable,
otherwise untreatable, diseases with a doctor’s permission on a
compassionate basis, patient permission, so they started treating secondary
progressive –

Paul Solis: And who is, “they?”

Rep. Collins: Virionyx. Provided the drug to physicians to treat their secondary
progressive MS patients absent of trial. So it’s called compassionate use.
Pretty hard to do in the U.S. Not so down under, certainly not in New
Zealand and the results were remarkable. All considered anecdotal, because
it was not a trial; it was not a study. So it wasn’t scientifically based, placebo,
etc., but it worked. And you know you get the reports back from the
physicians and say, “we got something here.” That led into ultimately you
know again, raise more money, raise more money, I was always – I’m more
than one occasion, the company was ready to go down and I made payroll.

Paul Solis: So what was your position with Virionyx at that point?

Rep. Collins: I was – because I led the investor group and we wanted a U.S. person, I’ve
always been on the board of directors.

Paul Solis: Since what time?

Rep. Collins: Since December ’05. So as the person who put together the investor group
and my friends, good friends were looking at me for, “how are we doing?”
You know, I give them an update, “we need to do another private placement,
investor or not, do your research.” Some did, some didn’t. Some have been in
Transcript of Interview of Representative Collins
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an every step, some only did the one time, so I guess it was a bad deal. I'll
take my $1.15 share loss and someday write it up. So I've always been a
director since my involvement, nodding with what they call an executive
director. So anyway, on more than one occasion, I believed in what we were
doing. I just – the compelling stories of Frank and of what we knew was
going on with some of the polyclonal antibodies, I wouldn't let go. So, on
more than one occasion, when they couldn't make payroll and again, at
down under, you don't make payroll, you shut down. If you're not going to
make payroll in the next four months, you shut down, you liquidate, the
directors don't get hit. I mean, it's overwhelming. You don't ever go to the
edge or the directors are going to lose everything. Just an interesting
mindset. So a couple of times –

Mark Braden: Think about what the bankruptcy lawyers do – they don't have anything to
do.

Rep. Collins: Well this is public company. So I don't know I could speak to private
companies necessarily and there's personal bankruptcy as well. But the,
sometimes when they make – you know when they run out of money, I
would loan the money and they'd say okay thank you for the loan, pay us
some nominal interest. We'll give you some options as an incentive and then
they'd see if anyone else will loan money as well and some people did and
some people didn't. It was never just me. So we had a combination of private
placements, combination of loans, sometimes with options you know time
and again, right up against the wall so I did this 2-3-4 times and...so things
started to look well on the secondary progressive. We did toxicity studies,
we got waivers because of everything we had done with the adjuvant prior,
especially in the animals. We ended up getting approval to do the 2A
trial by Medsave, which is the FDA equivalent in New Zealand. Timing was
probably 2010ish or something like that.

Paul Solis: Is Virionyx a New Zealand company at this point? Or Australian company?


Paul Solis: Okay.

Rep. Collins: So, we got permission to do the 2A – long and short of it, 2A was funded.
Again raising more money because they never had income or revenue. And
we launched into the 2A trial in New Zealand which was a basically safety
trial. Not double-blinded, not a placebo base to prove safety. But long behold,
we got some efficacy indication out of it. You know the feedback was very
positive, we knew every patient was on the patient, no placebo. I can't tell
you how many 20ish patients, something like that, but actually quite
compelling. Through the 2A trial, we discovered it doesn't work on
primary progressive because we didn't know. That's why you do trials. We
figured out the dosing at 500 micrograms. We looked at the timing of it,
again that's what you do in a 2A trial to kind of lock down the dosing, the
interval, etc., etc., and it was concluded successively. Little longer, they
always take a little longer than you think. Again, out of money, out of money. So, we decided alright, now we’re going to do a 2B trial. The investor based was tired. I was tired. My friends were tired. The New Zealanders, some of them invested at $10 a share. When this company went – was first formed back then, it was $10 a share. Then these folks had been in at it for 20 years. Some of them had died. There was no market for them. The high risk of drug development, especially when you got one. We ended up by a miracle of miracles, we ended up with a second drug. Normally the HIV goes down and you’re toast. Everyone loses everything, but the adjuvant as a standalone, which was surprising, ended up to have its own potential second market so the decision was made in mid-’13. There was only one way to raise money, we got to go public. And, we looked at the U.S., we looked at the brokers in the U.S., we looked at the fees in the U.S. They were all enough to choke a horse. Lo and behold, Australia came out with an incentive for R&D. They would reimburse 40% of any R&D done in Australia as an incentive. Saying if the R&D’s done it here, the jobs may come here. And they considered drug trials that would qualify for that. Kind of became a no brainer, somebody’s going to reimburse 40% of the trial cost, that’s money we don’t have to raise and indications didn’t quite work out. Indications were some aggressive brokers in Australia said that this would be a no brainer. What you’re doing in this size of the market, you know secondary progressive MS, what you’ve got in your 2A safety trial with efficacy and, and, and – this would be a no brainer. So they convinced us that they could succeed. You know we – so it’s an IPO in Australia. So it’s always been a public company, but it was not listed. So the first listing where people could trade it was in the Australian offer in December of ’13 and so clearly again, myself and others, we could not participate in an Australian offer, so and it’s not SEC, so we would do a private placement in the same terms as the IPO. So, did the IPO in Australia, New Zealand, private placement in the U.S. and got some new people in, some old people in and –

Paul Solis: Is that when the name changed to Innate Immunotherapeutics?

Rep. Collins: Yeah. It – actually, the name changed right after the HIV failed. So, probably 2008 or ’09. This has a bad taste. People hear the word Virionyx at $10 a share and lost a shit ton of money. They burned through an incredible amount of money back then. And so it was toxic, a toxic name. So now that it was no longer polyclonal antibodies, but a standalone adjuvant that stimulates the innate immune system, well guess what, Innate Immunotherapeutics. So the name was changed strictly to introduce the standalone drug for secondary progressive MS for the standalone drug called – which at the end, Innate has better, MIS416’s grown – you know just grows in a lab, we’re not injecting goats, we’re not plasmapheresing the blood, and purifying it, so it’s way better than our polyclonal antibodies. So we’re going to do the – we did the offer, Australian IPO. The brokers said it’s going to be oversubscribed. We had to raise 10 million bucks. He goes, it’ll be oversubscribed so the whole argument was what do we do with the
oversubscription? How do we cut people back? Who gets cut back first? How
do we cut people back in the U.S.? How do we cut back people in these other
places and so forth and so on. So I'm a happy guy, I'm putting in what I'm
putting in to keep my ownership at a 15ish-16ish percent range. My kids
own 1 or 2 percent so maybe after – you can't go over 20% in Australia
without hitting it with what they call a takeover...and effective takeover if
you go over 20%, you have to pull yourself back to 20%. So, the penalty is if
you're 21% you got to sell 1% to get back to 20%. I guess you would
consider that some kind of effective control so, I made sure it I wasn't there.
And I can't remember my kids' ages, but at that point, I made sure the four of
us – the three of us weren't there. They were under, I forget, 21. So I got the
phone call, I'm all in. I'll do 15% or whatever and I got a phone call on a
Thursday that the broker failed. That he not only didn't go over, he was way
under he was under by 1.3 million dollars. He raised 8.7. He didn't raise 10
million bucks. And if you do a public offering you neither – and the money
that was there, was going to have to be returned to all the investors. You
can't cash the check and spend it unless you've had a successful IPO. This
was a failed IPO. Raised 8.7, could've been 12, minimum at 10. Anything
short of 10, you're done. I got the call Thursday afternoon at like 11 in the
morning because it's Friday there, they're 16 hours ahead, “Chris, we got
some really bad news. The IPO failed. We're done. We have to close our
doors, we have to return our money. I don't know if there's anything you can
do with 24 hours' notice, but here's the facts. You raise 1.3 million dollars
the next 24 hours, we call it a success. We move on, otherwise the company's
done. Everything’s gone. Everybody loses everything.” Not a good day at my
family table again. I go home to my wife and I said, “we don't have any
choice.” So I put in 1.3 million dollars, luckily I had it in the bank, wired it to
Australia in the 24 hour timeframe. It was there when they opened at 9am,
Australian time on Monday. It actually went through on the weekend. There
was an issue of whether me getting it because of the 16 hour time difference
and the lawyer said, “no, if it's there at 9am, their Australian opening time,
it's a success.” So I did. That’s how I ended up at a higher percentage than I
wanted to be, which is give or take 18ish percent right now, but all of a
sudden now we're still alive. And so, the long and short of that was, the
trial's been moving along, way slower, we didn’t realize how hard it would
be to recruit patients in Australia. In some countries, U.S. and Europe and
Australia, the doctors won’t tell their patients they have no treatment
options. So they treat them with a relapsing remitting drug that doesn’t
work and the doctors know it doesn’t work. It's $60,000 for patients. They
don't do it in New Zealand; they budget differently. You're declared
secondary progressive, you've taken off all drugs, you're told nothing's
working, but it was hard – we had to have clean patients that weren't on any
drugs. We had to get the physicians in Australia to finally fess up to their
secondary progressive patients that they’d been getting injections through
relapsing remitting MS and the injections weren't working and won't ever
work. And they would suggest they stop the injections and once they're
clean for 60 days, they can go on an experimental trial, which was our
MIS416, but I forget, I think 30% are going to be placebo. So it’s not a good
day if you end up on the placebo because it was a double blinded placebo
based trial.

Paul Solis: I want to ask about the trials a little bit. But first –

Rep. Collins: So let me just finish this up right there. We got the trial approved; it took 2
plus years longer than we thought. I’m trying to remember when the first
patient was injected, but we didn’t get the last patient injected until April
of ’16. Which was why the trial ended April the ’17. It was at least 2 and a
half years that we thought would be 1 and a half years. So, again, during that
time, raise more money, because spend, spend, spend. Everything’s more
expensive than it’s supposed to. More private placements, blah-blah. I did
every step of the way, never missed one. And a couple times with you know
pricing, risk, I bought more. I was probably the only one that believed in it; A
to Z, start to finish, and then a few times I had no choice, put my money in it
or they would’ve died and that’s kind of where we are now. We’re –
including the last time we had to raise money, which was June of this year,
that was with Tom Price and myself and some others invested. Because of
this strict requirements on directors, we needed 4 more million dollars. So
we did the rights offer in Australia, I matched it with a private placement in
the U.S. which is how we had always done it because we’re not SEC. The U.S.
investors couldn’t participate in the rights offer – same price, it was .28 cents
New Zealand, .26-7 cents Australia, .18 cents U.S. – slight discount to the
market, to – because, well it’s not exactly a wildly traded stock.

Paul Solis: I want to talk about that too in a little bit.


Paul Solis: It’s okay. No, no.

Rep. Collins: You’ve almost got to go back to Frank Gelder, you got to go to the HIV, you
got to go to Hilary Clinton and you got to go to DARPA, you got to go to
anthrax. I mean this is ... we could make a movie out of this, truly.

Mark Braden: I hope it has a happy ending that actually cures people.


Paul Solis: Well no, I appreciate the background and that’s helpful I think to understand
the situation here. So, you’re currently on the board? Right?


Paul Solis: Okay and are you at all compensated for your role in the Board?

Rep. Collins: No and I cleared that through ethics. When I came to Congress, and Mark
handled this, I had a very complicated private sector situation. And we met
with ethics and the result was some of the businesses were put into my
wife’s name, others are still in mine. I got clearance from ethics to remain on
the board of ZeptoMetrix and a few other companies as well as Innate. All
not compensated. And in fact I can tell you, I went to ethics, the other
directors are compensated, give or take $30,000 a year with options. I said,
“I can take them, but can I have the company donate to the Boy Scouts of
America? My organization of choice.” And ethics came back and said, “No.”
They said, “That’s compensation.” I said, “What are you talking about?” They
said, “I believe someone will thank you for that.” I said, “Well, probably.”
“Well gratitude is compensation. So no you cannot director your director
fees nor your options to the boy Scouts of America.” That’s where I think
things got a little looney to me. So at this point, you know the Boy Scouts
would’ve probably had about a $160,000 of cash and options and something
that could be a good thing, instead they got nothing. So if you see, and I’m
sure you have all the annual reports and anything else, they always have an
asterisks next to my name and that says non-compensated, no options. By
the way, I’ve never been paid a commission, never been – never did anything
that wasn’t at exactly the same price going all the back to 2005. I wouldn’t
sleep at night if I did and yeah. Certainly all those shareholders would
acknowledge that as well.

Paul Solis: What markets is Innate currently traded on? What countries’ markets?

Rep. Collins: Well, it’s only Australia, officially. It’s on the AUX market. I think today was
about .76 cents with about a .74 exchange to the U.S., but a market popped
up maybe a year ago, pink sheet NASDAQ, so that’s just the wild west of
brokers in the U.S. buying it on the Australian exchange and they created a
symbol, INNMF versus IIL. And first there was one broker and I understand
now could be four or five brokers who it does trade on NASDAQ, over the
counter pink sheet unregulated, wild west – lo and behold, Morgan Stanley
and some of the others let their fidelity, they let their clients buy it. So there
are people in the U.S. which are not accredited investors who are buying it
on NASDAQ through the pink sheets; the company has nothing to do with it.

Paul Solis: And you know how long that’s been going on?


Paul Solis: About a year.

Rep. Collins: So, Innate has nothing to do with that. The Australian market has nothing to
do with that. It’s just the wild west of NASDAQ, pink sheet brokers. So...

Paul Solis: Who works at Innate? Does it have a staff?


Paul Solis: 14 people. And –

Rep. Collins: Research, quality control, production, we actually produce the adjuvant. We
grow it. It’s growing in bacteria. We’ve had to then you know, purify it to
being pharmaceutical grade in a GMT facility which we have. The small quantities of, give or take, 100 patients.

Paul Solis: Is the CEO Simon Wilkinson?

Rep. Collins: Yes. President and CEO.

Paul Solis: Who is Jill or Gill Webster?

Rep. Collins: Yeah. She’s the chief scientist.

Paul Solis: How long has she been in that role?

Rep. Collins: 6-7 years?

Paul Solis: Okay.


Paul Solis: And how often are you communicating with management at Innate? Either Ms. Webster or Mr. Wilkinson?

Rep. Collins: Well really it’s only our board meetings. We have quarterly board meetings. There could be an occasion for an emergency board meeting and there’s six or seven of us on the board. Mike Quinn is the chairman, so usually because of the time difference it’s about 7o’clock – 6 or 7o’clock depending on daylight savings time here, which is usually 9-10 in the morning the next day there. So we – I’ll be on the phone at 7o’clock Tuesday night and they’re on the phone their time, Wednesday morning.

Paul Solis: What about aside from board meetings? Would you ever phone call with Mr. Wilkinson? Or exchange an email?


Paul Solis: Okay, how often would you say that happens?

Rep. Collins: Well it depends what would be going on if – I mean many cases, certainly going back to ’05, I would be inviting him to Buffalo to present to our shareholders. Just kind of the update. He routinely went to, I think it was San Francisco for the annual pharma-bio conference and then he - because he’s already here, he would link in other visits from trips. I mean at some point it was to Harvard, because stuff was going on or whatever. He’d usually would come through Buffalo. I’d call all my friends in, we’d have wine and some hors d’oeuvres and he’d update everybody on what was going on.

Paul Solis: Does he ever come to D.C. to see you?

Rep. Collins: No. So, those were pretty regularly like I want to say at least once a year. And whenever we did a new placement, he would try to come, not always to explain what they were doing, the progress, you know the capital structure, how it was priced, so yeah. That kind of thing. I mean, yeah.
Paul Solis: You mentioned your family members hold some Innate stock. Which members of your family?


Paul Solis: And you said around ... is it 1 or 2% they hold?

Rep. Collins: They each hold right at 2%. So together about 4. And I'm at about 18.

Paul Solis: What about members of your congressional staff? Do any of them hold stock at Innate?

Rep. Collins: Yeah, most of them.

Paul Solis: Most of them. Could you name those individuals?

Rep. Collins: Well, certainly Michael Hook, former ... Michael McAdams, my district director Michael Proctor –

Paul Solis: Michael McAdams is no longer with your office?


Mark Braden: Probably the Republican Senatorial committee.

Rep. Collins: Yeah. Ted Alexander, but he's no longer with me either. He's gone to work with a law firm. He was my LD. At least heard rumblings and I never pressed them on it, but I'm pretty sure Erin Hook, whose Michael Hook's niece.

Paul Solis: She's currently serving in your office?


Mark Braden: Probably the Republican Senatorial committee.

Rep. Collins: Yeah. Ted Alexander, but he's no longer with me either. He's gone to work with a law firm. He was my LD. At least heard rumblings and I never pressed them on it, but I'm pretty sure Erin Hook, whose Michael Hook's niece.

Paul Solis: She's currently serving in your office?


Paul Solis: Yeah, she's my senior LA on telecommunications; she's been with me since I came here. Let's see...I know Chris Catt, my office manager in my Geneseo office owns it. I don't know the other particulars. I do know all of them own it and we – they all laugh about it. Because they pretty much all bought it on the wild west NASDAQ as they bought $100 worth, $1000 worth.

Paul Solis: And they told you they bought it?


Paul Solis: Okay. Did they have any conversations with you prior to buying it?

Rep. Collins: No. But I talked about it all the time. They know – I've certainly not made any...I think one of the things was, "who in Congress have you talked with about Innate?" And I said, "The bigger question would be, who haven't I talked to?" It was probably of all the things I will accomplish in my life, this will be number one on my tombstone. If because of my involvement, we have all the cured secondary progressive multiple sclerosis, the most debilitating disease known to mankind.

Paul Solis: Well you've talked about –
Rep. Collins: Without me, it would’ve gone down.

Paul Solis: You’ve talked about – you know, your initial discussion about the sort of the background of the company and the work that it’s doing. So you’ve talked a little bit about the drug and what it does. And I think you mentioned it’s the only compound that Innate produces right now, one that it works with.


Paul Solis: So, you talked a little bit also about the trial program right now and so can you tell me more about that? Is that just happening in New Zealand or is that also happening in Australia?

Rep. Collins: No, no. It was an Australian based trial; that’s how we got the 40% reimbursement. We opened up six trial sites with the promise that everybody will be loaded up in 90 days. So, we’re a year and a half in and we’re still not loaded up because excuses, excuses, excuses – the biggest issue was, the doctors wouldn’t be honest with their patients. And they would keep them on relapsing remitting drugs at very high cost which were not doing a thing. It was effectively a placebo and patients were still going down and they didn’t want to be honest with their patients. So, the patient will be like, “Well you tell me I got to get off this drug you’ve been giving me, doc. And I can’t be on it anymore and for the next 60 or 90 days, you know it’s got to clear my system and then I can go on this trial and 30% of them are in placebo. You know, doc, what’s going on?” And these doctors had just not been honest with their patients so, that was something we never saw coming. We just never...maybe we should’ve, we didn’t. So at the end, we opened two more trial sites in New Zealand. So they don’t have that problem, we filled those up fast.

Paul Solis: So there’s two countries right now where there’s trials being conducted?


Paul Solis: And now are those trials being governed by a –


Paul Solis: Those countries’ versions of like an FDA?

Rep. Collins: Yes. We have a CRO – clinical research organization – that coordinates everything. We also have a safety board, some of the top MS physicians in the world that are at a moment’s notices, if there’s a potential adverse event, they would have to decide is this reportable to the authorities in Australia and New Zealand? As an adverse event, we’re not and we’ve had a couple of instances where rashes, significant rashes – if somebody pulls out, you know, typically if you kick the immune system, you get a migraine – something like a bad, bad, bad case of the flu. You get a migraine, headache; you get fever and chills, so the irony is that everyone knows that they’re on the placebo or not. Social media, you know because the impact they kick in the immune
system is fever, chills, and probably severe headaches for at least the first four doses. So if you got nothing, you're on the saline. And a few patients overreacted to the migraine, headaches. I wasn't expecting this. So we've had maybe 8 patients drop out. Couple of adverse events that the safety board had to look at and they're independent, the company to determine whether or not these are reportable, how they're reportable. So now this, med safe in New Zealand and I forget what the organization is in Australia, abide by all the FDA requirements for safety, for advisory boards, for safety committees, for reporting, GMP manufacturing, it's – they're all, in fact it'll be the same way.

If somebody bought it the trials from either the safety board or the CRO, in other words, what's the interaction between Innate and the trials and ultimately some sort of adverse event?

Well, Innate has no interaction that I know of. We make the drug and that's it. At this point, the drug is provided to the physicians and to the research locations which all have their own oversight. So if a hospital is just – just like in the U.S. – a hospital's going to conduct a trial on any disease and has to go through what they would call ethics approval, to the hospital's safety committee to recognize the ethics of the drug, who's being recruited, that the efficacy, the safety – so all that's run by the clinical research organization, the CRO. They take care of everything. We've got the safety review board off to the side and effectively, Innate's not involved. We can't be.

Are there any Innate employees – you know you mentioned there's a science officer there. Do they conduct any of the trials in those two countries at all? Do they have any part in that?

No. Other than it was recruiting the trial sites. To getting, determining the payment schedule for the trial sites, how many patients they would commit to bringing on, certainly making sure those folks understood the reporting requirements and so forth. But, the trials continue in New Zealand.

Okay, I was just about to ask that. So –

The compassionate trials.

The phase 2B trial is completed in Australia, is that correct?

No, no. They do it at two sites in New Zealand.

Okay.

We couldn't recruit enough patients in Australia.

Okay, so that phase 2B trial never, it never was conducted in Australia?

No, no. The sixth – it was supposed to be only Australia. That's how we got the 40% rebate. We couldn't recruit enough patients because of the doctors not being honest with their patients. So at the end out of some level of
desperation, we decided – they decided, the board decided to set up two new
trial sites in New Zealand that we knew we could recruit because the
patients don’t – aren’t taking this relapsing remitting drug. They’re taking
nothing and they’re desperate for it, but we had to forgo the 40% rebate on
it.

Paul Solis: So what is the status of the trial in Australia?

Rep. Collins: Oh, no. They all ended at the same time. It was last patient in, last patient out.
So, last patient in was April 19th, give or take of ’16. So on April 19th of ’17,
that 100th patient, don’t quote me on that, maybe it was the 90 patients, and
we got three over that. 93rd patient ended the trial. So the trial’s over.

Paul Solis: In Australia?

Rep. Collins: No, everywhere. It’s last patient in, sets the trial date. I think in fact –

Paul Solis: I just want to get an understanding of the possible differences between a
trial that’s being conducted in Australia and a trial that’s being conducted in
New Zealand.

Rep. Collins: No difference. No, no. That was the same trial. But, as patients, one of the
hooks on these patients, placebo or not was, because we can do this in
Australia and New Zealand – you finish your one year; it’s one year. So, some
people finished a year and a half ago. I mean because they were the first
ones recruited in and when their year was done, they were allowed to stay
on the drug if they wanted under the supervision of their physician, back
onto that compassionate basis. So, it now goes back to being anecdotal. The
double blinded placebo based trial is 100% scientific. The patients aren’t
supposed to know whether they’re on it or not. The physicians aren’t
supposed to know other than the social media, you do know, but putting that
aside, there’s no data that is compiled until, in fact it’s still not compiled until
the trial is done.

Paul Solis: So Innate will receive that data later on?

Rep. Collins: Probably in the next 60 days.

Paul Solis: And just – you might’ve covered this earlier, but –

Rep. Collins: So all these patients, 90% of them are still on the drug. They moved back
onto the drug in Australia in – oh and by the way, because we weren’t
running the trial in New Zealand to begin with and we had always had a
compassionate program and we ran the – so we ran the 2A trial in New
Zealand, that was that. We filled it up, but there’s – it’s a desperate situation
there. We continued to let patients under the supervision of their doctor, get
access to the drug. At which point, we’ve always had that data. It’s not secret
data. It’s anecdotal data, but physicians would be sending us that data every
week as what’s happening with Sally and Margaret and Gertrude and –

Paul Solis: And that’s a provision of New Zealand’s specific regulatory law?
Rep. Collins: Well and also Australia.

Paul Solis: And what about phase 1? You might've covered this earlier.

Rep. Collins: Didn't have to do it.

Paul Solis: Didn't have to do it. Why didn't you have to do it?

Rep. Collins: They waved phase 1 because of all the work we'd done in HIV. And all the safety aspects of MIS416, we were able with the New Zealand regulatory groups, to wave out of the – because the phase 1 is a safety trial and so is a 2A, but with some level efficacy, we convinced them we had enough data that they waved out of the phase 1.

Paul Solis: So phase 1 and phase 2A were both waved out of?

Rep. Collins: No, no we did 2A.

Paul Solis: You did 2A.

Rep. Collins: That's the first time I had to go raise some big bucks.

Paul Solis: Okay, so that was –

Rep. Collins: But that's not placebo based double blinded. They never are. There was like 30 patients, primary focus, safety, safety, safety, safety, but oh by the way, if the physicians say it's working, that's some nice stuff to know. We didn’t’ – and it was only three months. Some were surprised we got efficacy in three months.

Paul Solis: Has there ever been an attempt to conduct trials in the United States?


Paul Solis: File any sort of paperwork with any type of regulatory body to begin that process or have any communications with a regulatory body?

Rep. Collins: No. Not to run a trial. I do believe they have hired some consultants at this point, not so much related to the trial, but to have a discussion with the FDA about what would be some next steps to better understand when we go to sell the program in late this year, which is a public – we’ve announced that from day 1 that we would have a good understanding of how a big pharmaceutical might look at the economic side of – because it’s going to have to...at some point get approval here.

Paul Solis: And who are those consultants?

Rep. Collins: I don’t know their names.

Paul Solis: Okay, did you take part in the hiring of those consultants?


Paul Solis: So how did you find out about it?

Paul Solis: Who took – who is the decision maker in hiring the consultants there? The board?


Paul Solis: Okay.

Rep. Collins: The board gave Simon authorization to hire the consultant.

Paul Solis: Okay and again, when did that vote take place? Or the authorization take place to give Simon authority?

Rep. Collins: Probably 6 or 8 months ago.

Paul Solis: Do you know what an IND is?


Paul Solis: Do you know if Innate has filed any paperwork at the FDA about that?

Rep. Collins: I don’t think so, but again we have a consultant. I don’t’ have any interaction with him. I don’t think so.

Paul Solis: I want to – I’ll show you something here and see if you can help me. Take a look at this. This is in the production you provided us. This is THCC_1173. And it’s entitled, “A phase 2 company treating secondary progressive multiple sclerosis.” The second page just forward looking statements, effective date, 19-April-2016.

Mark Braden: Do we have one of our stamps on it?

Paul Solis: Yes. This is a production that you provided to us.

Mark Braden: So it was April of ’16?

Paul Solis: It’s THCC_1173- excuse me, stop the recording.

Okay, this is Paul Solis speaking. We’re back on the record. Yes, it’s 1173-1199. Do you – have you seen this before, Congressman?


Paul Solis: And why do you say probably?

Rep. Collins: I’ve seen a lot of things. Have I studied this one in particular? No, but this looks like the kind of document that was probably on our website, frankly.

Paul Solis: On the third page it says, “An investment thesis.” Do you know if this is something that would be – that would be one of my questions. If this was something published on the website given –

Rep. Collins: Oh, yeah, yeah. This – well when I look at this, this is the website.
Paul Solis: Okay. Alright. If I could direct your attention to – let me think through this – page 13 in the document.

Mark Braden: Which would be which of your HH number?

Paul Solis: It's 1185.


Paul Solis: So if you'll look at two bullet points down, it says, "Ovarian cancer therapeutic vaccine. RPCI Physician 1, professor gynecology in obstetrics, Roswell Park Cancer Institute. IND filling expected in 2016." Do you know – what does that mean to you? IND filing expected in 2016? Does that mean anything to you?

Rep. Collins: Well, sure. That would be Roswell Park Cancer Institute is running a trial in ovarian cancer under the FDA and you can't do that without an IND. So this would tell me that and Dr. Kunle and Roswell were filing an IND in 2016 to run an ovarian cancer trial and they were including MIS416 as an adjuvant to their vaccine, which we've provided to several hundred researchers around the world. Because it is such a potent adjuvant. So yeah, that would not be an IND filed by Innate. This would be filed by Roswell Park Cancer Institute.

Paul Solis: And are you basing that on conversations you've had with Roswell Park or anybody at Innate that that's fact of the matter that Roswell Park would be –


Paul Solis: Who did you have conversations with?

Rep. Collins: Well this was a big board discussion on whether we were going to allow Roswell to continue to use our adjuvant. It was the potential, if – because it's the same drug. So the adjuvant standalone is our secondary progressive MS drug, MIS416. And what that means is – now just the joke is, micro-immune stimulant, but first inject it on April 16th, because scientists don't have a lot of imagination. So the 416 stands for April 16th, just as a sense of humor there. The worry was, if Dr. Kunle and Roswell, which they are now doing, they kicked off the human trial I think a week or two ago. If they get an adverse event, an adverse reportable event, would that be something we would have to report into our safety board? Even though we had nothing to do with it, but it is our drug that's part of their cocktail. Because they have their vaccine with our adjuvant. A lot of discussion, in fact I would say the board was fairly split on this. Simon was the biggest advocate; he'd been dealing with Dr. Kunle from day 1 saying, you know, "how can we turn our back on them? They've done all this work. Without it, their vaccines' no good. We pulled their bacon out of the fire." So, I do know Mike Quinn made some – because he shared this at the board meeting, he made inquiries into whether or not an adverse event in this trial would have a negative impact that we would have to report, which would not be fair to our shareholders.
Transcript of Interview of Representative Collins
June 5, 2017

The long and short of it was, because this trial is with ovarian cancer patients who have ovarian cancer, who had been treated, and now this will be to measure whether or not this vaccine keeps the cancer from coming back, the chance of any – the adverse event would be the cancer came back. But these folks already had the cancer and that’s the whole purpose of the trial. We decided in the name of humanity would not pull the rug out from under them and pull the adjuvant that would cause them not to be able to run their trial and we just said, “If that happens, we’ll deal with it. We don’t think it’ll happen.” But you can’t run a trial without an IND.

Paul Solis: Was there any discussion at the board meeting either amongst the board or with Mr. Wilkinson about Innate filing the IND?

Rep. Collins: Well, no. It wasn’t our trial. The sponsor with trial files the IND. This is Roswell Park. Sure not Innate.

Paul Solis: Okay.

Rep. Collins: You could call us a freely component supplier, just like the guy who sells paper towels and toilet paper. They didn’t file the IND either.

Paul Solis: So, you know you’ve talk a little bit about some of the data in the compassionate trials you were receiving. You know, what type of access does the board have to information that’s coming out of New Zealand and the application to patients? Is it just in that setting, just in compassionate –

Rep. Collins: Yeah. Well, there is no data available on our – we still don’t have data. When you run a double blinded placebo based trial, there literally is no data because everything is double blinded and placebo based. You don’t know until the data’s analyzed which is going on right now by the CRO. It takes 60 to 90 days, so if you go 60 to 90 days after April 15th, you’re into late June, July maybe even early August. Because there’s 400 pages of data for every patient. At that point it will be compiled and say, “alright. Here’s what happened with the placebo patients. Here’s what happened with the non-placebo patients. Boom, boom, boom.” Until then, there is no data. But the compassionate data is available on a weekly basis.

Paul Solis: And who is that available to? Is that available to the board, to Mr. Wilkinson? How does that relay to you finally?

Rep. Collins: I never saw the data. I would say certainly Simon was ...and Gill were right in the middle of it. And I would say the board never saw any data from that because it didn’t matter. It was anecdotal. All we would care about is, how’s it working? And the report would be, it’s working. Said, “good.” Alright, next item.

Paul Solis: Would you have access to that information that’s coming back from the patients?

Paul Solis: No? Okay.

Jeff Brown: How frequently is that the subject of conversation at these board discussions?

Rep. Collins: Oh, every board meeting. It’s an extraordinarily important thing to know –

Mark Braden: It’s your only product.

Jeff Brown: It’s the only feedback you have –

Rep. Collins: Well yeah, but it’s very important feedback because it’s – again, it’s a very unique situation. And it’s all public information too. In fact the videos were up on our website that you can run and do something – I don’t know if you can do this in the U.S., but certainly down under the compassionate use of drugs is accepted in – so, we always want to know. What’s the feedback on this? The feedback was always very positive.

Paul Solis: This is – let me show you an email here.

Rep. Collins: Oh, one of mine. There’s all my investors. You want to know who the investors are, there they are.

Paul Solis: This is marked CG_0062. This was not part of production from you to our office. Part of what I wanted you to do was take a look at this and I can ask you some questions about it.


Paul Solis: Is this your email address at the top?


Paul Solis: And this is May 4th, 2015. You actually just referenced the list of people here. Are these people current shareholders as of May 2015?


Paul Solis: They’re current shareholders? Are there any names on here that are potential shareholders?


Paul Solis: So you can verify that everybody on here is a current, at the time, current Innate shareholder?


Paul Solis: Are they all U.S. citizens?


Paul Solis: I wouldn’t want you to make a determination of every citizenship anybody can have on this list. But just generally speaking, you know, generally speaking – you recognize these names?

Paul Solis: That’s certainly what I wanted to – would you have any reason to believe that anybody here is an Australian citizen or a New Zealand citizen? To the best of your knowledge.

Rep. Collins: No. I can say with the exception of the coach of the Dallas Stars, former coach of the Buffalo Sabres, Lindy Ruff, everyone here is U.S.

Paul Solis: Is this a typical update you would send to shareholders?


Paul Solis: You know one of the questions too I wanted to ask is, I realize this is a couple of years old, but it was not in our production to our office. Do you know why that might not have been produced to our office? This email?

Rep. Collins: Sure, I delete my emails every day. In fact, generally three times a day. I delete all our texts, three times a day. I just always – I have a very uncluttered life and something like this would be absolutely no reason for me to hang onto it.

Paul Solis: So I want to just ask you some questions about some of things that are in here. So, for example, I’m looking and the font is small, but I’ll try to direct you. Maybe the third sentence, it says, “We did enroll 12 additional compassionate patients in New Zealand which allows us access to the deposition info. Unlike the trial, where all info is confidential until the end of the trial due to the fact that 1/5 are on placebo.” So, can you tell me what that means?

Rep. Collins: Well sure, it’s what I say earlier. The beauty of the compassionate trial in New Zealand is, those are – well the data is anecdotal. It’s not part of our trial data. It’s available real time by the doctors on a weekly basis because they’re injected once a week. We actually had a person on our staff while I didn’t see the data, she monitored it on a weekly basis. So the company itself, not me, was monitoring the compassionate trials on a weekly basis, real time, to know exactly what was going on. And as I said here, I just read, it was absolutely a proxy for the trial. So we have no data on the trial. We double blinded placebo based, we’re not going to see that data until maybe July-August of this year. But the patients who self-identified, they were recruited, in the compassionate, were the same profile. They were secondary progressive MS. If you looked at the protocol, there’s certain things we would not allow on the drug. Primary progressive, certain rashes, certain cancers or whatever. You could say that these patients could’ve been the patients in the trial and then that was kind of a beautiful thing. Effectively running the parallel, compassionate use group of folks who were parallel of folks we don’t know anything about, but they’re kind of, sort of the same folks.

Paul Solis: And who was the person at Innate who was monitoring that information?
Rep. Collins: It’s a lady...Roxanne? Anyhow, she works for Simon. If you rattled off all their employees, I could tell you which one it was, but...

Paul Solis: Okay. And then I’ll just direct you to the second to last sentence. You write, “All the patients that have continued to receive our drug after phase 2A trial, are pleased with the drug and their condition.”


Paul Solis: And you go on to say, “Some patients have now been on MIS416 for five years and are holding steady, which is an amazing accomplishment.” So how did you come to know that the patients who have continued to receive the drug after phase 2A trial are pleased with their condition?

Rep. Collins: Irene. Irene monitored. So Irene was on this like you know what on a you know what. She – this was her job.

Paul Solis: And she would relay that information to you?


Paul Solis: To Simon.

Rep. Collins: And then we’d talk about this at the board meetings.

Paul Solis: And is that how it always happened? Or sometimes happened? It would go from Irene to Simon to the board?


Paul Solis: So, would all board members have access to that information coming from the compassionate program? Compassionate patient program?

Rep. Collins: Well no, only Simon had access to it. That I know of. That was his job, nobody else is there full-time.

Paul Solis: I should rephrase. I think I didn’t state that as carefully as I should have. In the end, when the information then passed from Irene to Simon or went directly to Simon and then came to the board, would all the board members discuss it and have access to the information?

Rep. Collins: Oh, yes. Well, we never looked at hard data points. It would just be, everyone’s doing fine – how are we doing? Everyone’s doing fine. All looks good. Okay, next point on the agenda. These would not be – I mean that’s all we needed to hear, everything’s fine.

Paul Solis: Would you ever ask Simon individually what’s the status of what’s happening with the compassionate trials? Would you ever ask him for information on that? Or would he just bring it to the board?

Rep. Collins: He would bring it to the board, but if he and I were talking, because that would happen, I wouldn’t – or I don’t have any exact recollection, it would not be inconsistent for me to say, "hey by the way, are we still good?" “Yeah,
“yeah.” I mean the biggest confidence point we had was these compassionate patients who’d been on it five years and we had not slowed the progression, we had stopped the progression which is beyond the comprehension of most people in this field. So as time goes, and like five years is like an eternity. You know a lot of drugs are looking at 6 months and 9 months, so now we’re like, what 7 years? I mean this is amazing stuff.

Jeff Brown: Starting at the nomenclature down and so I understand, I think what you were saying earlier, when you were talking about the compassionate care patients, and then here we’re talking about the phase 2A –

Rep. Collins: They all went compassionate.

Jeff Brown: That went compassionate.

Rep. Collins: At the end of a trial, the trial’s over. But now you have patients that are suffering from secondary progressive MS and one of the hooks to get the people into the trial is when you are done with a trial, you will have continued access to the drug on a compassionate basis, under the supervision of your physician. At which point, Irene could then monitor that data.

Jeff Brown: And is, forgive me if you went over this, but phase 2A, is that double blinded placebo?

Rep. Collins: No, no. See that was straight on.

Jeff Brown: That’s 2B.

Rep. Collins: Yeah. So 2A, we always had the results on a weekly basis. It was like 30 patients, 20-30 patients, 3 months.

Paul Solis: And you mentioned something earlier about maybe a video on the website. To what extent is the information learned in the compassionate program made publicly through Innate? I mean can you talk about this video or instances like that?

Rep. Collins: Yeah. The videos and there’s been several of them, are patients just telling their story. And the story is how this drug has changed their lives. You know, they’re no longer contemplating suicide. That they’re kind of funny in a way. One guy said, “They had to slow my wheelchair down and now I can put it back up to the 5 speeds and go zip them down the highway.” I mean it’s really – it’s just amazing stuff.

Paul Solis: Is this currently on Innate’s website?


Paul Solis: And everybody who was in these videos or video, they’re taking part in this compassionate program?

Paul Solis: what about aside from a video with patients? Would Irene ever take that information she’s learning and put it on the website in a press release or something like that?

Rep. Collins: No. No I mean it’s a small company, you know 12-14…Simon is the whole face of the company, start to finish. I can’t believe the hours he works. Everyone else is a doer and Simon’s the orchestra leader.

Paul Solis: I’ll move onto the next email. If I could get that back, thank you very much. And this is marked CG_0177.


Paul Solis: Take a minute to look at that one.

Rep. Collins: Oh, this isn’t CG. This is Chris Graham. I have a Chris Grant as well. This is Chris Graham. He’s my partner at Volland Electric. So in July I see we’re targeting October for the last patient, well that didn’t happen until April. Missed that one by six months. Okay.

Paul Solis: So first of all, I was just going to ask you who Chris Graham is. You mentioned it a little.

Rep. Collins: He is the president of Volland Electric of which I’m a 50% owner.

Paul Solis: Is he an Innate shareholder?


Paul Solis: I basically just wanted to ask about – you said, “Hope you cash out mid-’17.” In what you meant by cash out.

Rep. Collins: Oh we’ve always said we’re going to sell the program within 6 months of the end of the trial. So in this case, saying that we were targeting this would’ve said if the last patient was in October of ’15, the trial would’ve been over in October of ’16. So you go, nine months out from that would’ve been mid-17. And that’s consistent with what we’re saying now, the trial ended in April and we’re looking to cash out in December of this year. So, yeah. We’re hoped to cashed out in mid which is the 9 month after the trials over, it’s always been our expectation that’s what we’re going to do.

Paul Solis: And when you say sell the program, what do you mean by that?

Rep. Collins: Whether it’s license or sell outright MIS416 to one of the big 14 pharmaceutical companies that are active in neurological disease and in particular, relapsing remitting multiple sclerosis.

Paul Solis: And this has been the intention of the board at Innate? Or Mr. Wilkinson or everybody there?

Rep. Collins: Yeah. Everybody there, the board, Simon, me and the shareholders, yup.

Paul Solis: Do you know how –
Transcript of Interview of Representative Collins
June 5, 2017

1 Rep. Collins: We’re not going to fund it beyond the end of this. One way or the other, this suckers gone.

2 Mark Braden: You can’t come up with a million dollar market – a billion dollar market you –

3 Rep. Collins: It’s gone at whatever price it goes at. And I hope it’s more than less.

4 Paul Solis: I might know the answer to this question, but you know this email was not provided to us from you or your attorneys as well. Again, same question as the previous. Do you know why this was not provided to us?

5 Rep. Collins: You know it would’ve been deleted on or about 9am on July 30th. I delete all my emails. I don’t keep myself cluttered. I would’ve never kept copies of this and so...It’s my simplified life.

6 Jeff Brown: Before we pull off on that one, just real quick. "Still hoping for an accelerated approval which means no phase 3 trial." Again, can you just explain what the science behind that? We’re just hoping –

7 Rep. Collins: Alright so, within the FDA they have something called accelerated approval. They’ve had that for years and years. And in rare cases, if there is a debilitating disease that does not have any treatment and a drug comes up that is deemed to be effectively 100% safe, with very good efficacy indications through a 2B, which is double blinded placebo based, that would be the type of drug – Duchenne’s Muscular Dystrophy was just approved on that basis. They did not run a phase 3 – Duchenne’s is a debilitating disease for young boys. It was actually a 12 person trial safety but not even compelling efficacy but it still got approved under what they call accelerated approval. It would be our belief that certainly secondary progressive MS today still has no treatment options. It is absolutely debilitating and that our drug which we know is 100% safety record going back to forever, if the efficacy signal when we get in August, is strong and it’s our thinking based on the compassionate trial and the anecdotal evidence that it will be, that this would be a drug that would be qualify for accelerated approval.

8 Paul Solis: With the U.S. FDA?

9 Rep. Collins: Correct. Because there’s no question this drug’s coming to the U.S. Not by us, but whoever acquires, I call it the program, the – because the MIS416 secondary progressive MS, but it’s also an ovarian cancer. It’s also in prostate cancer. It’s also in breast cancer. It’s also being looked at for all kinds of autoimmune things with researchers around the world. Because we give it to anyone that asks with an MTA, so the program we think would not just be secondary progressive MS. No one’s going to let us continue to have MIS416 as some product in another disease even though we think it has potential so...that’s what – when I say program, it’ll be the whole kit and caboodle.
Paul Solis: And Innate currently has the only and forgive me, I’m not steeped in background knowledge on this, but as the only I don’t want to say patent, but the rights to MIS416?

Rep. Collins: Yeah, it’s a very strong international, filed around the world patent.

Paul Solis: So it doesn’t originate or is governed by Australian law or New Zealand law. It’s a sort of a worldwide –

Rep. Collins: Oh it’s pretty much in every country in the world. We spent a bloody fortune on that.

Paul Solis: Shipping it to researchers all over the world.

Rep. Collins: Oh, the drug. I thought you were talking about the patent.

Paul Solis: Oh. Yeah, so I guess there is an existing patent?


Paul Solis: And where is that filed?

Mark Braden: There wouldn’t be anything to sell.

Rep. Collins: It’s filed pretty much in every developed country in the world. Its the U.S., its Australia, its New Zealand, its Canada, whatever you do in the EU, it’s yeah. If you don’t have a patent, you don’t have something you can sell. So the patent’s filed everywhere. And we are providing it to researchers in many countries under what we call a material transfer agreement, which means they keep it confidential.

Paul Solis: Does Innate receive any type of compensation or revenue based on those agreements?


Paul Solis: I’ll move onto another email here. This is CG_0018.

Rep. Collins: Took my same list of all the shareholders. Okay.

Paul Solis: That was going to be one of my questions. I’ll give you a minute to take a look.

Rep. Collins: Still missed it. 90 patients, November 31...

Paul Solis: Okay so, again this list of individuals, is this – again the same sort of questions I asked before, these are current Innate shareholders as of August 2015?


Paul Solis: And you recognize all these names?

Paul Solis: Okay. The subject is capital –

Rep. Collins: One of these days I'm going to learn how to – and I finally did – you can send it to one and BCC everybody else because then in effect, especially Lindy Ruff, he doesn’t necessary want everybody to know as the person like he is, it’s his personal email –

Mark Braden: There’s 30 guys that have it so.

Paul Solis: The subject is, “Capital raise for Innate.”


Paul Solis: Can you talk to me a little bit about the intention, or is a capital raise upcoming here? Can you discuss that a little bit?

Rep. Collins: Well sure. This would be a fairly typical – the board decided we were going to need to raise more money. And this here said we were looking to raise another 3 million dollars, Australia. And to do that, 20-25 million new shares, and 15-18 cents so I guess you hadn’t locked it down. If my memory serves me right, it ended up at 17.5 cents. So yeah, it was notifying these – all these people we’re going to raise more money. They can participate, but in order to know who to send booklets to, private placement book, you’ve got to let us know that you want a booklet and it’ll be...you know, this said if minimum investment 25 grand, because it was then you could buy it on the Australian market at the same price and arguably less, then go buy it on – if you’re going to buy it – see if you couldn’t invest 200 grand, you couldn’t get it in the market. But if you want 10 grand to stock there was enough volume, enough equity in the market to go buy a small amount so...That was the thought here and little update, which I always did on the 90 patients, and obviously kept moving because we kept getting disappointed by the folks in Australia.

Paul Solis: You say in the second paragraph, “This will be a private capital raise to quote on quote, named individuals.” Is that the same as a private placement or different?

Rep. Collins: Oh yeah. This was a private placement meaning, here you are, if you want to be one of the named people, let me know and we’ll make sure you get the offer.

Paul Solis: And is this something specific or special in relation to U.S. – potential U.S. shareholders or U.S. citizens? I mean is there something different about –

Rep. Collins: Oh yeah. Well no, what I’m saying is because it’s an Australian public company, U.S. shareholders cannot participate in what you would a call a rights offering there. The only thing you can do in the U.S. to raise funds is a private placement to accredited investors, people who self-certify their assets, their income and their sophistication to make decisions.

Paul Solis: And that term is that an Australian –
Rep. Collins: No, no. An accredited investor is an SEC term. That is a U.S. securities thing that allows you – private placement is a U.S. term probably everywhere, but within the U.S. security laws, private placement to accredited investors is recognized as a high risk potentially high risk, non-regulated offering, but to folks who are sophisticated, high net worth and alike.

Paul Solis: I’ll direct you to the second to last paragraph, “feedback from the doctors treating the patients is exactly what we expected, including the compassionate patients in New Zealand.” First of all, “feedback from the doctors,” is this information coming from – we discussed this before, it’s coming from this woman at Innate who –


Paul Solis: Or is there any other type of information that you’re getting specifically from doctors yourself?


Paul Solis: In the second part there it say, “Including the compassionate patients in New Zealand.” Is there some type of feedback you’re getting from doctors that is distinct or separate from the compassionate patient information you’re receiving?


Paul Solis: You used the word, “including.” And so I’m wondering if there’s a larger set of doctors –

Mark Braden: I would’ve thought there was a difference between the New Zealand and Australian, but...

Paul Solis: No, no, no. Everything was – I can only say we had – we’ve had people at 5/6 years and they came in with different things, different times. They were all in a compassionate – and I don’t know exactly why I would use that, but there was certainly no information related at trial, because there was none that we had.

Jeff Brown: Do you remember roughly when the New Zealand – you said there two separate sites in New Zealand, do you remember around the time you moved over to New Zealand?

Rep. Collins: No, we’d always been in New Zealand. That’s where the 2A trial was run.

Jeff Brown: You said you tried to do the 40% or you tried to do the –

Rep. Collins: 100% Australian to get the 40% rebate. But the 2A trial –

Jeff Brown: [Crosstalk inaudible] 2A compassionate care in New Zealand?

Rep. Collins: Alright, the 2A trial official 2A trial was run in New Zealand and only in New Zealand. And it was run at 2-3-4 trial sites at 100%. Meanwhile,
compassionate patients are treated one often at their doctor's office. It's not a trial. You got three patients and you got two and you got one...fine, here's the drug, no charge. The – so then when we went to Australia to get the 40% and the public offering you'd see all that and we'd just, they bombed. I mean you can see from these emails, one delay after another after another, after another. We finally threw our hands up and said, "Well, we had the 2A sites. They know the drug, they know the protocol; they know everything. Let's just knock it off and sure enough, within weeks, we got them set up – they've already gone through their ethics board for the 2A so it was...we just forfeited the 40% rebate. Not that that didn't matter because it did. But at some point time is of the essence.

Paul Solis: This was also not an email that was produced from you or your attorneys. Do you know why this email specifically wasn’t –

Rep. Collins: Because it would’ve been deleted the day I wrote it.

Paul Solis: Alright. This was from a production provided by your attorneys. This is –

Rep. Collins: They found something, huh.

Paul Solis: This is marked for us THCC_0826 although it shares the same bates number, OCE-00826. Now, it doesn’t appear to be that you are the author of this email, but I nonetheless wanted to ask you about it. But go ahead and take a look.

Mark Braden: So you're going to ask him about an email that he didn't either author or receive a copy of?

Paul Solis: I am. I am going to.

Rep. Collins: Which is true. This is the first time I've seen it. Kind of a strangely worded email. Oh goodness. So this was December ’15, okay.

Paul Solis: So this email is from Michael Hook to Bob Crine.


Paul Solis: Who is Bob Crine? Do you know who that is?


Paul Solis: On Marco Island? He's your friend?


Paul Solis: How long have you known him?

Rep. Collins: Let’s see I’ve been in Marco Island...been in Marco Island 8 years? 7 years? 6 or 7 years. Yeah, I golf with Hook and all of his buddies.

Paul Solis: And this is Michael Hook?

Paul Solis: He’s currently your chief of staff?
Rep. Collins: Yes, he is.
Paul Solis: When this email was written in December 9, 2015, was he your chief of staff at that point?
Rep. Collins: No. Let me think...boy, you get older, the years fly by and...he became my chief in the middle of ’15. So yes, he was my chief then.
Paul Solis: Okay.
Rep. Collins: Had been for a few months.
Paul Solis: I’m going to try to ask you questions that are only based on knowledge you might have. Understanding that you did not write this email, but if you look at the bottom of this paragraph, Mr. Hook writes, “compassionate trails –,” I assumed he meant trials, “secondary progressive MS drug (which the company gets info day by day) continues to go well.” Do you know how Mr. Hook would’ve had that information?
Rep. Collins: Well I’m sure he read it either from one of my updates or asking me – I wasn’t bashful if people would say to me, “How are things going?” I’d say, “Good.”
Mark Braden: Isn’t that what those emails that the last three emails [crosstalk inaudible]...
Paul Solis: So –
Mark Braden: [crosstalk inaudible] Michael Hook’s on those emails receiving that exact information.
Paul Solis: So –
Rep. Collins: Yeah, it’s consistent with –
Paul Solis: I’ll just ask my question.
Paul Solis: So, particularly in December of 2015, do you recall any conversations you might’ve had specifically with Mr. Hook, apart from these emails with other individuals, where you would’ve talked about how the drug was operating?
Paul Solis: Would you ever talk to Mr. Hook about the compassionate trials, apart from the emails that I just showed you, where he was one amongst many recipients?
Rep. Collins: Could be. I mean, I’ve never been bashful of anyone who would ask me anything about the company. Including fellow members of Congress or a
person in the grocery store. The compassionate data has been one of the
most compelling, even though it’s anecdotal, data that we’ve had to have the
confidence that I have, which is why I’m so frickin’ all in on this thing. And
others would consider that even though it’s not scientific. Certainly,
something that would give you confidence and it’s pretty unusual to have
this kind of data. And again, it was not insider information or – it was widely
disclosed and dispersed, but –

Paul Solis: What do you mean by wildly disclosed and dispersed?

Rep. Collins: It was talked about on a regular basis and even you know Simon would put a
presentation on in San Diego or San Francisco, I mean it was always part of
the slide deck of what’s going on with our trial and the fact that we have
these compassionate – it’s just always been front and center of any and all
presentations, materials and private placements – it’s quite compelling
actually.

Paul Solis: Given that’s probably some private information that some of the patients are
you know – would have concerning their health and the treatments that are
given to them, did the company – did Innate have any sort of confidentiality
policy about that type of information that was being received from their
treatments in the compassionate program? Was there a –

Rep. Collins: Blinding or something?

Paul Solis: Something or... you know, confidentiality of their names or personally
identifiable information, anything like that?

Rep. Collins: I do not know the answer to that, but the answer is everyone understands
confidentiality. Whether it’s the U.S. or any other developed country at any
rate and no one would ... ever release particular patient info.

Paul Solis: Do you know – was there anything written, company policy about that?

Rep. Collins: I don’t know.

Paul Solis: Okay. We’ll move onto a new email. Slowly getting through this.


Paul Solis: I think we’ll be finishing up pretty soon.

Rep. Collins: My tomato soups waiting for me. It’s still in the can. My wife –

Mark Braden: Gourmet –

Rep. Collins: See I live alone. My wife comes down like 4 times a year for the first lady’s
lunch, for the White House correspondence dinner, couple of things like that.
She’s just always like, “so you got tuna fish and tomato soup.” Because I eat
out most nights doing fundraising and stuff. Yeah you know what, if you’re
watching – if you’re eating out too much when you go to Capitol Grill and
you drink too much, then when you’re on your own, you have water and

tomato soup and crackers. Microwave 1.3 – 1.5 minutes.

Mark Braden: Another power dinner in D.C.

Paul Solis: This is TAM –


Mark Braden: That’s good. That’s a good starting point.

Paul Solis: This is TAM_0180.

Mark Braden: Safe to say that you didn’t get it from us?

Paul Solis: This did not come from your production.

Rep. Collins: That’s correct but it’s to my normal group.

Mark Braden: Okay we can save one question.

Paul Solis: Probably still going to ask.

Rep. Collins: This is December 16, ’15. We just kept – we’re going to have all of them by

January 31. Came in April 19th. You’re reminding me of how this thing just

kept dragging and dragging and dragging.

Mark Braden: Well this is the perfect explanation as to why people who don’t understand

how expensive it is to produce drugs. Just read these emails and it becomes

clear to you as to why it’s brutally expensive.


Mark. Braden: This has been dancing for a long time.

Rep. Collins: Sure has. Yeah that was a bad day. Okay. Fire away.

Paul Solis: Alright. So the first paragraph there, you talk about the 12 compassionate

patients in New Zealand that, “we monitor every month as a proxy for the

trial participants.” And then you say, “No surprises.” Are these 12

compassionate patients here you’re referring to, is this the group of people

in New Zealand that you’re receiving information on?

Rep. Collins: That’s right. That Irene is monitoring and reporting back to the board.

Paul Solis: Alright. And then you say, “We have opened a trial site in New Zealand to

complete the 90 patient recruitment.” Is this then the phase 2B trial?

Rep. Collins: Yup. This is where we got frustrated with Australians and said enough is

enough.

Paul Solis: The third paragraph, “We continue to talk to big pharma.” So, I think I know,

but I’d like to hear from you. What is big pharma?
Rep. Collins: Big pharma would be the 14 people like Teva and Pfizer and Novartis and Celgene and Biogenetics, who are in the neurological space with relapsing remitting drugs, the average one which is generating about a billion dollars a year. So 12-14 billion dollars of revenue across 14 or so relapsing or remitting MS drugs, who have been monitoring what we’ve been doing for years. But they’ve de-risked how they bring drugs to market and their investment point is at the end of the 2B. They used to in the old days – and we did talk to Merck Serono about buying it at the end of the 2A. We aggressively tried to sell the company then and not even go public and almost got it done. And then their board blew up and people got fired and we had to go it alone into 2B.

Paul Solis: When you say, “we,” in that paragraph there, in that sentence, what do you mean – who do you mean by, “we?”


Paul Solis: That was going to be a question I had. These series of emails that I’m showing you - where you email this group of people you know –

Rep. Collins: Yeah you can substitute, “we” for “Innate has opened a trial site”, “Innate continues to talk to big pharma”, “Innate is looking for –,” so I would represent myself as a board member and the largest investor as the, “we,” meaning Innate.

Paul Solis: Would the board of Innate know you’re emailing these individuals in all these emails I’m showing you? Would they know about that?


Paul Solis: You would just take that upon yourself to email them?

Rep. Collins: Mhmm (affirmative.)

Paul Solis: Would you ever share with the board the type of information that you’re sending to these people?


Paul Solis: Okay. The next paragraph it says, “We’re already looking at commercial production of MIS416.” What do you mean by “commercial production”?

Rep. Collins: Well, we are GMP, good manufacturing production compliant, GMP compliant for the 90 - which turned out to be 93 - patients in the 2B trial. Kind of like make it in this room and full GMP compliance, but if you’re going to –

Paul Solis: What is GMP?


Paul Solis: Sorry.
Rep. Collins: It's a terminology of – and it crosses borders so FDA uses same term. If you're going to – instead of treating 90 patients, you're going to treat 50,000 patients well you need a whole different rule. We're not making that in our little garage in New Zealand. There's been ongoing efforts now for some time, big pharma said to Innate, “we're watching you. We're watching you. We like what we're hearing. If there's anything you can do to de-risk our investment by getting and finding a commercial manufacturing facility that could make drugs for 50,000 people and meet the sterility requirements.” See, we're not a pill. We're not something that you make and sterilize, we're biologic. And it's very tricky to guarantee sterility for large quantities and right now, we use animal proteins as part of ours and that's a no-no in some – we use ... bovine calf blood as the growth media. That's a real no-no with a lot of pharmaceuticals. They don't want animal I think contamination or whatever – anywhere near their stuff. So we had to really do a worldwide search to find facilities and go look at changing our – the feed for our bacteria and we were – that was part of our fundraising, is to raise the money with pharma saying, “I'll tell you right now, every buck you spend on moving the manufacturing process along, will be paying you a dividend tenfold. If you're thinking you don't want to raise the money because you don't want to raise the money, we would encourage you to raise the money because when you line us up, the further along you are at identifying a bulk, commercial manufacturing source that meets sterility, the happier we're going to be.” So that was part of the fundraising to raise money to move that forward.

Paul Solis: You've talked about talking with big pharma, so ... would the board have meetings with representatives of pharmaceuticals?


Paul Solis: Simon would?

Rep. Collins: Yeah, he met with them on a regular basis and we also had a business development manager, blanking, but her ... was it Janine? Her total goal was to be in constant contact with big pharma and to present to the board updates of discussions, updates of concerns, potential competitive drugs, because there were other drugs for secondary progressive MS; they've all failed, but at various points there were some in phase 3 trials that failed.

Paul Solis: Were you ever present during any of the meetings with Simon and any executives or –

Rep. Collins: No. they were as he pointed out, typically out in San Francisco. I've never attended that conference.

Paul Solis: Okay well outside of San Francisco? Anywhere you attended a meeting with Simon and representatives of a pharmaceutical company?

Paul Solis: About how far back, to your knowledge – as you can recall, was Simon taking meetings with representatives of pharmaceutical companies? Do you know how far back?

Rep. Collins: Oh yeah, way back in the early 2A stages. He wanted to – we wanted to sell the company at the end of the 2A trial. And the 2A trial was back in the 2010 time frame. And yeah, he – I’m sure he’s been talking to big pharma for 10 years. 8 to 10 years.

Paul Solis: You’ll notice on the subject -

Rep. Collins: Oh by the way, one them is our biggest investors, so there you go. Merck Serono was one of the biggest investors in our company. Merck Serono the pharmaceutical company funded something called the United States fast forward fund. And that fund was Merck Serono’s money going in for them to invest through grants into companies working in the MS space, which there’s just been this dire need, so like ... 10 plus years ago, Innate applied for it was awarded $5,000 grant from the fast forward fund – the United State fast forward fund. It's not part of the United States government. Funded entirely by Merck Serono. Merck Serono got stock options as a result. Yeah it was Mark that got it, not fast forward fun. So the day came when we went public, we had to get rid of all the options. So Merck Serono cashed in their options for one penny a share and became one of our larger shareholders as part of it. They were the ones that almost bought the company and they also had a right of a first refusal at any time the company would be sold, Merck Serono could match at the price and snatch the company. It was just like the football player – that's not always a good thing for the management to have. Merck Serono triggered that. In like – right as we were ending the 2A trial, Merck Serono triggered the takeover option or right that they have as part of their investment through the fast forward options. And that was when we were this close to selling the company and they have their management shakeup and the board came back and said we’re not going to move forward. But the good news for us was that was – that could only be triggered once and they triggered it. Damn phone – I keep putting it ...it's on vibrate, but... Anyway. The best news for us was – the bad news was they didn’t buy us, the good news was that the right they had, the right of first refusal was gone. They could never exercise it again.

Paul Solis: When did that happen?

Rep. Collins: It was right after the 2A so that would’ve been back in ’12, ’11-’12 and something in that timeframe and you know, that’s when we had to go out and raise the money and do the 2B trial ourselves.

Paul Solis: You’ll notice on that email right there, the subject says, “updated investor facts sheet,” and then there’s an attachment I’ll show you –

Rep. Collins: Yeah, show me that. I don’t know what it is, but I guess you’re about to share that with me.
Jeff Brown: Before we jump down on that one, I just –


Jeff Brown: Had one quick question. If you look in paragraph one, you said, “65 patients are in the trial,” –


Jeff Brown: And then in paragraph two it says, “We got about 93 patients now identified.” How are you getting information regarding enrollment in the trial?

Rep. Collins: From Simon at our board meetings.

Jeff Brown: Okay. And you know you talked a little bit about the confidential nature of the trial, but I take it that enrollment is not confidential, obviously you guys need to know those sorts of things?


Jeff Brown: Okay.


Paul Solis: Enrollment is different than actually starting to administer the drug?

Rep. Collins: Yeah, because see, everyone’s got to – their systems got to be clean of any drug for 90 days. So, these would be – this would be a neurologists or a clinical site identifying potential 6 patients, but then we would run tests on them for and do background checks and probably got about 80% of them in, but there would be some that we have some strict protocols that would wash them out. But then you had to usually wait 90 days for their systems to clear of any relapsing remitting drugs they’re on. So it was never an exact, but in that estimate.

Jeff Brown: And then how does Innate you know publicize, “Here’s where we are with enrollment, here’s where we got them?”

Rep. Collins: Much of it would be on the website, sometimes it could be a presentation slide deck that Simon would use. He was talking with pharmaceutical companies; it was never treated as anything really confidential. The key wasn’t so much that there’s 63 in, it’s like when is that goddamn last person getting in. And that’s what you saw kept moving. So all our estimates were wrong. We kept saying it would be June, then we would say it would be August, then we’d say it was November, then we’d say it’s in February, and then it would end up in April, so the disappointment was we missed every projection.

Paul Solis: So attached to that email I just showed you is this – that’s the fact sheet. And this is numbered TAM_0181 and 0182. Again, it was attached to this email you had sent on December 16th, 2015. And if you’ll notice in parenthesis in the bottom right corner, it says, “16th-December-2015.”

Paul Solis: What – you know, it's named, “Fact sheet- updated investor fact sheet,” are you familiar with an investor fact sheet? What is it and how is it used?

Rep. Collins: Oh, yeah. This would be something that would've been on our website. As a public company, you got to provide all kinds of timely information. You don’t' keep anything in your back pocket. So this would be – and I’m sure there’s many of them, I haven’t looked at the website in a long time, but this would’ve been under the investor information section, I would expect of what’s going on, just keeping the market appraised and potential investors and shareholders of what’s going on to keep them up to date.

Paul Solis: Would you take part in the development of this document?


Paul Solis: Who would create this?


Paul Solis: Would the board ever see this to approve it at all?

Rep. Collins: No. I can't speak for Mike Quinn. Mike Quinn is the chairman – is quite involved. The rest of the board, well, there's also some employees in the company that are on the board. I’m probably the least involved because I'm in the United States and whatever, I think – so, I've had no involvement. This would've been a work product of Simon and I would have expected that other members of the board who are either the chairman or employed by – because there’s some data here that you know others would have had input on.

Paul Solis: How would you have received this in order to the send it to the group of people in that email?


Paul Solis: So, it wouldn't have come from Simon or another employee at Innate? You would've taken this from the website and sent it to these people?

Rep. Collins: I might’ve taken it out of the website. I might’ve gotten it as part of our board papers. I can't speak to exactly – I don’t know exactly how I got it, but I thought it was – looking at a great summary for me to share with all the shareholders.

Paul Solis: And then this is actually something I pulled and I think it's currently –

Mark Braden: That's up on the website?

Paul Solis: Yeah.

Paul Solis: There’s no bates number affiliated with this. No, that’s actually – they’re separate and I wanted to ask you about – you can compare them if you’d like.

Rep. Collins: Oh, they just look similar.

Paul Solis: I think they are very similar.

Maggie Abernathy: They’re two separate [crosstalk inaudible].

Rep. Collins: Oh, this was December 15 –

Paul Solis: Yup.


Paul Solis: The first one I showed you was December 2015, now at the bottom right, you’ll see 27-September-2016. You know, they do look very, very similar. I just wanted to ask you similar questions. Whether this document, to the extent that it has some differences, whether you took part in the creation of this document that’s currently on the website, at least as of a couple of days ago.


Paul Solis: No?


Paul Solis: Okay. And this would’ve been – this is Simon … would be the one –


Paul Solis: Would develop the information on this?


Paul Solis: Okay.


Paul Solis: Moving on, this is CG_0312.

Rep. Collins: Yeah, that’s what I call Chris Grant. Chris Graham’s, Chris Graham. CG is Chris Grant, my former chief. So this was January of ’16, so couple months before we finished our recruitment. End of February, first week of March. No, it was April 19th. Alright so this explains what I was talking about earlier on the manufacturing. Okay.

Paul Solis: So the second paragraph, similar to the previous one I’d asked you about, it said, “We continue to have very promising conversations with big pharma.” How did you come to know that? How did you come to know that Innate is having promising conversations with big pharma?

Rep. Collins: Well again, we would talk about that at a lot of our board meetings. Again, we had a person that’s her full-time job and whether it’s Simon at the
conferences at San Francisco or otherwise, the encouragement was always, “get this damn thing over with. Get the 2B, get those...,” what we’ve said along. We had to get the trial enrolled. We had to go a year. We had to – and it was just the encouragement of keep on plugging.

Paul Solis: You say that, “we are the only drug that treats SPMS.” How would you know that? How would you come to know that you’re the only- that Innate is producing the only drug to treat SPMS?

Rep. Collins: I don’t know. The sun came up this morning too; it’s very well known that there is no treatment for secondary progressive. It’s the best known fact of the ugliness of the multiple sclerosis world.

Paul Solis: Is there, to your knowledge, attempts by the manufacturers or by researchers to come up with something that’s not as advanced as MIS416?

Rep. Collins: Oh, yeah. I mean there’s – as I said, there’s been one multi-billion dollar failure after another. Celgene had a, they bought out Receptos for 8 billion dollars and Robert Peach, the founder of Receptos is now on our board. They felt like they had the, they had a solution. Just like there’s 14 relapsing remitting drugs, doesn’t mean there could only be one secondary progressive, okay? Competitions good, wipes out others’ appetite, but their drug failed. And others have failed as well. They’ve tried to take relapsing or remitting drugs or repurpose them into secondary progressive and again, they’ve had 0 success. It’s, there’s been just one huge failure after another, after another. And I mean this is the holy grail of the multiple sclerosis market place because there’s no treatment. There’s no current options; the first person in owns the market. That’s a big deal. So, it’s a well-known fact that there are none; whether you want to google it or otherwise and...researchers have – you know the 2 billion’s probably frankly low, but it’s going to be...whoever ends up and gets final approval is going to make a lot of money on it.

Paul Solis: In the third paragraph, third sentence, I believe, “we grow our drug in bacteria and have to have a sterile process from start to finish to satisfy FDA.” Is FDA the food and drug administration?


Paul Solis: And that’s the U.S. food and drug administration?


Paul Solis: Why would you write that? Why is that significant to say, “Satisfy FDA?”

Rep. Collins: Well because ultimately, whoever buys our company is going to go to the FDA. The big market’s in the U.S. I mean if you look at the size of Australia and New Zealand, why there’s a significant percentage of folks with multiple sclerosis. It’s nothing the size of the U.S. I mean the U.S. is the holy grail. So whoever buys our company is going to get and push to get FDA approval,
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whether they have to raise – do a phase 3 or not, that’s unknown. If they get
accelerated approval that would be a very good day at the office, but to
satisfy the FDA, you got to have a sterile product. In fact, you could go
beyond that to satisfy anybody. Australia, New Zealand or Europe, you got to
have a sterile product. Sterility is right there, but in particular I guess I
mention the FDA because we all known that’s the end game. Somebody’s, not
us, but somebody’s going to be taking this through the FDA.

Paul Solis: And that’s for the purchase of?

Rep. Collins: Yeah. But again, they told us that the more work we can do to shorten the
timeframe – because somebody…they can’t be out doing it. They don’t know;
they wouldn’t do it. Anything we can do to shorten the timeframe of
somebody acquiring our business and then being able to be in commercial
production is gold. These guys. So it was their encouragement to us, go raise
the money, spend the money, because you’ll get a damn big return on it
assuming that somebody acquires you to take what might be 16 months and
you put 8 months of work in and you identify this, this and this. We’re
actually looking at other changes you make so they can get it out in 8 months
instead of 16 months. But they’re dangling…you’ll probably get 10 to 1 by
using your money. They put that kind of money out there. You spend your
million, you’ll get back 10. If we buy it.

Mark Braden: If we buy it.

Paul Solis: This is CG_0161.


Paul Solis: So the subject of this is, “Next offering,” other than the subject, could you
provide a little more background on what this email is about?

Rep. Collins: It was, again, it was our last fundraising, hopefully, the 20 million new
shares, this is the piece that really got the scrutiny of everyone, Tom Price
and myself were part of this. 20 million new shares, 10%, it was 200 million
out, so there’s your 10% dilution and the tentative price of 25-18, I think it
actually ended up 26 and 18 because of that. 5 million – 4 million bucks U.S.,
5 million bucks AUS, you know, carry the company through was
what…explaining why we were going to do this last offering and would be all
the shareholders...

Paul Solis: So this is the first – this is the private placement that had sort of been in the
press and discussed?

Rep. Collins: That’s it. This is the private placement that’s in the press; that’s correct.

Paul Solis: If you look in the third paragraph, you say, “This offering will be to existing
NZ/AUS shareholders or U.S. shareholders I identify.” Does that mean you
personally?

Paul Solis: “I identify?”


Paul Solis: Did the board give you authority to do that? Or how did that come to be, where you’re identifying these people?

Rep. Collins: I’d always been the lead in the U.S. So, these would be new shareholders. So you know, we…it’s easy to identify all these people, but there were always folks who kept hearing about it and said if there’s ever any another offer, let me know. And actually, we got 6 or 8 new shareholders, who had never, ever participated before. And primarily they were people, friends of mine who had known about the company and accredited, sophisticated investors who then said, if you’re interested you know, I’ll get you a booklet.

Paul Solis: So there’s some people who are on the recipient chain of this email who might not yet be shareholders?

Rep. Collins: No, these are all shareholders.

Paul Solis: Okay.

Rep. Collins: Well, in fact as it turns out, a few of them identified people. So it’s like if – it’s almost like – if you got somebody that’s accredited and they’re interested, get the names to me so I could put them on a list and get them a booklet.

Paul Solis: And were you the one deciding eligibility on –

Rep. Collins: No. People...this is in the U.S. This is self-certification.

Paul Solis: So any of these individuals or people who these individuals might then contact, would contact you and say, “I’d like to take part in this?” Is that how it would work?

Rep. Collins: Yeah. I mean if somebody – yeah, I would get them the booklet. Yeah. I would say to Simon, “Somehow, some way, add so and so this to your list. They got – they’ve expressed some interest.” And they might or might not follow through. I will point out though, the 6% fee didn’t pay them out. There was no 6% fee.

Paul Solis: Okay.

Rep. Collins: We had discussed you know, time and again, the brokers disappointed us. And this was another one of those instances. However, they were thinking of doing it, it did not – that was preliminary and at the end of the day, there was no 6% fee and so forth. It was just a straight –

Paul Solis: Or discount.


Paul Solis: There was no discount?
Rep. Collins: No, no. Well, the discount was...the .18 cents and .25 cents was a slight
discount to the closing share price of the prior 30 days which you do with
private placements, otherwise some of these go on the market and for stock,
there was thinly traded you know, 20 grand a day trade and you’re trying to
raise 5 million bucks, you got to get people to pony up. They expected that’s
tradition. That’s how all private placements work and so this whole idea of a
6% fee or a discount in line was...that never occurred. That was a thought,
but didn’t occur.

Paul Solis: Was there another private placement offering also that summer in 2016 or
was this the only one?

Rep. Collins: Yeah because this one – there was people, like I said, who missed the
deadline. The paperwork finally came out and said you got to have your
paperwork in by 5PM, June whatever. And that’s when I chased down my
friend Paul, who was the procrastinator and I said, “Paul, where’s your – I
just found out you’re not in here.” And some folks overheard my
collection and said well what are you guys talking about? And I said,
“Well, Innate’s doing another offering and Paul as usual is late in getting in
stuff.”

Paul Solis: And who is Innate Investor 2?

Rep. Collins: He was my finance chair on my committee, but he was one of my original
investors in ’05.

Paul Solis: What’s his last name?

Rep. Collins: Harder. And I was a big investor in his company, which was sold to Ford. So
he and I go back to YPO, Young President’s Organization, 35 years ago. And I
was just the chairman and so he’s personal good friend and we’d been fellow
investors in each other’s companies over the years and I think I’ve made him
more money than me, but we’ve done pretty well. And, so he’s been one of
those that’s been on every round. He’s always done it and –

Paul Solis: And you know, I see Mr. Hook’s name here. Did he take part in this round of
private placement offering?


Paul Solis: Did any other congressional staff members of yours take part?

Rep. Collins: No. He’d be...he would be the only accredited investor. I don’t pay my staff
enough to qualify.

Paul Solis: And, is Secretary Price listed on this? I don’t see his name. Do you know – did
you send him an email about this?


Paul Solis: I guess I –
Rep. Collins: No, no. because he wasn’t a … I did not know he had at one point bought stock on his own. He never shared that with me. And because he wasn’t a part of this, no he never got this email.

Paul Solis: So then, walk me through how it came to be that Secretary Price became aware of the private placement offering and you know, how it all went down.

Rep. Collins: Sure, well unbeknownst to me, Tom had purchased stock in the – again, I talked to everybody about it. Tom was the only one that I know, pretty sure he was the only one, who after a conversation at dinner or something else, we’re sitting on the House floor, went home and did some research. Looked up Innate because it’s a public company and was like, “I kind of like this.” And unbeknownst to me, I think I even read in the paper, he bought some stock – not a lot, in 2015. Which then put it on his radar. Went and invested money – even though he never shared that with me.

Paul Solis: Now if I could just stop you, when you said after a conversation on the House floor, does that mean a conversation between you and him on the House floor about Innate?


Paul Solis: Okay.

Rep. Collins: I mean I – again, when we’re sitting on the House floor, killing time during a motion to recommit, we talk about our kids, and we talk about our vacations and we talk about…the New York Yankees, in my case, my companies. Oh, yeah. So general conversation where if you look at what we’re watching on C-SPAN, nobody sits in their assigned seats and nobody's paying attention. They all got their phones out and they’re emailing. That’s just what happens. So yeah, it would’ve been a discussion. It could’ve been elsewhere, it could’ve been at a dinner, but primarily Tom and I, you know we’d sit down next to each other on the House floor and chat and so I would’ve …he would’ve asked about the company and I can’t tell you the total context because I can’t remember but, somehow it would’ve been yeah, we’re doing one last offering. And at which point, he said, “I’d like to consider participating. Can you get me the documents?” He’s a sophisticated guy. He knows how private placements go. I said, sure. Write your name down, I’ll have Simon get it to you.

Paul Solis: Okay and that’s in relation to this specific placement?


Paul Solis: So he had – so you… just so I can recount what you just told me. If I get it wrong, you can tell me. You’ve probably had some conversation initially about the company. He then took it upon himself to do some research, make a purchase. And then you had an additional conversation about the private placement in 2016.
Rep. Collins: Yes. In one context or another as, again you just all about things, how are things going with Innate. I’d say things are going pretty good. We like what’s going on, blah, blah, blah and I’d say, you know, we’re doing one last fundraising and which then, “oh, really?” I said yup. We finally see the end. The last patient’s in, we know how much money we need to stay alive. We want to have a little cushion. We’re going to raise 4-5 million bucks. And he would’ve then said something along the lines of, “Gee I’d like to take a look at that.”

Paul Solis: And was that a specific conversation you had around this time in June of 2016?

Rep. Collins: It would’ve been, sure.

Paul Solis: Where were you when you had that conversation?


Paul Solis: You said probably, is there something else coming to mind? Somewhere else you might’ve had the conversation with him?

Rep. Collins: I mean we all see each other all over the place. I mean it could’ve been over at the Capitol Hill club, at a main street partnership, you know, breakfast meeting at ...I mean, I would say most members of Congress, 90% of their interactions is on the House floor. Because otherwise, we’re busy with meetings in our office or we have hearing; how our days go; or we’re fundraising...so I’d say it’s a safe bet, about 90% of our, “How are you doing? How’s the family? When are you getting married? Where’s your venue?” that’s the general chitchat on the House floor. You voted and the clocks ticking, you got to wait 5 minutes to get to the next vote.

Paul Solis: And then he did end up taking part in the –

Rep. Collins: Yes he did. He got the booklet and made his own decision. I never talked to him about it; in fact did not know what he subscribed to until after the fact.

Paul Solis: Was the eligibility for this private placement at all restricted by people who had previously taken part in the private placement?


Paul Solis: No?

Rep. Collins: We had at least 8 or 10 new members – not new members. Every time we did an offering, we’d let new people in. Because we never, we always wanted more money not less. This was no exception to that.

Paul Solis: And I only ask that because I you know, I had seen some press reports about something to the effect of there could have been a restriction based on previous engagement in a private placement as a restrictor, but that’s – so is it safe to say it’s pretty much open to anybody as long as they were considered an accredited, sophisticated investor?
Rep. Collins: That’s correct. And knew about it and since this was not widely publicized, with maybe one exception pretty much all the other folks were people I knew because that makes sense. I knew about 8 new folks came on this.

Paul Solis: So, hypothetically if somebody on that list knew somebody who was a sophisticated investor, you didn’t know them, but again, they had a connection to one of those recipients, called you up and said, “I’d like to take part.”

Rep. Collins: I think there were one or two of them. Oh yeah, for sure. We were always looking – you always want more not less.

Paul Solis: I think it’s really all I have on that. Jeff, did you have any questions about that?

Jeff Brown: I did want to come back to just one question. You were talking about the videos with the compassionate care patients. What’s the, you know, what’s the point of putting those up on the website from you know marketing perspective? Or, it’s not really marketing –

Rep. Collins: It’s gold. The real person on the drug saying I no longer consider suicide and I now work in the garden or the one, the funniest one, the guy who said, “I had to have – they geared down my wheelchair because my hand coordination, even though I was doing it and now they’ve sped up my wheelchair because” –

Jeff Brown: I guess sort of, to rephrase that. Are the, is big pharma going to check out these videos?

Rep. Collins: No. Has zero value to selling the company. Zero. Big pharma, they’re sophisticated, they’re going got look at the market place at some point in the next 60 or 90 days to have some access to at least our top line data, the comparison of placebo patients to patients that are on it. Everything that pharma will do is going to be their individual decision company by company, guessing the market place, looking at the potential of accelerated approval versus phase 3, any data we give them; they’re going to do their internal analysis and say…

Jeff Brown: And if they’re the end goal though, is – are the videos like a recruiting pitch for others to join the trial?

Rep. Collins: Yes. Yeah we were sucking wind on recruiting patients under the trial.

Paul Solis: Well –

Jeff Brown: Before we move on, I’ve got to use the restroom. If you guys want to keep moving –

Mark Braden: How much more do we have?

Paul Solis: We’ve got a little bit more, not too much longer. I can continue I think, if you don’t mind.
Jeff Brown: Yeah.

Paul Solis: Jeff's going to exit the room, but I'll keep on.

Paul Solis: So, I want to move on to a little bit different topic. And this involves the NIH. This involves, I think, maybe a meeting that you took part in a few years back at NIH and meeting with some officials there. So, I guess I'll first ask though, background – have you been to the NIH campus before?


Paul Solis: How many times have you been there?


Paul Solis: Just once. Okay. And when was that time?


Paul Solis: Okay, but you recall going there?


Paul Solis: What do you recall about that?

Rep. Collins: My guess early on in my congressional – so I came here in January 2013, it was probably in '13 or '14. I really don't remember back...getting old. I don't remember too much about it other than it was pretty amazing, some of the stuff they were doing.

Paul Solis: On November 18th, 2013?


Paul Solis: Does that ring a bell?

Rep. Collins: No, but that would make sense.

Paul Solis: And when you attended NIH, you went up there, were you there in an official capacity as a member of Congress, or as a member of your committee you were on at the time?

Rep. Collins: No, I was on the science based technology committee. I was not on energy and commerce. I went there really as just a general point of interest. My company, ZeptoMetrix, had been dealing with the NIH forever. And here I was just like I'd go to the Smithsonian, really...had an opportunity to go see some of the good stuff they're doing and I'm sure I asked my staff to see if we could just kind of...do a tour. I love to plan tours.

Paul Solis: So you were there to just do a tour of NIH?


Paul Solis: No other reason besides that?
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Paul Solis: And you said you attended like you would attend the Smithsonian or something, but I just want to make sure, I mean – that visit to the NIH, was that precipitated by a hearing or something that you –

Rep. Collins: No, again I wasn’t on energy and commerce. I was on science based, technology, small business and agriculture.

Paul Solis: Right. Back when you were on that committee –

Rep. Collins: That’s when I went.

Paul Solis: Right. Did your visit – was that precipitated by a hearing or something in your official capacity?


Paul Solis: No. Okay.


Paul Solis: So again, as best you can recall then, how did the meeting come to be? You said you might’ve had some staff set it up. What can you tell me about that?

Rep. Collins: I would’ve had staff set it up.

Paul Solis: Do you know – so the reason why you would’ve gone up there is just because you were interested?

Rep. Collins: Oh yeah. Again, ZeptoMetrix and the NIH have a very long-standing relationship and they have level 3 biocontainment labs, so do we...I had – the company I had founded in February of 1999 and so... to actually be here and have a chance to go see the good stuff they were doing you know...too good to pass up and I was able to do it. It was if I recall it, it was just a very informative field trip.

Paul Solis: Who did you meet with while you were up at NIH?

Rep. Collins: I couldn’t recall a name if my life depended on it.

Paul Solis: What staffers attended with you? From your congressional staff?

Rep. Collins: I can’t ... I don’t know that either because back in ’13...I can’t. I mean I’ve had so much staff turnover, probably Jeff Freeland who was probably then, my senior LA? I don’t think he was my LD at the time. I’m guessing there. I really don’t know.

Paul Solis: Okay.

Rep. Collins: It was probably just like two of us. I would not have brought an entourage there.

Paul Solis: And why would Jeff go if it was just...

Paul Solis: They don’t trust me to go to Dunkin’ Donuts alone.

Mark Braden: Sometimes you follow instruction [crosstalk inaudible].

Rep. Collins: My ability – no he did not say that. He did not body slam that reporter. He was provoked.

Paul Solis: Well I have a document here I’ll have you look at. This is HR_0197.


Paul Solis: Okay, that’s good. That’s good. So after taking a look at that, can you tell me anymore about your visit and do you recall meeting some of these individuals here?

Rep. Collins: I mean, clearly, now that I see this, I – because of my role with Innate, also had clearly an interest in what they were doing. In basic research and so forth, so...I think this does something pretty well. I mean, again, it was a field trip. It was a discussion with Mr. Freeland. While I today, don’t recall this being the agenda, clearly this was the agenda.

Paul Solis: And when you say field trip, I just want to make sure I get this because “field trip” sometimes in congressional parlance has a specific meaning and sometimes...yeah. Well sometimes committees will do field hearings –

Rep. Collins: Oh, field hearings. This wasn’t a field hearing.

Paul Solis: Right, right.

Rep. Collins: This was like a high school field trip.

Paul Solis: So I mean, I guess want to know, did this trip have any relation then to your duties on the science and technology committee at the time?


Paul Solis: It was – you were there purely as a private citizen?


Paul Solis: I see NIH Employee 2; do you see that name up here? Investigator, neuroimmunological diseases unit?


Paul Solis: Do you recall any specific conversation you might’ve had with her?


Paul Solis: Do you know if you asked her to meet with anybody from Innate?

Rep. Collins: No, I don’t believe I would’ve.
Paul Solis: Do you recall handing anything to her?


Paul Solis: The rest of the individuals here, Dr. Avi Nath, Dr. Pascal Sati, what about meetings with them? Does this help sort of refresh you on any discussions you would’ve had with them?

Rep. Collins: Clearly I did, but no.

Paul Solis: Okay.

Rep. Collins: This is so far back in my past, I have to admit.

Mark Braden: Is this from NIH?

Paul Solis: Yeah.

Mark Braden: We’ve never seen it before.

Paul Solis: Right, I understand. I’m just wondering if this helps jog his memory a little bit. I can’t get into where we received –

Rep. Collins: Well, no it does help jog my memory that after seeing this, I’m not surprised. It makes perfect sense that these would’ve been topics I would’ve wanted to discuss because they’re certainly important topics to me in my role at Innate. And just like you go to conferences or whatever, and clearly the biomarker is the thing to do. There is no biomarkers for secondary progressive MS. It’s the real…it’s the real bitch of everything to do with it. If I – since I know there aren’t any, I’m sure that’s what they confirmed there aren’t any.

Paul Solis: Did you discuss Innate with any of the individuals on this list?


Paul Solis: I want to move onto –

Rep. Collins: But you know, I would also say whatever they gave me, would not have been considered anything other than good old fashion research going on. Nothing proprietary or confidential or …

Paul Solis: And I asked the initial question about whether or not there was a hearing or something that might’ve precipitated this meeting and you know, I actually took a look at a hearing where there was a Dr. Landis from NIH, and you had given her some questions. And she invited you to come up to NIH during the hearing, and I’m wondering if –

Rep. Collins: Oh, really? What hearing was that?

Paul Solis: It was back in, I think it was in July…June or July of 2013.

Rep. Collins: Oh. Well then that probably does explain this. But what … group was hearing on that? It must’ve been the science committee.
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Paul Solis: Yeah, it was. It was the science committee.

Rep. Collins: What were we talking about? Because normally this would be energy and commerce stuff. So what you're telling me, makes sense. That if it was in July of '13 at a science committee hearing and someone from the NIH –

Paul Solis: There was a Dr. Landis. Her name Story Landis.

Rep. Collins: I'm so bad on names –

Paul Solis: She was testifying...

Rep. Collins: Tom...I'm just I'm so bad on names. I'm the same with you, Sam.

Mark Braden: I'll give you a break; it was four years ago.

Paul Solis: No, I totally understand.

Rep. Collins: If – I guess I was sort of kind of blanking out, that actually helps me understand where this came up and why I went there.

Mark Braden: She invited you up apparently.


Mark Braden: Is that what it shows? I'm just curious.

Rep. Collins: It would appear so. I would jump all over that.

Paul Solis: This is another email here. Three pages – you're on this email, but you're not the author of it. This is TAM_0257-0259.

Rep. Collins: So this is from Tom McMahon – okay, CUBRC, to Simon...Okay. Yeah, by the way, CUBRC is a research company that 98% of what they do is with the U.S. government. So, okay let's see. Okay.

Paul Solis: And totally understand that you're not the author of this email, but in this email, it is a purported recounting of information you might've shared with Innate Investor 3. First of all, is Innate Investor 3 a business associate of yours or is he a friend of yours?

Rep. Collins: I would not call him either of those. He's an investor – CUBRC is an investor in Innate and Tom is the CEO, subsequently got permission from CUBRC to invest on his own.

Paul Solis: So, CUBRC is an investor and then Innate Investor 3 is –

Rep Collins: CEO of CUBRC. And he then personally invested as well.

Paul Solis: This, you know he writes, “in my conversation with Chris last week ....”

Mark Braden: Which one?

Paul Solis: This is the first paragraph and he's writing –
Mark Braden: Of which one?

Paul Solis: Of the first page.

Mark Braden: Okay so it's the last paragraph. They go in the sequence of production of emails so I'm assuming the first ones are back here and this is the last one?

Paul Solis: I'm referring to the Wednesday, September 24, 2014 at 10:29am.

Mark Braden: Okay.

Paul Solis: And in the first paragraph it mentions, “Conversations we had at Chris’s home back in January.”

Rep. Collins: That would've been one of the many investor updates that Simon would give. I'd have folks to my home when he would update them on pretty much all the people on the list. He would come speak to them at the house.

Paul Solis: So this conversation that Innate Investor 3 is referencing at your home, you know, referencing, "Chris is retelling of a briefing he attended." Did that occur? Do you recall having this conversation with Innate Investor 3 and Simon about meeting with the NIH person?

Rep. Collins: I don't recall it no, but in reading this makes perfect sense.

Paul Solis: And at the bottom you see this NIH Employee2?


Paul Solis: You know she was present on that last agenda I showed you as someone you may have met with there. These ... does this provide any further – I'd asked you previously about your conversations with her – you know, what can you tell me about any conversations there, you said you couldn’t recall. Does now seeing this, does this help jog your memory as to any conversations you would’ve had with NIH Employee 2?


Paul Solis: Okay.

Rep. Collins: Sorry, but I mean reading this, everything in here makes a whole lot of sense.

Paul Solis: Okay.

Rep. Collins: Other than we never did do any team agreement.

Paul Solis: On the third paragraph it says, “As I recall Chris’s telling of it, they had further brief discussions following the session.” And again I think this is you and NIH Employee 2, “which led to a visit by Chris to the NIH from which he thought, some element of NIH might consider funding development of MIS416.”

Paul Solis: Did that occur? Did you relay that to Innate Investor 3 that NIH might consider funding development to MIS – for MIS416?

Rep. Collins: Clearly I said that I can’t tell you whether I would’ve gotten that from the NIH or whether I would’ve just known that as a basic thing in my own head.

Paul Solis: Did you have further conversations with NIH Employee 2?


Paul Solis: Do you know –

Rep. Collins: Best to my knowledge that was just a one day meeting and whatever you told me I was with her for an hour or something.

Paul Solis: Did NIH Employee 2 have any further discussions with any employee of Innate?


Paul Solis: Alright.

Rep. Collins: And again, I think the other thing is, Tom was obviously pitching something to Simon, but that never did occur.

Paul Solis: Okay.


Paul Solis: I have one –

Rep. Collins: They don’t make any products.

Paul Solis: I have one final email to show you about referencing this time at NIH. And then we’re off that subject. This is HR_0219. Again, I’m going to give you another caveat that you – I don’t believe you’re the author or recipient of these emails, but I want to ask your knowledge about something that might be discussed in these emails.


Paul Solis: So, and I only want to focus on the top part there. NIH Employee 1 thanks – this is from Jeff Freeland to NIH Employee 1. It says, “Thanks so much for putting this altogether. It looks great. Just have one quick thing I wanted to tell you over the phone. Could you give me a call at the office when you have a moment?” Do you know what Mr. Freeland wanted to discuss with NIH Employee 1 over the phone?


Paul Solis: Did he have any conversations with you saying, “I want to talk to NIH Employee 1 privately about something or not over email?”

Rep. Collins: No, nothing that I can recall.
Paul Solis: Did you direct him to make a phone call to NIH Employee 1?

Rep. Collins: No. But this would be consistent of Jeff putting the meeting together. That's kind of what he did/would do. Typical thing of my staff.

Paul Solis: The last little bit, I wanted to talk to you about, sort of very briefly is the Roswell Park stuff you mentioned earlier. So I'll just get right into it and we're definitely nearing the end of our interview.


Paul Solis: Do you know anybody who works at Roswell Park?


Paul Solis: Okay, okay. That's what I figured. It's based in Buffalo, right?

Rep. Collins: It's across the street from my biotech company.

Paul Solis: You mentioned –

Rep. Collins: In fact we do joint ventures with them. I have office space there.

Paul Solis: Okay.


Paul Solis: Okay, so you're pretty familiar with Roswell Park?


Paul Solis: Just briefly, can you give me a little bit of the background on Roswell Park's connection to Innate and MIS416 or any other capacity, how that started and where that's at now?

Rep. Collins: I can honestly tell you I have no idea it started. Other than knowing factually that Dr. Kunle, who's a world renown researcher in things like ovarian cancer, had a vaccine that he thought would help prevent people who had ovarian cancer had surgery, to keep it from coming back like cancers do. And I do know just factually that his studies basically failed. And I can't tell you how he subsequently linked up because I never – I don't know Dr. Kunle, but he –

Paul Solis: Have you ever met him?


Paul Solis: And where and when did that happen?

Rep. Collins: I think I met him at Roswell? And I don't 100% recall what, when, where and why, but he is a well-regarded guy and I would bet I met him, but I couldn't put a face on it if my life depended on it. And if I was, it was maybe once or possibly even a social setting, but somehow he and Simon did hook up. Again, what our adjuvant does, which is help cancer vaccines become way, way,
way more important. And we have...could well be a 100 researchers around
the world doing it and actually human trials with prostate cancer and breast
cancer. That would be something Kunle would know about. So I never had
any discussions on it at all, other than to certainly at some point I was aware
from our board calls and from Simon that we were providing MIS416 to
Roswell under traditional MTA, no money's changing hands or anything, but
just a confidentiality, material transfer agreement to see if it could help them
take their stalled- call it failed – vaccine program and juice it up and it did. It
worked incredibly well.

Paul Solis: Are they currently in a trial right now?

Rep. Collins: Yes, the human trial, to my knowledge started about a month ago. Few
weeks ago to a month ago.

Paul Solis: So they get this IND then in order to –

Rep. Collins: They would’ve had to. You can’t get a trial without an IND.

Paul Solis: Do you know who initiated the conversations between Innate and Roswell to
sort of, as you said, hook up and link up to make it –


Paul Solis: Do you know if anyone from Innate has continuing contact with RPCI
Physician 1?

Rep. Collins: Oh, yeah for sure. Oh yeah. No, once he got MIS416, we had this – yeah that’s
– we don’t just let the dog go wild on that.

Paul Solis: And do you speak with RPCI Physician 1, personally?


Paul Solis: Who would at Innate?

Rep. Collins: Simon or Gill? I think or both. Primarily Gill as our chief scientist. She keeps
her arms around all that stuff.

Paul Solis: This is I think maybe the last email – this is from your production –

Mark Braden: Good. It wasn’t a total waste.

Paul Solis: 105 – This is – we marked it THCC_1058. Your bates number was OCE_1058.
I’ll let you take a look at it and I really just wanted to ask one small question
about it. Two small questions.


Paul Solis: So you mentioned an agreement you have with Roswell Park that Innate has,
is that something the board would approve?

Paul Solis: Who would approve that or sign onto that agreement?

Rep. Collins: MTA’s would be Gill, probably. I don’t even think Simon would be involved because it’s just something we do. We protect our patent rights by doing an MTA, but again, this was –

Paul Solis: But the board wouldn’t have to be apprised of it?


Paul Solis: Do you know if the board was apprised in this circumstance of sending that compound to Roswell Park?


Paul Solis: So how did you come to know? You have a very good explanation with kind of the history here between Roswell Park. How did you come to know a lot of this information?

Rep. Collins: I think probably between conversations with Simon and certainly as some of the shit was hit in the fan… I did not get Kunle’s name right, but I knew I spelled it wrong because I put the question mark there.

Paul Solis: I mean you write that, “The board discussed this at length and decided the risk was nil so we’re –

Rep. Collins: Oh, no, no yeah so that we did. And I think I mentioned that when it came time for them to actually go into human trials, it was a very robust discussion of whether we would allow that to happen because of the potential adverse effect, adverse event that might happen in their trial, using MIS416 that then would backwash onto our trial. So, it was a fairly robust conversation at the board level, whether we – because we could’ve pulled the rug on them. And then that’s when I think I said earlier, how we researched through the likelihood of that happening was slim and none and this was too important and as I say here, would’ve been unconscionable through all these years to tell them. Now that you got your IND, you got your pool to do the trial, your compound is your vaccine in with MIS416, now you pull out MIS416, and the entire program would fall apart.

Paul Solis: The last part of this paragraph that you write, “But typically an adjuvant supplier would receive 5% of the revenue.” When would that happen and sort of what’s the circumstances of that –

Rep. Collins: The going if there’s such a thing of a going rate, if you’re a participant in somebody’s drug like with an adjuvant, which is not the drug itself, but in this case kind of a boost to it, a 5% kind of royalty would be fairly standard in quote the industry.

Paul Solis: Would that be part of the agreement you have with them?

Paul Solis: How would that get –

Rep. Collins: Well the agreement right now is you can use MIS416 in your trial. There’s no agreement that allows them to use it in a product going to market. The material transfer agreement and the use of it at no charge and no compensation, would be limited to the trial. So if they ever did, you know 10 years later or whatever, actually have a successful trial and then someone who was going to take this to market just like other things, you have to go cross the T’s and dot the I’s with the attorneys to make sure you’ve got legitimate access to use it, of which they would then have to come back to Innate and tell Innate, “we’ve had a good trial here. We want to use MIS416 as the adjuvant. Let’s sit down and talk.” And if we did, my expectation would be, no guarantees, it might end up in something that looks like a 5% royalty.

Paul Solis: You mentioned a 12 million dollar grant. Where did that come from?

Rep. Collins: Yes. I think that came from the NIH. That’s a big deal for them.

Paul Solis: Did you take part in any way in discussing with NIH that grant?


Paul Solis: Did any of your staff members?

Rep. Collins: No. We were pleasantly surprised. It was good for Buffalo.

Paul Solis: Do you have any questions about Roswell Park, Jeff?

Well that is really it, except lastly I just have to ask, you know, it’s common with all our reviews. Besides your attorneys, have you discussed with anybody the fact that an OCE investigation exists or that we had contacted anybody as a witness? Have you talked to anyone besides your attorneys about our review?


Paul Solis: Okay, who have you spoken with?

Rep. Collins: Certainly my family, my business partners. I talked to a woman at the airport about it today. I have not –

Mark Braden: You saw how closely he follows his attorney’s advice on what he should be talking about at the airport.

Rep. Collins: I haven’t been...I’ve not exactly kept this close to my vest.

Paul Solis: Anybody that’s received a request for information from us, has anybody reached out to you and said, “Hey I got this letter.”


Paul Solis: Okay and who would that have been?
Rep. Collins: One of them was Chris Graham, my partner at Volland. Another was Glenn Arthurs, my long time stock broker at UBS. He's another one – so Glenn, Chris Graham – who else might’ve...oh, Bill Grove, William Grove – he was best man at my wedding. Those three in particular called to tell me – they were contacted by the OCE and asked me what they should do.

Paul Solis: And what did you say?

Rep. Collins: I said I can’t tell you what to do. I will admit I told them to go to Wikipedia and to Wikipedia the authority and the leverage the OCE has and I would’ve stated definitively that the OCE does not have subpoena power and beyond that, make your own decision. Get your own counsel; I can’t tell you what to do because I can’t tell you what to do, but make your own decision.

Paul Solis: Okay.

Rep. Collins: Don’t take that the wrong way, but that was pretty much how I worded it.

Paul Solis: That’s good, that’s good. I asked a question and that’s a straightforward answer. What about Guy Agostinelli?


Paul Solis: Not your attorney in this matter?

Rep. Collins: No, no. Mark is in this matter. He’s my attorney on all my business dealings and represents my businesses including, he did tell me that Joe McMahon, who is an investor, who’s my partner at Autobot Machinery, and Chris Graham who’s my partner at Volland Electric, he represents both those companies and I do know that both Joe and Chris called Guy Agostinelli and I guess asked him for advice, relative to the OCE. And I can see here for sure, Chris Graham produced documents. I don’t know if Joe McMahon did or not.

Paul Solis: Did you call Mr. Agostinelli or did you have a conversation with him about Mr. Graham being contacted by us?

Mark Braden: I’ll object. You’re asking any questions about his counsel. Or conversations he’s had with counsel. I’m just saying he’s not going to answer any questions regarding any phone call he had with somebody who represents –

Paul Solis: Yeah, well certainly not all information you discussed with your attorneys, is privileged in any way, certainly that’s not the case. Moreover, -


Paul Solis: Okay.

Rep. Collins: I mean that’s the easiest thing, never talk to –

Mark Braden: That’s a good solution [crosstalk inaudible].

Paul Solis: I have an email here I’d like to show you. This is CG_0175-0176.
Mark Braden: Again we have another email where he’s neither the author nor the recipient of, but you’re going to ask him about?

Paul Solis: Yes, where the Congressman was discussed, possibly communicating with the author of the email so yes, I am going to ask him a question about that.

Rep. Collins: Which order does this go in?

Paul Solis: I’m only going to ask about the top email on March 23, 2017 at 3:07PM.

Mark Braden: That’s the last one on the chain?

Rep. Collins: So Guy to Chris Graham. “Chris, I was anticipating around CCC advised you got this letter … [inaudible].” Okay, sure.

Paul Solis: Although your name isn’t spelled out here, the email does say CCC advised you got this letter.

Rep. Collins: That would be me.

Paul Solis: I had previously asked you before if you had any conversations with Mr. Agostinelli. Here he writes, “CCC advised you got this letter.” Again, did you have any conversations with Mr. Agostinelli about Chris Graham receiving an RFI from our office?

Rep. Collins: I don’t believe I did. I may have sent him an email … as far as talking to him, no.

Paul Solis: Okay, so did you send Mr. Agostinelli an email about it.

Rep. Collins: May have.

Paul Solis: Okay.

Rep. Collins: I don’t know. I don’t keep my inbox.

Paul Solis: Do you know what may have been in that email?

Rep. Collins: Again, Chris Graham did call me. And I would’ve said exactly what I said to you which I would’ve told Chris Graham. And Chris Graham would’ve said to me, “I’ve been in touch with Guy Agostinelli,” and I would’ve said, “Well, that’s great,” and something along those lines.

Paul Solis: Okay. I think that’s all we have for you Congressman, so thank you very much.


Paul Solis: You’ve been very cooperative and we’ll conclude the interview, thank you.

Rep. Collins: Tried to be as much as I could.

Paul Solis: Thank you.
Exhibit 2
Paul Solis: This is Paul Solis with the Office of Congressional Ethics. It's May 17, 2017. I'm joined by Omar Ashmawy from the OCE, Michael Sexton, Terry Connors, for an interview of Dr. RPCI Physician 1. I have provided RPCI Physician 1 with a copy of 18 U.S.C. 1001. He has signed an acknowledgement form signifying that I have provided him a copy of the statute and we can begin the interview.

So RPCI Physician 1, I'll get right to it. I'd like you to walk me through in your experience your involvement or interactions with the company called Innate Immunotherapeutics.

RPCI Physician 1: So the interaction with Innate Immunotherapeutics started right about 2010 or thereabout when I became aware that they had a compound called MIS416. MIS416 is a compound derived from bacterial cell wall and has the potential to be a good adjuvant for cancer vaccines.

Terry Connors: Adjuvant?

RPCI Physician 1: Adjuvant means-

Paul Solis: Adjuvant.

RPCI Physician 1: -a help. Adjuvant essentially is a compound that helps wake up the immune system so that it can react to a foreign pathogen. So because of the potential promise of MIS416, we started a collaborative agreement with Innate Immunotherapeutics to test. I wanted to test whether it in fact has potential promise to be translated to the clinical trials. So we embarked on a number of pre-clinical studies that demonstrate that it has potential to be of clinical benefit in patients.

Pre-clinical testing was primarily in ovarian cancer so that was the involvement and coincidentally even before engaging with Innate Immunotherapeutics, we had a grant that allowed us to test a concept. Okay so the primary scientific concept is whether the use of a drug called Rapamycin will enable generation of what we call memory immune cells, memory T cells because you want immune reaction when you vaccinate to be long lasting and durable so that when a patient gets with an infection or cancer again, the immune system can protect.

That was a proposal in the grant. So we studied a clinical trial with NIH funding to test that hypothesis using a vaccine obtained from a company called Sanofi Pasteur.

Paul Solis: Could you spell that out for me?

RPCI Physician 1: Sanofi is S-A-N-O-F-I. Pasteur P-A-S-T-E-U-R. Okay? So our proposal was for custom using a vaccine manufactured by Sanofi Pasteur to test our hypothesis. Remember what I said about generation of memory T cells. About three years into the clinical trial funded by a NIH grant, Sanofi Pasteur made a business decision to discontinue production of their vaccine.
When that business decision was made, our clinical program, clinical trial, became paralyzed and we started looking for alternatives. By this point, we had generated sufficient data to convince us that MIS416 could be a good alternative for taking forward to the clinic as part of our vaccine.

Let me make sure that you are clear that the same way that I was interacting with Innate Immunotherapeutics, I was interacting with other entities. So the vaccine that we then proposed to the NIH, so we said to the NIH that we are no longer able to use Sanofi Pasteur. We need to switch to something else and I’m coming up with ... I proposed that we use MIS416 as the adjuvant and to use a protein. The adjuvant alone is not sufficient. MIS416 alone is not a vaccine. You need to mix it with something else.

I had another entity that we were dealing with called the Ludwig Institute for Cancer Research to supply us with a clinical grade, the actual vaccine target which is a protein called NYES01. The vaccine actually is a composition of MIS416, plus NYES01 and that’s what we proposed.

We put this together in our new clinical protocol that we, since we can no longer use Sanofi Pasteur, we switched to MIS416 plus NYES01 protein for the vaccine approach that we proposed. But let me point out to you that you know that to actually run the clinical trial, you need to get Institution Review Board approval. You also need to get FDA IND approval. We got Institution Review Board; the protocol was under one scientific review as well as ethical review.

The next step of getting the FDA approval, we still have not got it yet. The clinical trial has actually not started. We have not treated any patient with MIS416. To get FDA approval I need two things. One is a letter of cross filing from the Ludwig Institute which we have, a letter of cross filing from Innate Immunotherapeutics which we don’t have yet because Innate has not yet obtained IND approval in the United States. We are waiting for that. Once we have that then we can go ahead with the clinical trial.

Paul Solis: Okay, well thank you for that clear explanation. That was very helpful. I’d like to ask a little bit more about when you became aware that Innate existed. You mentioned around 2010 you became aware of Innate, so how did you become aware?

RPCI Physician 1: That was through one of our colleagues. Actually he ... can I confer with my counsel?

Paul Solis: Sure. Well I can pause the recording if you’d like to step outside.

RPCI Physician 1: Okay, sure.

Terry Connors: I think I know what you want to know, but come on Doctor.

Paul Solis: Okay, we’re back on the record.
RPCI Physician 1: Okay, so the person that brought this to my attention was Dr. David Hohn. Dr. Hohn talked to me and said he’s aware of this compound that is supposed to stimulate the immune system. Did I want to take a look at it? Essentially I discussed this with him and he sent me, I can’t remember, I think he sent some documents to support it. It looked very interesting because MIS416 is derived from bacterial cell wall. Remember, as I said the whole concept is an adjuvant, something that would help the immune system [inaudible], so very interesting. I was immediately interested and I wanted to explore it further.

Paul Solis: Did Dr. Hohn tell you how he became aware of Innate?

RPCI Physician 1: No Dr. Hohn did not.

Paul Solis: He did not say how he became aware of Innate?

RPCI Physician 1: No.

Paul Solis: Then what happened next? Did you communicate with Innate, representatives of Innate, or what happened next in the process?

RPCI Physician 1: I don’t remember the exact sequence of events, but what I do remember is that we then had, so somebody from Innate was coming into town. I think that was the-

Paul Solis: To Buffalo?

RPCI Physician 1: To Buffalo, the chief executive I think was coming to town. I can’t remember whether he came alone or with somebody else. So Dr. Hohn invited me to a meeting at a place called CUBRC. C-U-B-R-I-C, I think that is the spelling. We just, and the reason I remember this very clearly it’s across the way from the airport. It’s just across from the airport. I went to that meeting and I heard a little bit more about MIS416 and my interest remained even after that meeting.

Paul Solis: Who was present at that meeting?

RPCI Physician 1: The people that I remember, Dr. Hohn, people from CUBRC, and Congressman Collins

Paul Solis: As you mentioned, some Innate employees as well. Does Simon Wilkinson, does that name ...

RPCI Physician 1: Yes.

Paul Solis: Okay, He was at that meeting?

RPCI Physician 1: I think so, I think he was at that meeting.

Paul Solis: Okay, Did Congressman Collins say anything at the meeting?

RPCI Physician 1: I don’t remember.

Paul Solis: Okay.
Omar Ashmawy: Do you recall approximately what year this meeting would have been?

RPCI Physician 1: This must be 2010. That was, I think 2010 and there was my only interaction with Congressman Collins. I have not had any communication with him since then.

Terry Connors: He wasn’t a congressman then.

RPCI Physician 1: Right, he was not even a congressman at the time.

Paul Solis: So, since that time, back in 2010 until this point and you just described where you’re at in the trial process; what kind of communication do you have with Innate Employees?

RPCI Physician 1: I’ve had very good communication. So, there is a Chief Science Officer, her name is Gill Webster. She actually has visited Buffalo a few times to check progress, we collaborate and in fact she, for a long time, she remained the main contact person that we talked to when we needed more MIS416. She arranged for shipment, we discussed results. We’ve had a few phone calls with her and I also still have some communication, less so, with Simon Wilkerson. But much more with Gill Webster who is the science officer.

Paul Solis: What about other people at Roswell Park? Do you know if anyone else is in communication with Innate?

RPCI Physician 1: Well, the only … I shared MIS416 with other scientists. So there’s one other scientist we’ve very collaboratively. So, I don’t know that he communicates directly with them: Dr. Siegel. He is also testing MIS416. Working collaboratively with us.

Paul Solis: What about anyone in the administration at Roswell Park? The Board of Directors or Executives at the institute, anybody in leadership, do you know if they have any interactions with Innate?

RPCI Physician 1: Not to my knowledge.

Paul Solis: Okay, All right. You did touch upon this a moment ago … as Congressman Collins … since you saw him that time back in around 2010 at that meeting, has he emailed you, or called you or made any communications with you?

RPCI Physician 1: No.

Paul Solis: Okay, If your ever on an email with Dr. or Ms. Webster or anybody in Innate, is he ever cc’d on an email, if you recall?

RPCI Physician 1: I don’t recall. I don’t recall any suggestion like that.

Paul Solis: How often are you in contact with Ms. Webster or somebody affiliated with Innate?

RPCI Physician 1: It fluctuates. I mean it depends on what it is … for example, the communication with her for the past year has been very few. But there was a time when it was very intense. We were having a lot of results that we
needed to discuss. So, I couldn't tell you if it was a particular frequency, so it just depends on what’s going on.

Paul Solis: You mentioned something too, about ... you used a phrase: "collaboration agreement", what does that entail? What does that mean?

RPCI Physician 1: So, the typical way we work, as you know in any academic institution you can have concepts, but ultimately we cannot manufacture every product that we want to test. So, when we are collaborating, when we're working with a company, then we have MTA or a collaborative agreement in place. MTA if we are transferring materials, collaborative agreement if we are then going on to do some testing such as the ones I described where I wanted to test MIS416 in pre-clinical models in the lab.

Paul Solis: Does that, do those agreements ... Well, first of all, are you yourself a party to that agreement or is it with the institute as a whole?

RPCI Physician 1: It’s with the institute. I’m a party to it ... so, the Investigator would be the PI that would describe the scope; what exactly is going to be done with that agreement.

Paul Solis: Okay.

RPCI Physician 1: And then it goes through the office of the legal counsel to review it before anyone signs off.

Paul Solis: Is there any mention in these agreements about should the trial be successful, a financial stake by a company or a party that provides some of the science behind it or provides a compound, in this case? Is there anything in the agreement about that?

RPCI Physician 1: Not to my knowledge, I can't recall the details of the argument right now, but in general, we don’t agree to those kinds of ... it’s usually not part of the way the agreements are written.

Paul Solis: Okay.

Omar Ashmawy: In an agreement such as the one you describe, I imagine both parties derive some benefit from the relationship; what, in your opinion, is the benefit to immunotherapies to enter into an agreement with Roswell?

RPCI Physician 1: The main benefit for us is that it advances or mission. Our mission to prevent, understand and kill cancer. So we have a scientific concept that we think holds promise. And we want to test it in people. So, the main benefit for us is to advance our mission.

Omar Ashmawy: And how about for them?

RPCI Physician 1: For them, obviously, if our efforts translate into success I’m sure that we would like to build upon that success in terms of larger clinical trials. The clinical trials that I can do is usually phase one. If that shows that the
compound is safe for them, it allows them to build on their product. But, that's me speculating. I cannot speak for that.

Paul Solis: Is Innate providing the compound to Roswell Park free of charge? What is, is there any discussion about that?

RPCI Physician 1: So, the compound is provided free of charge; however, one of the ... as part of the agreement sometimes they provide, companies provide, some kind of support to conduct the pre-clinical experiments. So, because they are so very expensive experiments. In this case, Innate did provide some funding to support part of the pre-clinical research. But, when it comes to the clinical trial, Innate will provide the compound completely free of charge.

Paul Solis: Okay. Was that part of the discussions you had with Innate to come to that understanding that the compound would be given free of charge, or is that a common practice?

RPCI Physician 1: That is a common practice. We have other ... I just talked to you about the Ludwig Institute, it's exactly the same practice. They provide the NY-ESO-1 Protein free of charge as part of a collaborative research agreement. It's a standard practice.

Paul Solis: When did you sign that collaboration agreement? When did that come to fruition?

RPCI Physician 1: The agreement for the pre-clinical studies was signed probably 2010 or 2011. The clinical trial has not even taken off, so we will have to do another document, a clinical trial agreement with who will provide the drug free of charge.

Paul Solis: Did you or somebody else in Roswell reach out to Innate in 2016 and ask to use the compound and they denied you that ability. Do you recall anything like that happening?

RPCI Physician 1: Not at all, if anything ... no, not at all.

Paul Solis: So, you recall any effort made by anyone at Roswell to ask for the compound at a specific time and Innate, a board member or Innate said: not at this time.

RPCI Physician 1: The only reason that we have not started the trial is that we don't have the IND documents. That's my knowledge. It's not because Innate is saying we're not going to give you the compound.

Paul Solis: Roswell has the compound right now?

RPCI Physician 1: Correct.

Paul Solis: You just are waiting some of the elements that you need in order to--

RPCI Physician 1: Right.

Omar Ashmawy: What is the IND? Is that an acronym for something?
RPCI Physician 1: I’m sorry I didn’t explain that. Investigational New Drug. Each time you put in something new, either completely new, or a new combination into people, you get what is called IND, Investigational New Drug approval from the FDA.

Omar Ashmawy: And that’s still pending for--

RPCI Physician 1: Still pending for the MIS416. We have it for the Ludwig protein. And the vaccine will be mixing both together to inject into people.

Omar Ashmawy: For the compound coming from immunotherapies, do you know what the delay is with the FDA?

RPCI Physician 1: Typically the FDA has questions, they may ask you to do some more testing, and essentially FDA is all about safety. So I understand the FDA has some questions, of course I did not read the FDA document and they are trying to respond to the FDA comments and go back and submit for the IND.

Paul Solis: Has anybody at Innate discussed with you their efforts or their discussions with FDA or the process that they’re going through right now?

RPCI Physician 1: I had a discussion probably about a month, 2 months ago with Mr. Wilkinson about this because obviously there are patients waiting for this trial. I wanted to get a sense of the timeline and what is the hold up and he basically indicated that we need to get the IND approval before we can do anything.

Paul Solis: And is it your understanding they’re currently engaged in that process to get an IND approval?

RPCI Physician 1: That is my understanding. Correct.

Paul Solis: So again this is just based on your knowledge on how this works. The compound is being tested by FDA or right there are just basic questions about the nature of the compound?

RPCI Physician 1: I don’t know those details, but I’ve worked enough with the FDA to know that FDA can have questions. FDA will ask you to go back and maybe test for purity, or test to make sure it’s not contaminated. There are all kinds of things the FDA can ask for so I suspect that once it is completed, they will go back to the FDA.

Paul Solis: Would a company sometimes submit a compound to the FDA for testing at the FDA?

RPCI Physician 1: No usually not. It’s all that company’s responsibility.

Paul Solis: And they’re just asking for data that the company has to help inform the decision about safety?

RPCI Physician 1: Correct.
Paul Solis: Has Roswell received any grants? I know you discussed one earlier before your involvement with Innate you said there was a grant with this, excuse me--

RPCI Physician 1: With rapamycin. The use of Rapamycin to generate memory cells.

Paul Solis: Okay. Since you've been involved with Innate, has there been any NIH funding or any grants from the federal government, the U.S. federal government based on the work with MIS416?

RPCI Physician 1: No.

Paul Solis: So this is, as I want to show you, this is just taken off the clinicaltrials.gov website. Here's a copy for you, sorry. Again, this is a publicly available document that we took a look at. Just so you can help me, walk through this a little bit and match up with some of your statements about this and take a look at it. First off, I guess I should ask what does this represent to you?

RPCI Physician 1: Yes. So this is the clinical trial that I explained that we proposed in the grant to test the concept of the use of rapamycin. Rapamycin is also called sirolimus. But the use of rapamycin can generate a specific type of immune response that is desirable in fighting cancer. So the question is, to test that you need a vaccine, you need rapamycin in patients with ovarian cancer. So the vaccine here is what I described to you which is the NYES01 protein along with MIS416. So the cancer cells express this protein NYES01, and so we use the protein and mix with MIS416 to generate immune attack against the cancer cells. So essentially this protocol is the concept, but if you imagine that prior to this we had as a vaccine, the vaccine from Sanofi Pasteur that was also an NYES01 vaccine but a different adjuvant in that Sanofi Pasteur put in a virus. Just like in MIS416 which is a bacteria cell wall product, so this was a virus plus NYES01.

Paul Solis: A look in the second page there. Well first off I should say, I see Phase One. Are you in Phase One right now of this trial?

RPCI Physician 1: This trial has not started.

Paul Solis: I figured that was your answer, I just wanted to confirm it with that part of the description. And if you go on page 2 about midway down, it talks about anticipated study start date, May 15th, 2017 with study completion date of August 2018.

RPCI Physician 1: It's not going to happen because the trial has not started.

Paul Solis: So these are just proposed dates?

RPCI Physician 1: Proposed dates.

Paul Solis: And are you updating the clinicaltrials.gov? Do you know who that's run by or administered by?
RPCI Physician 1: It's administered by the NCI. So our Office of Clinical Research Services worked to update this. So maybe this is lagging behind by a few days.

Paul Solis: But Roswell in part is responsible for making the updates here?

RPCI Physician 1: Correct. For sending the information for update.

Paul Solis: And would Innate have any responsibility to makeup dates on this public document?

RPCI Physician 1: Not at all. This is all from Roswell.

Paul Solis: So this information could change really at any time.

RPCI Physician 1: It could change with the specific, dates but unless the FDA does not allow us to do the clinical trials for one reason or the other, this is the information about the clinical trial. The only thing that is fluid is the date because we don't know when that is going to happen. We have estimates but--

Paul Solis: So let's say, hypothetically speaking, if Innate receives its IND approval from the FDA, what happens next?

RPCI Physician 1: Then we will put together a document. But Innate's IND approval is for the use of Innate MIS416 alone. Okay?

Paul Solis: Right.

RPCI Physician 1: So we will put together a document based on our clinical protocol and our hypothesis, as well as some of the pre-clinical studies that we've done for the past 5 years that we will submit to the FDA, cross filing Innate's filing IND because the FDA has seen the product, they've reviewed all the documents, they've said it's safe it's okay to be used in humans. We will put the IND letter from Ludwig because Ludwig has tested the NYS01 protein in many clinical trials. Put the 2 documents together, submit to the FDA so we will get a new IND approval for this combination. So to get it we need Ludwig and we need Innate documents to put them together with supporting information from all of our pre-clinical studies.

Paul Solis: And then Phase One [crosstalk].

RPCI Physician 1: And then the Phase One could start.

Omar Ashmawy: Doctor, are you aware of any other U.S. based clinical trials that involve MIS416?

RPCI Physician 1: I am not, but for Innate to be trying to file an IND for the product, I suspect they are trying to use it in the United States but I don't get into those details.

Paul Solis: And why would you suspect that?

RPCI Physician 1: Why would they be filing IND in the United States?
Paul Solis: Well you mentioned in order to conduct this specific trial with Roswell, they would have to --

RPCI Physician 1: Right. If they didn’t do it, we would have had to do it ourselves except this works in different ways. We would have had to obtain all of those supporting documents from them and be the primary filer of the IND. So that’s another mechanism that you could use, but because when we wanted to file IND they said we’re already going to be filing IND with FDA, why don’t you wait, and we said fine. Because working with the FDA is a lot of work as well.

Paul Solis: And who said that to you that they would already be filing that?

RPCI Physician 1: I think Gill Webster.

Paul Solis: Do you recall when she would have told you that?

RPCI Physician 1: I don’t.

Paul Solis: Would it have been in the past 2 years? Realize it’s an approximation.

RPCI Physician 1: I don’t remember. I can’t recall.

Omar Ashmawy: If I just may ask the difference between Roswell filing for an IND and Immuno Therapies filing for an IND. If Roswell were to have filed for it, would have the use of the compound only been permissible at Roswell for this particular clinical study, or would have Innate as a result of the approval of the IND, had the ability to use it anywhere in the United States?

RPCI Physician 1: IND is study specific.

Omar Ashmawy: Oh okay.

RPCI Physician 1: They only thing is when you get the first IND, it paves the way, it tells you the FDA has reviewed the compound extensively. So each time, unless it becomes approved for commercial, for general use - it’s called registration of a drug - unless it gets to that level, each time you use MIS416 or NYES01 protein, you have to file an IND. The only thing is it makes it easier each time because you can cross reference. In other words, tell the FDA you’ve seen this before, we’re using the same product that you’ve reviewed before so it makes life easier for everybody.

Omar Ashmawy: I’m wondering if there’s any benefit to Immuno Therapies, if they file it as opposed to letting Roswell file it.

RPCI Physician 1: We did not even discuss that because for me, it’s a lot of work to file an IND and when I heard they were going to file an IND, it’s like, better you than me. It’s a lot of work. It’s a lot of paperwork, regulatory work. Documents that you need to submit, so that’s the best I can say to your question.

Paul Solis: It’s significant to us, as best you can to get an idea when Ms. Webster might have told you that. That we’re going to go ahead and file this with the FDA. If
you just could maybe spend a moment to think what time frame that might have been. Would it go back to the earlier, 2010-2011 when you began this engagement with Innate? Would it have been back then or would it have more recent?

RPCI Physician 1: I think later. I mean, every drug company in the world wants to do clinical trials in the United States so that's no secret. So I know they've been thinking of clinical trials either with us or with someone else. We just happened to be using their MIS416 for cancer indication. They did not design it, to the best of my knowledge originally for cancer indication. So I suspect they've been thinking of this for a long time, but discussions about the IND probably did not take place until the point when--

I can give you before and after type of answer?

Paul Solis: Okay.

RPCI Physician 1: It probably took place after we made the decision to switch from Sanofi to MIS416. From the Sanofi vaccine to MIS416. And that decision was made, probably 2015. Right about 2014-2015.

Paul Solis: I just am wondering then if you had been told by Dr. Hohn about the compound back in 2010 and you knew about Innate, where was your relationship with Innate and the compound from 2010 until 2015 when you decided to make that switch?

RPCI Physician 1: I just explained to you. I needed to validate that this compound does what I think it would do. Which is, does it induce immune responses? Do I see better control in the other models of the ovarian cancer? This is a very rigorous experiment that takes time. So the fact that there are still experiments as we speak, testing other aspects of how to use this compound.

Paul Solis: And when Sanofi decided to make that business decision, as you mentioned earlier, that's when you decided this is the right time--

RPCI Physician 1: This is the next thing that I have that can substitute for what I was using Sanofi vaccine for. So it wasn't a very difficult decision. It was a scientific decision.

Michael Sexton: We can't do the switch without taking the time to do the research.

Paul Solis: Understood.

Omar Ashmawy: Were there any other options besides MIS416?

RPCI Physician 1: Yes, but less effective options. In fact if you look at our pre-clinical experiments we tested some other adjuvants in the markets. Some of the well know adjuvants. The one that is most well known is a product called Montanide, or incomplete fruit adjuvants. It's almost like your gold standard so we compared it with MIS416 and we found that MIS416 was better. Of course there are still other adjuvants but again I don't have primary pre-
clinical data with some of those other adjuvants that are out there. I was working on MIS416, it was a natural switch.

Omar Ashmawy: Were you working on any other adjuvants?

RPCI Physician 1: Montanide. The one I just mentioned.

Omar Ashmawy: And you had pre-clinical data on that particular adjuvant?

RPCI Physician 1: In fact, side by side comparison of Montanide and MIS416 with a vaccine. MIS416 came out superior.

Paul Solis: During your time of researching the compound and if you talked about a time period from 2010 until the present, had anybody in the leadership of Roswell Park ask you about the status of this. I mean, I realize they would have an interest just generally but did anybody ask specifically about Innate Immuno therapeutics and your work being done on MIS416?

RPCI Physician 1: Nobody.

Paul Solis: Did anybody mention Representative Collins’ name in any way to you?

RPCI Physician 1: Nobody.

Omar Ashmawy: Is Mr. or Dr. Hohn still at Roswell?

RPCI Physician 1: He is Emeritus. He is retired, but he’s still on staff.

Paul Solis: Think that’s all the questions we have for you Doctor, so thank you very much for your time.

RPCI Physician 1: Okay, thank you.
Exhibit 3
This is Paul Solis with the Office of Congressional Ethics. It is May 17th, 2017. I am joined by Omar Ashmawy, Dennis Vacco, Stacey Moar, for an interview of Innate Investor 1. I've provided Innate Investor 1 a copy of 18 U.S.C. 1001. He has reviewed the statute and he has signed an acknowledgement form, attesting that I have provided him a copy of the law. So, with that, we'll get started. Innate Investor 1, where are you currently employed?

I'm not.

You're not. You retired, or ... Okay. What are some other things you're doing? I know, for example, you said you have a board meeting later on today. Tell me a little bit about what you're up to.

I sit on a number of business and civic boards. I am a ... Partner, I guess, quasi in a little venture capital firm that a couple of us put together a few years ago. And we've been making investments, typically in local companies that are involved in game changing, disruptive technologies.

What's the name of that venture capital firm?

Really doesn't have a specific ... It's not a registered name, but we call it Buffalo Capital Partners.

Are you a partner in that firm?

I'm a co-investor with any of the other potential co-investors that go into any of these deals that we spot.

Okay.

Evaluate, and either choose to or not invest.

How many other investors are a part of that organization?

It varies. There are five kind of principal, and then we all bring family and friends along.

Are you a principal?

Well, it's not ... I guess in function, but not technically or legally.

Okay.

It's really just a group of guys who have decided that we want to do things here in western New York and we believe by investing jointly, we can have a bigger impact on those companies and also larger say in the governance of those companies once we invest.

Does Representative Collins, Chris Collins, have a role at this Buffalo Capital Partners?

No.

Okay.
Innate Investor 1: Nor has he invested in anything we've invested in.

Paul Solis: Okay. I want to talk about Innate Immunotherapeutics. Can you describe your involvement with them and sort of when you first learned of their existence?

Innate Investor 1: I heard about it ... I don't know, seven or eight years ago at its inception. And ... Primarily from Paul Harder, although, from time to time, Representative Collins would make mention of it. But at that point in time, I wasn't involved in investing in startup companies, so passed on it. And only in the last year or so, Paul Harder again ... Paul and I have had an ongoing relationship business wise for years. I was on the board of a company that he was president of. And we've always talked about business stuff. In fact, all of us came together through YPO, which is the Young President's Organization, and you're always talking about business opportunities and issues and pass forward. So we've always been talking about deals, and he brought up Innate, again. And ... So I took another look at it and made an investment.

Paul Solis: Okay. Who is Innate Investor 2? I mean I ...

Innate Investor 1: The local business guy. He's a kind of a serial entrepreneur. He's owned and built up and sold off several different companies. He was president and CEO of ... A company down in Dunkirk, New York, that makes fruit juice. He asked me to come on the board of that company to work with the owner of the company and determining next steps for the business, which ultimately resulted in the company being sold. So that's ... He's just a local business guy.

Paul Solis: Okay. What did he first say? What did he first tell you about Innate when you said you heard about it at its inception back ... I mean how many years ago, approximately, was that when you first heard it?

Innate Investor 1: I think ... I'm not positive. But I think it was seven or eight years ago when Innate first got started.

Paul Solis: Okay.

Innate Investor 1: They mentioned it. And I had no interest at that point. And then it was several years later that all six or seven years later that ... I'd heard about it along the way, but hadn't paid any attention to it because it wasn't my focus. And then he brought it up again in a conversation that we were having as something that I still ought to consider. And ... I had recently retired and had sold off a lot of the stock that I owned in the company that I had run ... Had been part of for 42 years, so I had a lot of cash and ... At this point in time there aren't many good alternatives to invest in with the bond market being where it is today and the stock market being where it is today. It's a hard time to find a good spot to find money. So it ... I think when I first bought, it was 18 cents a share. And I said, "Gee, 18 cents for 18 thousand dollars. I can own a lot of share, and if that ever goes anywhere, I'd make some money. And if it failed, that 18 cents a share is not the end of the world."
Paul Solis: What was the name of the company that ... You know, you said you retired. What was that company you were at before? I should have covered that earlier.

Innate Investor 1: A company called Gibraltar Industries.

Paul Solis: Okay.

Innate Investor 1: Publicly traded company traded on the NASDAQ stock exchange.

Paul Solis: When Innate Investor 2 first discussed Innate with you, did he mention Representative Collins' involvement with Innate to you?

Innate Investor 1: Well, through YPO, I knew already that Chris was involved.

Paul Solis: And what did you recall about the extent to which he was involved?

Innate Investor 1: Chris?

Paul Solis: Yes. Representative Collins, yes.

Innate Investor 1: An early stage investor.

Paul Solis: Okay. It did ... Do you recall anything about him being on the board of Innate? Or having a more substantial role other than being an investor?

Innate Investor 1: I don't.

Paul Solis: Okay. Are you aware that he's on the board now? Have you heard that before?

Innate Investor 1: I am now, yes.

Paul Solis: Okay. From that time where you first heard about that with Innate Investor 2, he told you about Innate, did you hear at all about Innate from Representative Collins? Did he ever go to you during this seven to eight year period? Prior to your now ... First initial investment, did he ever discuss Innate with you?

Innate Investor 1: No.

Paul Solis: No? Never mentioned it in passing, a name, indirectly?

Innate Investor 1: I don't recall.

Paul Solis: Okay.

Innate Investor 1: There wasn't ... I had one kind of a relationship with Paul and another one with Representative Collins.

Paul Solis: What is the nature ... The difference between those two relationships?

Innate Investor 1: Chris and I have known each other for a long time and I respect the work that he did. Both as Erie county executive and the work he's doing as a congressman, but you know, it's not like we ever hung out together. Where with Paul Harder, we play golf together and we do other things together.
Transcript of Interview of Innate Investor 1
May 17, 2017

Paul Solis: More of a personal relationship?

Innate Investor 1: More of a personal ... Business and personal.

Paul Solis: Okay. So, that first investment you made with Innate. Can you describe it and tell me a little bit about it? You mentioned a share price, how much it was for, some of those details if you can recall?

Innate Investor 1: I don't have a specific recollection. There are three or four purchases including the secondary private placement that the company did. But I don't recall the exact specific ... I have lots of investments.

Paul Solis: Okay.

Innate Investor 1: Typically once I decide to make them, they get logged in and I get a report, but I don't really spend a lot of time looking at it.

Paul Solis: And have all your investments in Innate been in the past two years or so? More recent?

Innate Investor 1: More recent than that. I think all of them went in in ’16.

Paul Solis: You just mentioned something about a private placement. Can you tell me more about that?

Innate Investor 1: I got paperwork from Innate, from the company that said they were having a private placement of stock. And I think you have the documents.

Paul Solis: You did provide some of that from your ... Some of the documents you received from Innate, and yeah, we have that. So I appreciate that.

Innate Investor 1: I think that was all of the documents that I received from Innate. And so I ... because I think the stock price is higher than the offering price, so I bought some more shares. I looked at that document before I came over here so I think I bought ... Somewhere around 40 or 50 thousand dollars’ worth in that transaction.

Paul Solis: This is an additional amount?

Innate Investor 1: This is through the private placement.

Paul Solis: Okay, okay.

Innate Investor 1: Which is in addition to the one’s I bought on the open market.

Paul Solis: And the decision to add more shares and to make further –

Dennis Vacco: So, I ... I'm sorry. So the staff, pardon me for interrupting you Paul, but you just said something that I want to make sure that we clarify it. The 18 cents per share, you bought on the open market?

Innate Investor 1: Mm-hmm (affirmative).

Dennis Vacco: Okay.
Paul Solis: Okay.

Innate Investor 1: Yup.

Paul Solis: And is that on the Australian Stock Exchange or where did you buy that?

Innate Investor 1: I believe I used a local broker who I do transactions with and he went into the open market, and I assume he had to get it from the Australian Exchange although I honestly can't tell you that I know that for sure.

Paul Solis: Okay. This-

Innate Investor 1: But it was an open market trade. How he did it, I don't know.

Paul Solis: Okay. This more recent private placement you discussed, where there any discounts in that private placement? Did you hear anything about, for friends and family or US investors, that there was a discounted nature to the price of that stock? Do you recall that?

Innate Investor 1: I know, what I believe the offering price was 26 cents a share. I think, at the time, the stock was a little bit above that. So I'm not sure if that's what you mean -

Paul Solis: Yea, I'm just wondering ...

Innate Investor 1: - Or not.

Paul Solis: I'm just wondering if, through your interactions with anybody at Innate or when you were sort of beginning to think about this private placement, what details were shared with you about the nature of the price?

Innate Investor 1: I don't know anybody at Innate.

Paul Solis: Okay.

Innate Investor 1: Other than through written correspondence signed by Simon someone?

Paul Solis: Simon Wilkinson? Does that name-

Innate Investor 1: Wilkinson.

Paul Solis: Okay. You never had a phone call with anybody at Innate?

Innate Investor 1: No.

Paul Solis: Okay. Your communications with anybody at Innate would have been limited to ...

Innate Investor 1: Email.

Paul Solis: Email, okay. Okay.

Innate Investor 1: Maybe text but I ... Electronic communications.
Paul Solis: Okay. Okay. I'll show you some of your documents you provided to us. This is BL0003 and 0004. Take a look at that. Give you guys a copy.

Paul Solis: Thank you. And all the documents I'm going to show you are from the production you provided to us.

Innate Investor 1: So this didn't even come directly to me but I got it somehow. Is that right?

Paul Solis: Oh, I was going to ask you that. But yes, it appears that way.

Innate Investor 1: Yeah. It came from Paul Harder to me, okay.

Dennis Vacco: So did you receive this? I thought you just said a moment ago you didn't know how you got it?

Innate Investor 1: Well, I just read it at the top.

Dennis Vacco: Yeah. Okay.

Paul Solis: I mean, I guess the first question is, do you remember receiving this email from Innate Investor 2?

Innate Investor 1: Not specifically.

Paul Solis: Okay.

Innate Investor 1: But I must have because it was in the envelope.

Paul Solis: Is this your email address?

Innate Investor 1: Yep.

Paul Solis: At the top? Okay. Okay. Understanding you did not author this email, do you know why Innate Investor 2 wrote confidential in the body at the top?

Innate Investor 1: I don't know.

Paul Solis: Okay. I want to direct your attention, and again, as far as I can see that you are not on this part of the email. This appears to be a forward to you at the top here but under it, it's an email from Simon Wilkinson on May 10. If I could direct you to the, I guess it would be second paragraph that starts with, "Early next year." That first line. It says, "Early next year and in preparation for licensing the program or selling the company," what did you know at this time, this is May of last year, what did you know about any intention to sell Innate in any way?

Innate Investor 1: I knew nothing specific.

Paul Solis: Okay. Did you know anything generally?

Innate Investor 1: Well, I would've thought that this kind of a company would get a certain level of FDA or whatever medical approvals they could, and then they would go market the company.

Paul Solis: Okay.
Innate Investor 1: I mean, some of the other investments that we've made, that's the strategy that these start-up companies are using. They go and get FDA approvals to a certain level and then the companies generally are getting purchased by larger pharmaceutical companies.

Paul Solis: And that understanding is just based on your past history of investments or did anybody talk to you about this, about that intention, Innate Investor 2 or anybody from Innate?

Innate Investor 1: I don't recall specifically about that. No, I don't recall specifically anything about that.

Paul Solis: Okay.

Innate Investor 1: Paul is an investor, not unlike me, and typically, we talk about potential strategies for various businesses that we're involved in. So it may have been discussed as a concept or a theory but I don't have any specific recollection that he had knowledge that that was what was going to happen. I certainly didn't.

Paul Solis: Okay. Some of the other names here, Jim Notaro, you know Christopher Collins.

Innate Investor 1: Yep.

Paul Solis: Who's Jim Notaro, do you know that name?

Innate Investor 1: I know the name but I don't know him.

Paul Solis: Okay. And then in the email address, there's a csshealth.com. Do you know what CSS Health is?

Innate Investor 1: No idea.

Paul Solis: Okay. Okay. Move on to another one here. This is BL105. You can give that second page to Dennis if you ...

Dennis Vacco: Thank you.

Innate Investor 1: Okay.

Paul Solis: So at the top, it appears to be your email address. Right?

Innate Investor 1: Yes.

Paul Solis: Okay. Do you recall sending this email to Scott Friedman?

Innate Investor 1: Scott is one of the people we work with in the Buffalo Capital Partners Group, so I correspond with Scott on a regular basis. I don't specifically remember this but it looks like it's mine.

Paul Solis: His email address, is that ... Is he-

Dennis Vacco: He's the chairman of this firm.
Paul Solis: He’s employed by this firm?

Dennis Vacco: He’s the chairman.

Paul Solis: Okay. If I could direct you to the bottom there, and this appears to be from Scott to you, the same day, June 22, 2016. The first line, he mentions Tom McMahon. Do you know who Tom McMahon is?

Innate Investor 1: I met Tom once. As it says, he’s the CEO of CUBRC, which is another ... I don’t even know what you’d call it. They have a number of investments in high-tech type companies and CUBRC was one of the companies that we met with but did not invest in.

Paul Solis: Is CUBRC based out of Buffalo?

Innate Investor 1: Yeah.

Paul Solis: Okay. Do you know anything about CUBRC’s relationship with Innate Immunotherapeutics?

Innate Investor 1: I do not.

Paul Solis: I do not know.

Innate Investor 1: Is there one?

Paul Solis: That’s what I’m asking you.

Innate Investor 1: Okay. I don’t know.

Paul Solis: I always like it when witnesses ask me questions. I don’t know.

Dennis Vacco: Might be an investment opportunity there.

Paul Solis: So, yeah. But you’re not aware of CUBRC’s relationship with-

Innate Investor 1: I am not. I am not aware.

Paul Solis: Okay. So going back to the top, and this is the portion that was authored by you, let’s see. I wanted to ask ... Okay, so the open market, do you see that at the top? The first sentence, email.

Innate Investor 1: Yes.

Paul Solis: Okay. Can you walk me through that? And we talked a little bit about the timing of your purchases and making them through your broker. You mentioned a little bit on, the broker purchased it on the open market.

Innate Investor 1: Yep.

Paul Solis: Does this email reflect sort of our initial discussion about that?

Innate Investor 1: It does. I didn’t get specific on the price but I said around 20 cents a share. And I think I mentioned 18 cents in our earlier conversation. And this is
referencing the secondary private placement, and I thought it was around 50,000 bucks that I invested in that.

Paul Solis: I should’ve asked you, if I didn’t ask you this before, if I did excuse my repeating, but that private placement, how did you first hear about that?

Innate Investor 1: I think anyone who had previously invested received it. But I’m not positive about that.

Paul Solis: And by received it do you mean an offer to [crosstalk 00:20:42] included…?

Innate Investor 1: An offer to be included, to participate, yeah.

Paul Solis: Do you recall how you received that offer, would it be by email, or by word of mouth?

Innate Investor 1: Well, the documents came through email. So, I assume that’s how I learned about it.

Paul Solis: I’ll direct your attention to the second paragraph there. It says, "Chris thinks it will be at 18 per share soon". Who is Chris?

Innate Investor 1: Chris is Congressman Collins.

Paul Solis: Okay, and why did you write that to Scott?

Innate Investor 1: Well, Scott and I are looking for investments that are going to grow in value and Paul Harder told me that Chris thinks the stock is going to go to the moon. I know Chris well enough to know that he can be overly exuberant, at times. But went on to say that Paul, who’s also familiar with the company, believes it has upside potential. But nowhere near what Chris is saying.

Paul Solis: Now, $18 per share is…you know that’s a specific number, did you have a conversation with Congressman Collins about it?

Innate Investor 1: No. I did not.

Paul Solis: So how would you formulate that idea, that Chris thinks it would be at 18 per share?

Innate Investor 1: From my discussion with Paul Harder.

Paul Solis: Okay, so Innate Investor 2 told you what Chris was thinking?

Innate Investor 1: Yeah.

Paul Solis: Okay. Do you know how often Congressman Collins and Innate Investor 2 speak?

Innate Investor 1: I would say, probably, regularly. But I don’t know for sure.

Paul Solis: Okay.

Innate Investor 1: Because Paul Harder is also Chris Collins’ financial...
Dennis Vacco: Chair.

Paul Solis: For his campaign committee?

Innate Investor 1: For his campaign committee.

Dennis Vacco: He plays a role in the campaign committee. I don't know if he's chair or not, but...

Paul Solis: Okay. How often do you speak with Congressman Collins, and I know you said you don't have a personal relationship with him, but...an approximate...

Innate Investor 1: Couple times a year. He just...when President Trump addressed the joint session of Congress, he had one ticket and he offered that to me. And I took it and it was a heck of a night. But...and we talked recently about that, although, when I, after going, I emailed him and thanked him for the ticket, but we didn't actually speak.

Paul Solis: Okay. Alright, I'll move on to another email here. This is BL0044 and 0045. Thank you. So this is from CC-Collins, I believe that's Congressman Collins, I mean do you recognize that email address? Is that him?

Innate Investor 1: I don't recognize it, but I'm pretty sure it is.

Paul Solis: Okay. July 13th of last year. I guess, first off some of the names, and I'm not going to ask you to go through and read every single name but, generally, are these Innate shareholders, as far as you can tell, or from your role as an Innate investor, do you recognize some of these names?

Innate Investor 1: I would say I don't recognize most, but I do recognize a few.

Paul Solis: Okay. And do you know if these individuals have a relationship with Innate or their investors, or potential investors?

Innate Investor 1: I know of the names that I know. I'm not even sure if they're all investors or not.

Paul Solis: I mean, quickly, is there a name or two that you recognize that are...that you know to be investors in Innate?

Innate Investor 1: Uhm.

Paul Solis: I see Mr. Friedman's name down there. Do you know if he...

Innate Investor 1: I hadn't gotten quite that far yet...

Paul Solis: Okay.

Innate Investor 1: But, I believe, but I'm not positive...I think Michael Hook is and it's possible, but I don't know for sure...

Paul Solis: Okay.

Innate Investor 1: We don't share investments...
Paul Solis: Right.

Innate Investor 1: [crosstalk] among themselves.

Paul Solis: In that previous email I showed you, you had a discussion with Scott about Innate...

Innate Investor 1: Yeah.

Paul Solis: Do you know if Mr. Friedman ended up purchasing shares?

Innate Investor 1: When we talked, we weren't positive we were talking about the same company. And later we did sort out that we were talking about the same company, but he did not declare whether he invested or not, to the best of my knowledge.

Paul Solis: Okay. This type of email, from Congressman Collins, you provided documents to us, but is this something he would do regularly, or somewhat frequently? I mean, how often would he send an email like this?

Innate Investor 1: Any one that I have received, you have.

Paul Solis: Okay. I want to direct you to the third paragraph, and it's maybe the third sentence at the end..."Big pharma has indicated that money spent now to move the production process for the substantial benefit the company would sold late next year..."

Innate Investor 1: Wait a minute.

Paul Solis: Third paragraph.

Innate Investor 1: Oh, third paragraph, okay. Big pharma has...money spent now...okay.

Paul Solis: At this time, July of last year, what did you know about Innate's discussions or big pharma, or Congressman Collins' discussions of big pharma and selling the company? Did you...what did you know about it back then?

Innate Investor 1: I didn't know anything.

Paul Solis: Okay.

Innate Investor 1: This is a start-up company. Usually with a public company you'll get a quarterly report and an annual report and that's how you stay abreast of what's going on with the business, but I don't have any of that with this company. This was a flyer.

Paul Solis: What do you mean by that?

Innate Investor 1: I took a little bit of money and hoped it would turn big and if it didn't, it went away. And that's simply how I looked at this and, frankly, it's how we look, our full capital of partners looks at investments that we're making. They're very high risk investments.

Paul Solis: Has...
Transcript of Interview of Innate Investor 1
May 17, 2017

Innate Investor 1: With high potential return, if they work, but a strike out if they don’t.

Paul Solis: Has Buffalo Capital Partners ever made any investments in Innate?

Innate Investor 1: Not as Buffalo Capital Partners and I can’t speak to what the individual members have done.

Paul Solis: Okay. Alright. I think I just have one more for you here.

Innate Investor 1: Fact is, we don’t even invest as Buffalo Capital Partners. We’re all individual investors and we just kind of label ourselves.

Dennis Vacco: Yeah it’s loosely, I mean it’s not an entity.

Innate Investor 1: It’s not an entity in any way.

Paul Solis: It has no corporate status, no LLC status?

Innate Investor 1: Nothing.

Paul Solis: Okay. This is BL0127. Gather up these for you as well.

Dennis Vacco: Well, those are mine.

Paul Solis: Oh, okay. I mean, do you have copies of these; we usually just take them back.

Dennis Vacco: Oh, okay.

Paul Solis: But, if you want to reference them, sure I can...I just was cleaning up the table a little bit for you.

Dennis Vacco: Yeah, well I wouldn’t have made...so I just, you know, made some highlights....

Paul Solis: Oh, okay.

Dennis Vacco: If I had known you were taking them back, I wouldn’t have done that.

Paul Solis: No problem. Take a look at it? Okay. Do you recall receiving this email from Congressman Collins?

Innate Investor 1: I do.

Paul Solis: Okay. And can you give me a little bit more background on this. This isn’t you know, "Unfortunately you missed the cut", what is-. I realize you can’t go inside his head to know exactly what he meant but what is this referencing?

Innate Investor 1: The cut is the time period that this investment opportunity was open to the public. And I had been traveling or something and the papers sat on my desk and all of a sudden I looked at it and realized, oh my gosh today’s the day. And unfortunately I didn’t get the paper work in on time so I missed the cut.

Paul Solis: Did you end up being able to take part in the placement though?

Innate Investor 1: No. There was a subsequent one I believe that I did participate-. There was one that I did and one that I didn’t.
Paul Solis: Okay. Both would have been around the same time in the summer of 2016?

Innate Investor 1: I don't know for sure. Yeah, probably.

Paul Solis: And that previous emailed I showed you where you were discussing with Scott and you mentioned the 50,000 in a-

Innate Investor 1: Right.

Dennis Vacco: Just read that paragraph please. Read that paragraph to yourself.

Innate Investor 1: Okay.

Dennis Vacco: And then look at the dates of the emails.

Innate Investor 1: Yeah I don't remember the dates of the private placements though.

Paul Solis: Okay so just refresh your recollection, at the top here this is July 13th, 2016, just so I can get an idea of which private placements you were able to make the cut and which ones you weren't, so this one is June. You mentioned that, you know, "I purchased 50K worth on top of the initial 100,000 shares" right? So I just want to get an idea, were you able to take part in a private placement first around June and then maybe you tried a second one in July and you missed that one?

Innate Investor 1: Can I ask him just to look at the documents again please?

Paul Solis: Sure, sure.

Dennis Vacco: So just for the record there I'm asking him to look at BL0127. So just read this paragraph to yourself, but focus on the end. And I'm referring to Paul - the second paragraph, okay? Second paragraph of the first email in the chain.

Innate Investor 1: So what, what's-

Dennis Vacco: Well here there's a [crosstalk].

Innate Investor 1: I'm just coming off of a bad cold. I'm not following what I'm-

Paul Solis: I understand, I understand. I just want to get a sense of, you were able to take part in a private placement and then it seems like there was another opportunity but you may have missed the deadline.

Innate Investor 1: I believe that's accurate.

Paul Solis: Okay, okay. And just so, you know the best of your recollection based on these emails, the earlier, the first attempt was successful and then the second attempt may not have been. Is that how it went?

Innate Investor 1: I don't recall it that way. I thought it was the second one that I got in.

Paul Solis: Okay.

Innate Investor 1: Not the first, but I don't have a clear recollection on the sequence of events.
Transcript of Interview of Innate Investor 1  
May 17, 2017

1 Paul Solis: Okay, that’s all right.

2 Innate Investor 1: I do know that I purchased in the open market and then subsequent to buying in the open market, participated in a private placement.

4 Paul Solis: Okay, I’ll just direct you to . . .

5 Dennis Vacco: Paul, so pardon me for interrupting, but maybe you want to take him back to the dates of these emails. I mean I’m looking at 0105, which is June 22nd, where he makes an affirmative statement about purchased. So that’s before this email that’s dated July 13th.

9 Innate Investor 1: So maybe it was the first one that I did get into and the second one that I missed. I’m just not clear on that.

11 Paul Solis: Okay, that’s fine. Yeah that’s what it looks like by the dates of the emails, but you know just trying to confirm with your recollection and-. I’ll direct you back to 0127, Representative Collins writes, I think it’s still a great opportunity with an 18 month pay day. Do you know what he meant by that? By pay day or 18-month pay day?

16 Innate Investor 1: I don’t know exactly what he meant by it but it goes back to what, how I think about this type of an investment and anyone that we make, or I make, I hope to get a quick payoff rather than a seven or eight year payoff. So I think what he’s talking about is he expected with this company was that hopefully in 18 months they’d be able to sell it.

21 Paul Solis: Had you had any one on one communication with Representative Collins about this? Aside from this email, did he ever explain to you that he wanted to have a quick turnaround with this or it could be an 18-month pay day, anything to that affect?


26 Omar Ashmawy: Beyond Representative Collins, did you have any conversation with anyone, say Innate Investor 2, about specific interests in purchasing the company? Specific details regarding a potential sale of immunotherapies?

29 Innate Investor 1: Us purchasing the company?

30 Omar Ashmawy: No. Any interest in, you know the reference to Big Pharma, but any interest in another company wanting to purchase immunotherapies?

32 Innate Investor 1: No, no. We’ve never had any specific discussion like that. Again, the theory behind these is that Big Pharma comes along and there’s, if you take the time to look as an investor at what happens with startup companies on the pharmaceutical space, they either fail or typically they’ll get bought by Big Pharma at a substantial multiple.

37 Paul Solis: You mentioned you saw a Representative Collins recently right? He had an extra ticket for you to the joint session.
Transcript of Interview of Innate Investor 1
May 17, 2017

1 Innate Investor 1: Yeah right.

2 Paul Solis: Did you talk about Innate with him there in DC?

3 Innate Investor 1: We had dinner that night with Michael Hook and a couple of lobbyists and then he dropped me off at the capital and next morning I got up and left town. And I didn’t see him after because he was, the news media wanted to talk to him after the event.

7 Paul Solis: Did you discuss Innate with him at any point during your time in DC?

8 Innate Investor 1: I don’t recall that we did. It was a very fast paced night and-. Michael Hook picked me up from my hotel, he and I went to the restaurant, Chris came in, the lobbyists were already there. So the conversation was all what the lobbyists wanted to talk about.

12 Paul Solis: Okay, do you know who those lobbyists were? How did you know they were lobbyists?

14 Innate Investor 1: On the way to dinner, Michael Hook told me, "We’re having dinner with a few lobbyists".

16 Paul Solis: Okay. Do you know what companies they worked for, who they represented?

17 Innate Investor 1: I don’t.

18 Paul Solis: Okay. I had shown you this email, this BL0044. Right here. And I’ve asked you about recognizing names on that list and out of the names you recognized would anybody be invested in Innate? You mentioned Michael Hook.

22 Innate Investor 1: Yes.

23 Paul Solis: How do you know Michael Hook is invested in Innate?

24 Innate Investor 1: I don’t.

25 Paul Solis: Okay. You don’t know if he has any Innate stock?

26 Innate Investor 1: I don’t know.

27 Paul Solis: Okay.

28 Innate Investor 1: You asked me for names I recognized on this list who might be investors and that’s what I was referring to.

30 Paul Solis: Okay, and why do you think he might be an investor in Innate?

31 Innate Investor 1: When I look at this list I look for names who I know have known Chris for a long period of time and I know that Michael has worked closely with Chris for many years and so that’s why I mentioned his name.

34 Paul Solis: Okay. Do you have any knowledge of Innate having communications with Roswell Park Cancer Institute, or any attempts to have a compound or a
drug that Innate develops present at Roswell Park to conduct a trial there?
Do you have any awareness of that?

Innate Investor 1: I do not.

Paul Solis: Okay. Lastly I suppose I would just ask, you know in all of your, I just talked about one conversation, one meeting you had with Representative Collins recently and I had asked you, did you discuss Innate at all, did Innate come up and you said, "Not that you recall". Is that correct?

Innate Investor 1: That's correct.

Paul Solis: Okay, any other times since you became aware that Innate existed, up until, excluding this most recent time that I just asked you about, have you ever had a conversation with Representative Collins about Innate?

Innate Investor 1: There was a telephone conversation a while back, right about the time the stock started moving upward and we discussed it at that point. Although I don't remember what the rest of the conversation was about.

Paul Solis: And what did you discuss about Innate with him?

Innate Investor 1: Just the fact that the stock had moved up.

Paul Solis: And he initiated that call, or did you call him?

Innate Investor 1: I don't recall.

Paul Solis: Okay. In the best that you could recall, the most specific approximation of when that happened?

Innate Investor 1: Last summer.

Paul Solis: In 2016?

Innate Investor 1: Yep.

Paul Solis: Did he discuss with you any plans that Innate had or anything with the drug trials that were going on? Any substantive parts about Innate's work?

Innate Investor 1: He always was a big believer in Innate immunology. Not the company but in the-

Paul Solis: The science?

Innate Investor 1: Concept. The science behind it. He just was a strong believer that it was going to solve all kinds of problems for humankind.

Paul Solis: He ever talk about intentions to sell Innate with you?

Innate Investor 1: No. Well if anything from what I've seen written on the paper, he's buying shares, or had been buying shares all along or investing more in the company. So I don't think he's thinking of selling.
Paul Solis: Is that based on just what you see in the newspaper or is that based on any direct knowledge you have from him?

Innate Investor 1: What I’ve read in the newspaper.

Paul Solis: Okay. [crosstalk].

Innate Investor 1: Investors generally don't talk about how much money they're investing or even what their strategy is so, maybe that they're involved but that's about it.

Omar Ashmawy: In any of the interacting you had with Representative Collins about Innate Immunotherapies, did any specific details of drug trials come up?

Innate Investor 1: No.

Paul Solis: Okay. Have you been contacted at all by Representative Collins or? I should just limit it to that, have you been contacted at all by Representative Collins about our review, or about the fact that the OCE was conducting a review?

Innate Investor 1: No.

Paul Solis: So when I contacted you, was that the first you had heard about our office?

Innate Investor 1: Through the letter?

Paul Solis: Yes.

Innate Investor 1: Yeah, that was the first.

Paul Solis: And since that point has anybody, has representative Collins attempted to contact you about our review?

Innate Investor 1: No.

Paul Solis: What about anyone representing Representative Collins, or anyone associated with him?

Innate Investor 1: No.

Paul Solis: Okay. I think that is all we have for you.

Innate Investor 1: Okay.

Paul Solis: Then we'll conclude the interview.

Omar Ashmawy: We appreciate your time. Thank you.

Innate Investor 1: You're welcome.
Exhibit 4
To: Tom Massung <tmassung@yahoo.com>; Kevin Geary <kevin@aol.com>; Joe Geary <jgeary@gmail.com>; Gary Toomey <gtoomey@graphiccontrols.com>; Sam Haleba <sah@graphiccontrols.com>; Jim Pokornowski <jim.pokornowski@allsafe.com>; Joan Snyder <jsnyder@froghollow.us>; Sam Narins <snarins@benchmarkgrp.com>; Clarke Narins <cnarins@benchmarkgrp.com>; Hadley Narins <hlnarins@gmail.com>; Lynn Ritchie <lynn.ritchie@gmail.com>; Al Bluemle <al@markerys.com>; Chris Skomra <cskomra@yahoo.com>; Dhanusha Chevli <dchevli@aol.com>; Bob Alexander <balexander@gmail.com>; Lisa Ross <lros@email.com>; Norm Schreiber <nschreiber@aol.com>; Asha Partnership <asha@aol.com>; Kirk Graham <kg2003@volland.com>; Glenn Arthurs <glenn@roadrunner.com>; John Hoffman <hoffman@verizon.net>; David Korzak <dkorzak@earthlink.net>; Jim Buzzard <jim@verizon.net>; Paul Shine <paul@truetreasuresinc.com>; Phil Delmont <phil@verizon.net>; Rick Taylor <rusty@hotmail.com>; Charles Koller <ckoller@wnyycpa.com>; Paul Clark <paul@nchpasc.com>; Beverly Mazur <beverly@roadrunner.com>; Bill Grove <bgrove@roadrunner.com>; Brian Geary <bgeary@aol.com>; Craig Schreiber <cschreiber@northtownauto.com>; Jim Hengst <jim@zeptometrix.com>; Kent Chevli <kchevli@wnyurology.com>; Lindy Ruff <lindyruft@aol.com>; Lori Luzi <lori@gmail.com>; Michael Laurie <michael@yaoho.com>; Mike Murphy <mike@alapiper.com>; Phil Corwin <pcorwin@yahoo.com>; Tom McMahon <tmcmahon@cup.org>; Ralph Lorigo <ralphlorigo.com>; Michael Hook <mhook@comcast.net>

Subject: Fw: Updated Investor Fact Sheet

Attach: IIL Factsheet 151216.pdf

To all: Thought you might want to see the investor summary we use at Innate. All is going well. 65 patients are in the trials with some completing the 1 year very soon. Most, if not all, will stay on MIS416 after the trial. Safety and Efficacy are exactly what we expected and we have 12 compassionate patients in NZ that we monitor every month as a proxy for the trial participants. No surprises.

We have opened a trial site in NZ to complete the 90 patient recruitment. We have 93 patients now identified to complete our 90 patient recruitment. Hopefully all will be on the drug by 1/31/16 to start the 12 month clock ticking on the trial completion.

We continue to talk to big Pharma and will attend the JP Morgan Pharmaceutical Conference in San Francisco in January. We also stay in contact by email and phone. We continue to have no competition for our SPMS patients who are dying from a debilitating disease.

We are already looking at commercial production of MIS416 which is very different for 50,000 potential patients vs. 90 patients in the trial. We want to have the manufacturer identified when we hopefully monetize our investment in 2017. The more we derisk the investment the higher our return, and locking down the manufacturing process is a big deal.

We will probably have one last fundraising round in the May-June time period next year. With the trial full, and the end date known, we will have a firm grip on the expenses through mid-2017. Hopefully our share price will be much higher than the current $.20 AUS we see with limited volume on the Australian Stock Exchange. We still have little to no coverage outside the MS world.

Unfortunately the Pro-Rata shares that were tied to a successful completion of the trial by 12/31/16 will expire. That refers to the 1 for 3 new shares that would have been issued (at no cost) on 12/31/16 based on the number of shares owned when we did the IPO. Everyone is disappointed we didn't get the 90 patients in the trial several months ago. There are a number of reasons, but bottom line is it didn't get done. So, there is no way to complete the trial "successfully" by the end of 2016.

Hope everyone has a wonderful Holiday Season and Happy New Year. All the best, Chris Collins
Exhibit 5
To all: We currently have 93 patients signed up for the trial. Yea - a long time coming! Approximately 80 are "on drug" and 13 are waiting to complete evaluation and have their first dose of MIS 416. It will probably be the end of Feb or first week in March when the 90th patient is "on drug" which starts the 12 month clock ticking to complete the Phase II B trial.

We continue to have very promising conversations with big pharma. MS seems to be in the news more than ever with one high profile person after another being diagnosed with MS. We are the ONLY drug that treats SPMS. And it is recognized that we have a potential $2 billion drug based on the market size and sales of the 8 - 10 RRMS drugs on the market with annual sales in the $10 billion range.

We have been urged by big pharma to move forward with a plan for large scale manufacturing of MIS 416. Our drug is not a "pill" that is easily produced in a traditional pharma facility. We grow our drug in bacteria and have to have a sterile process from start to finish to satisfy FDA. You can't sterilize MIS 416 at the end of production. As an injectable, facilities needed for our drug are not as common as traditional pill manufacturing. But, we are talking with several and doing our due diligence to choose a suitable manufacturer. We will be spending $$ to move this forward as it is a significant factor in the final value of Innate. The further along we are with the large scale manufacturing, the more desirable ($$$) our company.

I continue to have a very positive outlook for Innate.

All the best, Chris Collins
Exhibit 6
To all: Tentatively the IIL offer will launch July 15 or thereabouts. Tentative price of $25 AUS or $18 US. 20 million new shares or 10% of outstanding shares. 10% dilution if current shareholders don't participate.

Raise $5 million AUS to carry the company 18 months and allow for investment in manufacturing scale up. Plan is to monetize our investment in that time frame. So this is the last planned offering.

This offering will be to existing NZ/AUS shareholders or US investors I identify. There will be a lead underwriter in NZ/AUS. He will be paid a 6% fee and will be required to purchase any unsold shares.

US investors will be considered underwriters and will get a 6% fee or discount in line with the underwriter down under.

Price is a 10% discount to the 20 day weighted average price.

Actual details and paperwork will be provided end of June or early July.

Since US investors will be considered underwriters we will have to know who is participating and they will be part of the offering documents to NZ/AUS investors. We are doing this because the legal costs to do an actual offering in the US is prohibitive. This is our workaround.

Please let me know your level of interest. I believe you have the Gordon Capital Research report that was done in anticipation of this last round of funding. If, for any reason, you don't have the report, let me know and I can forward to you. It's very detailed and fully explains the upside prospects.

At last, the end is in sight.

Thanks to all for your past support. All the best, Chris
Exhibit 7
From: C C Collins <*****@prodigy.net>
Sent: Tuesday, June 7, 2016 9:31 PM
To: Tom Massung <*****@yahoo.com>; Kevin Geary <*****@aol.com>; Joe Geary <*****@gmail.com>; Gary Toomey <*****@graphiccontrols.com>; Sam Haleba <*****@graphiccontrols.com>; Jim Pokornowski <*****@allsafe.com>; Joan Snyder <*****@froggholow.us>; Sam Narins <*****@benchmarkgrp.com>; Clarke Narins <*****@benchmarkgrp.com>; Hadley Narins <*****@gmail.com>; Lynn Ritchie <*****@gmail.com>; Al Bluemle <*****@markversys.com>; Chris Skomra <*****@wnyurology.com>; Dhansukh Chevl <*****@aol.com>; Bob Alexander <*****@gmail.com>; Lisa Ross <*****@froggholow.us>; Norm Schreiber <*****@aol.com>; Asha Partnership <*****@aol.com>; Kirk Graham <*****@volland.com>; Glenn Arthurs <*****@aol.com>; John Hoffman <*****@aol.com>; David Korzak <*****@earthlink.net>; Jim Buzzard <*****@gmail.com>; Paul Shine <*****truetreasuresinc.com>; Phil Delmont <*****@verizon.net>; Rick Taylor <*****@hotmail.com>; Charles Koller <*****@wnycpa.com>; Paul Clark <*****@cnchpas.com>; beverly Mazur <*****@roadrunner.com>; Bill Grove <*****@roadrunner.com>; Brian Geary <*****@blochinstudies.org>; Chris Graham <*****@volland.com>; Chuck Kolkebeck <*****@aol.com>; Craig Schreiber <*****@aol.com>; Kent Chevli <*****@wnyurology.com>; Lindy Ruff <*****@aol.com>; Lori Luzi <*****@gmail.com>; Michael Laurie <*****@aol.com>; Mike Murphy <*****@dapipe.com>; Phil Corwin <*****@gmail.com>; Tom McMahon <*****@comcast.net>; Ralph Lorigo <*****@lorigo.com>; Michael Hook <*****@comcast.net>
Cc: Tom Price <*****@gmail.com>; James C. D. Hengst Ph.D. <*****@zeptometrix.com>; Mike Draveck <*****@gmail.com>
Subject: Innate Offer
Attach: IIL - Offer Letter from US Investor.doc

Dear All: Two things. 1 - the subscription offer attached to this email. 2 - the comments below on today's announcement that Biogen's MS drug trial failed. Bad for Biogen. Good for Innate.

1. The new offer situation has now been finalized with a slightly different offer to US investors than investors in AUS and NZ. And, the US offer will take two forms.

A. In order to show US commitment as part of the AUS and NZ rights offer, we are offering US investors the opportunity to subscribe for shares in the next 2 days (deadline is Thursday 5:00 PM). The form is attached and will need to be filled out and emailed to Simon by that time. (innateimmuno.com). The minimum is $25,000 US. The incentive to subscribe in the next two days is that funds will not have to be wired until September 5, 2016.

As you read the letter, the only "related party" is me because I am a director. Doesn't apply to anyone else.

The show of support is important and I hope those who definitely intend to subscribe do so in the
next two days by filling out and returning the subscription letter to Simon by Thursday. That total US commitment will be included in the official rights offer to AUS and NZ shareholders which will be finalized this Friday.

B. For anyone who doesn't subscribe by Thursday, official private placement documents, similar to documents provided in the past, will be finalized this week and sent around. Payment for those shares will have to be made by July 5, 2016.

Let me know if you have any questions. Thanks for your support. Chris Collins

Dear All

Robert Peach (director) comments on this morning’s announcement from Biogen was as follows:
This result is a major torpedo in the Biogen MS ship. They were banking on this breakthrough therapy and will now be very hungry to bolster their MS pipeline (they really don’t have anything else except their alzheimers antibody).

The study was in “relapsing forms of MS” meaning both RRMS but also SPMS patients still suffering relapses, ie the ‘transitional population’. So while not being a ‘true’ SPMS population from Innate’s perspective, it is nonetheless significant from a strategic standpoint that this programme has failed. This latest setback in Biogen’s MS pipeline comes after the failure last year of Tysabri in a major Phase 3 study in ‘true’ SPMS patients.

Best – Simon Wilkinson
CEO

Biogen Reports Top-Line Results from Phase 2 Study of Opicinumab (Anti-LINGO-1) in Multiple Sclerosis

-- Opicinumab Missed the Primary Endpoint --
-- Biogen Continues to Analyze Data to Inform Next Step in Clinical Development Program --

CAMBRIDGE, Mass.--(BUSINESS WIRE)--

Today Biogen (BIIB) reported top-line results from the Phase 2 SYNERGY study evaluating opicinumab (anti-LINGO-1), an investigational, fully human monoclonal antibody being developed as a potential
neuroreparative therapy in people with relapsing forms of multiple sclerosis (RMS). In the study, opicinumab missed the primary endpoint, a multicomponent measure evaluating improvement of physical function, cognitive function, and disability. However, evidence of a clinical effect with a complex, unexpected dose-response was observed.

“It is only through taking thoughtful, calculated risks that we can bring major advances to patients,” said Alfred Sandrock, M.D., Ph.D., executive vice president and chief medical officer at Biogen. “Achieving repair of the human central nervous system through remyelination would be a substantial achievement, and while we missed the primary endpoint, the SYNERGY study results suggest evidence of a clinical effect of opicinumab. Due to the complex nature of the data set, we continue to analyze the results to inform the design of our next study.”

Opicinumab also did not meet the secondary efficacy endpoint in SYNERGY, which evaluated the slowing of disability progression. Safety and pharmacokinetics (PK) were also assessed as secondary endpoints. Opicinumab was generally well-tolerated and the safety profile was consistent with what has been observed in prior studies. Opicinumab showed a linear, well-behaved PK profile over the studied dose range. SYNERGY results will be presented at future medical meetings.

**About the Opicinumab (anti-LINGO-1) Phase 2 Development Program**

The two Phase 2 trials (RENEW and SYNERGY) were designed to assess the biological activity and clinical potential of opicinumab (anti-LINGO-1) in central nervous system (CNS) demyelinating diseases.

RENEW was a randomized, double-blind, placebo-controlled Phase 2 study designed to evaluate the effect of opicinumab treatment following a first episode of acute optic neuritis. Opicinumab 100 mg/kg was administered intravenously once every four weeks for 20 weeks (total of six doses). Results from RENEW showed improved latency recovery, as measured by the primary endpoint full-field visual evoked potential (FF-VEP), among opicinumab participants, compared with placebo. The study showed no effect on the secondary endpoints of change in thickness of the retinal layers (optic nerve neurons and axons) or visual function, as measured by spectral domain optical coherence tomography (SD-OCT) and low contrast letter acuity, respectively.

SYNERGY was a randomized, double-blind, placebo-controlled, dose-ranging Phase 2 study that evaluated the impact of opicinumab among 418 participants with relapsing forms of multiple sclerosis (both relapsing-remitting and secondary progressive) over 72 weeks. The primary endpoint of the SYNERGY study was a multicomponent measure evaluating the number of study participants who experienced three month confirmed improvement of ambulation (Timed 25-Foot Walk; T25FW), upper extremity function (9-Hole Peg Test; 9HPT), cognition (3-Second Paced Auditory Serial Addition Test; PASAT) and standard measures of physical disability (Expanded Disability Status Scale; EDSS). Secondary endpoints measured slowing of progression on the same components, as well as the safety and pharmacokinetics of opicinumab. Statistical testing assessed the dose-response trend based on the primary or secondary endpoint. Opicinumab was administered intravenously every four weeks at doses of 3 mg/kg, 10 mg/kg,
30 mg/kg or 100 mg/kg. All study participants received concurrent treatment with 30 mcg interferon beta-1a intramuscular injection once weekly.

About Biogen
Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. Founded in 1978, Biogen is one of the world’s oldest independent biotechnology companies and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For more information, please visit www.biogen.com. Follow us on Twitter.
Exhibit 8
To all: In case you missed this news on Innate joining the MS Consortium. This really is a big deal. We continue with enrollment in our Phase 2B trial at 5 sites. 3 of the sites are doing well, with the other 2 a little slow with recruitment. We did enroll 12 additional compassionate patients in NZ which allows us access to the physician info (unlike the trial where all info is confidential until the end of the trial due to the fact that 1/5 are on placebo). The patients in NZ have the same profile as the patients we have enrolled in Australia so access to their data on a monthly basis gives us a proxy for the patients in the trial in Australia. All the patients that have continued to receive our drug after the Phase 2A trial are pleased with the drug and their condition. Some patients have now been on MIS416 for 5 years and are holding steady, which is an amazing accomplishment with SPMS.

The stock price hasn't moved, which is not surprising since we really don't have news to report. It continues to trade at approximately $.20 AUS, which was the price in the IPO. We anticipate an additional fund raising later this year.

All the best, Chris Collins
Exhibit 9
To all: As most of you know, the price of Innate stock jumped from the mid to high 20's (AUS) to high 30's low 40's (AUS) over the past 4 weeks. Our offer to sell 22 million shares at $.18 US / $.25 AUS was based on an exchange rate of .72. The US dollar has also weakened substantially over the past 4 weeks and is now at .75.

The Rights offer (1:9) was substantially oversubscribed (2:1) in Australia/New Zealand. This was probably due to the jump in the stock price where people could buy the stock for $.25 AUS and sell for $.40 AUS. As a result, the offer was fully subscribed without any shares being available to US investors who missed the 5:00 PM May 31 deadline to subscribe for shares. Those shareholders who did subscribe by 5:00 PM on May 31 will get all the shares they subscribed for at $.18 US.

A dozen or so US investors subscribed for shares after the deadline passed and are now being offered shares in a follow on offer at $.26 US per share ($.34 AUS). We are raising $1 million AUS with 3,000,000 new shares being offered to interested investors in the US, AUS, and NZ. Directors decided the extra funds would benefit the company in pushing forward the ramped up production of MIS 416. Big Pharma has indicated that money spent now to move the production process forward would substantially benefit the company when sold late next year.

The new offer letter is attached and is available to all of you who are copied on this email. The minimum subscription is $5,000 US. The deadline to subscribe is midnight July 18 (Monday night). Funds must be paid by September 5, 2016.

I know you are probably disappointed you can't buy at $.18 per share, but the new offer at $.26 per share is still a 15% discount from current pricing on the AUX stock exchange for IIL stock.

Your subscription letter should be emailed to innateimmuno.com. Please copy me on your subscription.

Best regards, Chris Collins
Exhibit 10
Hi Heather,

I understand you've been working with Jeff Freeland from our office to get Congressman Collins up to the Labs in Bethesda. We can do Sept 9 or Sept 30th. How do those days look for you? I typically fly him to DC at 1:30pm, but if we need to get him in earlier, I can do that as well.

Let me know what works best for you and we will try to accommodate!

Thank you,
Ashley

Ashley Noland
Executive Assistant/Scheduler
Congressman Chris Collins (NY-27)
1117 Longworth House Office Building
Washington, DC 20515
202
www.chriscollins.house.gov

Vision: The United States of America will reclaim its past glory as the Land of Opportunity, restoring the promise of the American Dream, for our children and grandchildren.

>>
>>-----Original Message-----
>>From: Rieff, Heather (NIH/NINDS) [E] [mailto:rieffh@nih.gov]
>>Sent: Tuesday, August 06, 2013 9:29 AM
>>To: Freeland, Jeff
>>Subject: RE: NIH Intramural Labs
>>
>>Sounds Great. I've got a meeting in a few minutes, but will try you
>>after that.
>>
>>Thanks,
>>Heather
>>
>>Heather Rieff, Ph.D.
>>Office of Science Policy and Planning

17-3509_000109
From: Freeland, Jeff [mailto:Jeff.Freeland@nih.gov]
Sent: Tuesday, August 06, 2013 9:24 AM
To: Rieff, Heather (NIH/NINDS) [E]
Subject: RE: NIH Intramural Labs

That would be great! Thanks Dr. Rieff. I'm driving back to the
district today around noon, so if you can't get me at the office,
please just shoot me an email and I'll call you.

--- Original Message ---
From: Rieff, Heather (NIH/NINDS) [E] [mailto:rieffh@nih.gov]
Sent: Tuesday, August 06, 2013 9:23 AM
To: Freeland, Jeff
Subject: RE: NIH Intramural Labs

Hi Jeff, I'd be happy to discuss this with you, and we'd love to your
boss come visit. I'll give you a call later today.

Best,
Heather

---
Heather Rieff, Ph.D.
Office of Science Policy and Planning
National Institute of Neurological Disorders and Stroke National
Institutes of Health

--- Original Message ---
From: Pak, Chol (NIH/OD) [E]
Sent: Monday, August 05, 2013 7:00 PM
To: Yamada, Richard; Freeland, Jeff
Cc: Mullman, Lauren (NIH/OD) [E]; Rieff, Heather (NIH/NINDS) [E]
Subject: RE: NIH Intramural Labs

Thanks Richard for the introduction. I'm out of the office this week
but I'm CCing NINDS' leg contact along with my colleague who handles
NINDS for our office. We would love to have Rep Collins out to NIH.

Let me know if you have anymore questions. My colleague Heather or
Lauren will be in touch.

Chol
From: Yamada, Richard [Richard.Yamada]
Sent: Monday, August 05, 2013 4:36 PM
To: Freeland, Jeff
Cc: Pak, Chol (NIH/OD) [E]
Subject: Re: NIH Intramural Labs

Hi Jeff,

Hope you’re enjoying the August break. The NIH liaison is Chol Pak, whom I have cc’ed to this email. He’s great! Hope you 2 will connect and get your boss to the campus.

Best,

Richard

From: Freeland, Jeff
Sent: Monday, August 05, 2013 04:32 PM
To: Yamada, Richard
Subject: NIH Intramural Labs

Hey Richard - Thanks for putting together a great hearing last week. When my boss asked his question to Dr. Landis, she mentioned that he’s welcome to come out to their intramural labs that are working on M.S. research.

Could you link me up with one of the NIH government liaison folks?

Thanks!

Jeff

JEFF FREELAND
Legislative Director
Rep. Chris Collins (NY-27)
1117 Longworth HOB
(202) Office
ChrisCollins.House.Gov

Vision: The United States of America will reclaim its past glory as the Land of Opportunity, restoring the promise of the American Dream, for our children and grandchildren.
Exhibit 11
Ashley --
Monday November 18th will work from our end in the afternoon. Would something like 3-4:30/5 work?

-----Original Message-----
From: Noland, Ashley [mailto:Ashley.Noland]
Sent: Tuesday, October 29, 2013 2:57 PM
To: Rieff, Heather (NIH/NINDS) [E]
Subject: Re: NIH visit

Heather,

I'm so sorry, I just must have hit a 9 instead of an 8. I meant 11/18, is that a possibility?

Please forgive me!

Ashley

On 10/29/13, 2:52 PM, "Rieff, Heather (NIH/NINDS) [E]"
<rieff_hm...>

>Hi Ashley--
> I think November 19th will work for at least some of our folks. May be
>slighter shortened from what we had previously planned but I think he
>will still be able to learn a lot about our MS research program. What
>would be the timing of the visit?
>
>Thanks,
>Heather
>
>-----Original Message-----
>From: Noland, Ashley [mailto:Ashley.Noland]
>Sent: Tuesday, October 22, 2013 4:01 PM
>To: Rieff, Heather (NIH/NINDS) [E]
>Subject: Re: NIH visit
>
>Heather,
>
>Lets look into November. Perhaps 11/19?
>
>Thanks,
>Ashley
>
Exhibit 12
Transcript of Interview of NIH Employee 1
May 19, 2017

Jeff Brown: Okay. It looks like it's on. For the record, this is Jeff Brown with the Office
Congressional Ethics. I am here with Paul Solis. Before us today, we have NIH
Employee 1 and, I'm sorry. Could you identify yourself Anna?

Anna Jacobs: Sure. Anna Jacobs with the HHS Office of the General Counsel.

Jeff Brown: Thank you Anna. It is about 11 o'clock on, I believe it's May 19. The False Statements
Act warnings have been given to NIH Employee 1. All right, NIH Employee 1, thank
you again for being here. We'll start off with the easy stuff. Can you give us your
current title here.

NIH Employee 1: Sure. I am a health science policy analyst in the Office of Science Policy and
Planning at the National Institute of Neurological Disorders and Stroke.

Jeff Brown: Okay. About how long have you had the role?

NIH Employee 1: I've been in the job since December 2002. I left for about a year, I was at
another institute at NIH.

Jeff Brown: And if you could just sort of generally tell me what it is your office does and what -

NIH Employee 1: Sure.

Jeff Brown: - you do in that office.

NIH Employee 1: Our office has a number of roles. We handle and manage our congressional
interactions and that has been my main role, certainly for the last eight or so years.
We also handle strategic planning activities, disease-specific strategic planning
activities. NIH, we interact with on NIH-wide strategic planning activities. Our office
also handles any evaluations of NINDS programs.

Jeff Brown: Okay. What percentage of your time is devoted to congressional liaison or the other
stuff you just mentioned?

NIH Employee 1: Maybe about 60/40, 60 congressional interactions and 40% the other. But it
fluctuates on a day-to-day, week-to-week basis.

Jeff Brown: How much of that is visits just versus interacting with individuals over on the hill
with requests regarding documents etc.?

NIH Employee 1: It's hard to give a number on that. I would say in any given year, I'm maybe
involved, in terms of members who come visit campus, maybe five or six visits.
Something like that.

Paul Solis: And that's per year?

NIH Employee 1: Yeah. In terms of members coming to campus, our Director Dr. Koroshetz is
often asked to meet with members on the hill and so I help prepare him for those
visits and then accompany him to those visits too. Yeah.

Paul Solis: Okay.

Jeff Brown: I guess I want to start by just really talking about congressional visits generally.
Transcript of Interview of NIH Employee 1
May 19, 2017

NIH Employee 1: Okay.

Jeff Brown: So if there’s one of those five or six congressional visits in any given year, can you sort of walk me through your role start to finish?

NIH Employee 1: Sure. It depends a little bit on the visit because the main NIH legislative office, the Office of Legislative and Policy Analysis, is often quite involved in coordinating these visits. So our role, depending on the member and their interests, there may be more than just NINDS involved in the visits, and then OLPA sort of helps coordinate those visits as well.

Jeff Brown: I’m sorry, NINDS, can you just give that to me one more time?

NIH Employee 1: Yes, it’s the National Institute of Neurological Disorders and Stroke.

Jeff Brown: Okay. That’s in your signature line.

NIH Employee 1: Yep. And OLPA is the Office of Legislative in the Office of the Director at NIH.

Paul Solis: Then what are the circumstance where they would become involved, versus you just handling it on your own?

NIH Employee 1: So again, if there are other institutes. So NINDS is one of the 26, 27, yeah, I always forget the number, of institutes at NIH. For example, we’ve been involved in visits where NINDS has had one part or showcased one of our labs but the National Cancer Institute has also showcased a lab. Off-

Jeff Brown: So there’s an equivalent in that office that has a role similar to yours that may or may not be involved in a visit?

NIH Employee 1: Right. That office handles purely legislative activities. Our office handles much more than just legislative activities. But yes, that’s correct. There have been a couple instances, and both of the visits you asked about are examples of that, where our institute, NINDS, was really the lead in that visit because of the interest of the member. But in those cases, someone from OLPA is always looped in and is usually involved in helping to plan the visit, as well as getting clearances and keeping HHS informed.

Jeff Brown: Okay. And sorry, I interrupted you. But your role in the congressional visit, I realize that there are probably various [crosstalk]-

NIH Employee 1: No, no. But that’s-

Jeff Brown: -but if there’s sort of like a little bit of background.

NIH Employee 1: Sure. So typically the request will come in through a staffer who says, "My boss has an interest in this topic." And they come about for different reasons and we can talk about that if you’re interested but I usually, at that point, I would loop in OLPA and they’ll loop in the department. My role is to help put together an agenda, given the member’s interests. We typically like to bring them to campus and have them meet with our institute director. They often meet with NIH leadership if they’re available, and then we like to showcase some of the research we’re doing
here on the campus. We usually take them to one of our labs to meet with one of our scientists. And then my role is to interface with the congressional staff, set up the time, how they get here, share draft agendas, say, "Does this look good? Is that what the member ... Does this reflect his or her interests?"

Jeff Brown: And then on the day of, can you talk a little bit about your role?

NIH Employee 1: Sure. I typically attend the whole visit. We often have the NIH police or security meet the visitors and escort them to whatever building they're going to, and that just helps with parking and getting everyone through security. And then I would typically take the staffers and the member of congress around to ... I would describe my role as a tour guide.

Jeff Brown: Okay. Again, I know this'll vary member-to-member, but if you had to describe sort of the purpose of, or the varied purposes of these congressional visits, can you sort of walk me through what those tend to be?

NIH Employee 1: Sure. I would say probably the main purpose is to highlight NIH's research. Specifically, to highlight a lot of the research that we're doing here on campus.

Jeff Brown: Okay. You don't have to get into who the member was, but just walk me through one or two of your more recent-

NIH Employee 1: Sure.

Jeff Brown: -congressional visits.

NIH Employee 1: I mean, I can ... If you're interested, I-

Jeff Brown: Before we get to that.

NIH Employee 1: Okay.

Jeff Brown: Yeah.

NIH Employee 1: There haven't been that many recently that I have been the lead on. Most of the visits I've been involved in recently have been through OLPA. I don't remember when exactly this was but Chairman Cole came recently, I think maybe within the last six months, I'm not positive on that date, with some members of his subcommittee. And OLPA coordinated that visit and asked us to be involved in showcasing one of our labs.

Jeff Brown: Okay. Do constituents come frequently or not so frequently, with a member?

NIH Employee 1: It happens occasionally and in fact, the only visit where that happened which I have been involved in was one of the visits that Dr. Bielekova was involved in. Representative Frelinghuysen has done us several visits to NIH where he has brought constituents with him, who are either patients or patient advocates who are constituents of his.

Jeff Brown: So the constituents coming would be a more infrequent occurrence?

NIH Employee 1: Right.
Jeff Brown: Okay.

NIH Employee 1: Often there are constituents involved in meetings where we go to the hill. I would say that's probably a little more frequently.

Jeff Brown: How about when a member comes, are they usually accompanied by staffers or colleagues?

NIH Employee 1: They are typically accompanied by staff.

Jeff Brown: Okay. Did you want to talk about any other background before we sort of launched into more specifics?

Paul Solis: No, I think I was given a pretty good ... I mean, I'll just follow-up on Jeff's question about staffers. Is it committee staff or staff directly from the member's personal office?

NIH Employee 1: I think it's probably a mixture of both. I couldn't tell you specifically, in all cases.

Paul Solis: And do the staffers attend all of the meetings with the member? Or are there ever private sort of breakout sessions, where the member would go off with an NIH employee and have their own discussion?

NIH Employee 1: In all the visits I've been at, the staffers have been present with the member.

Jeff Brown: And I should ask before, you said ordinarily the request will come through the member's office. Is that usually scheduler that ordinarily reaches out to you?

NIH Employee 1: It depends. It sort of depends on maybe how the initial contact came about.

Jeff Brown: It may be easier if we just launch into talking about a specific-

NIH Employee 1: I think so.

Jeff Brown: So we'll go there. Thank you for providing the documents again and on such short notice, we appreciate that. You were involved in Representative Collins' Congressional visit. You scheduled that as we've seen from the emails. What was your day of role?

NIH Employee 1: What was the day of what?

Jeff Brown: The day of role.

NIH Employee 1: So it was similar to my role in other visits.

Jeff Brown: You attended...

NIH Employee 1: I attended. I brought them to the different- I mean I don't remember much of the day of given that it was several years ago, but.

Paul Solis: Why don't you, the best you can, with as much specificity as you can, from the time you first received an email or any communication from Representative Collins' office till the day that they came. Just walk us through what happened.
NIH Employee 1: Sure. So that visit came about because our director at the time, Dr. Story Landis, had testified at a House science subcommittee hearing, which was on brain research. And at the hearing, Representative Collins asked her a question about MS. And she replied by saying we have this great intramural program, research program, on our campus. We’d love to have you come visit. Collins’ staffer reached out to the committee staff who had organized that hearing, and through that interaction Collins’ staff was put in touch with me.

Paul Solis: And how did you come to know about the Dr. Landis interaction and all that. Did Dr. Landis discuss this with you?

NIH Employee 1: Right, so one of my other roles as part of Congressional activities is I accompanied her to the hearing. I prepped her for the hearing, I was present at the hearing where he asked the question.

Paul Solis: Oh okay, when he asked the question about MS.

NIH Employee 1: Correct.

Paul Solis: Was in an open hearing format or was it after the hearing?

NIH Employee 1: No it’s in the hearing transcript.

Paul Solis: And then after the hearing did they have any private conversations that you were a part of?

NIH Employee 1: Not that I’m aware of.

Jeff Brown: Do you remember about the time of that hearing? The date and time?

NIH Employee 1: I believe it was July of that year. It was June of 2013. June or July of 2013.

Paul Solis: Okay so, they contacted, you found out about it, and then you what? Attempted to schedule the meeting?

NIH Employee 1: So the staffer contacted me.

Paul Solis: Do you know who that was?

NIH Employee 1: I believe it was Jeff Freeland initially.

Paul Solis: Do you know who that was?

NIH Employee 1: I believe he was, I don’t know if he’s still there, the Health LA. And the other staffer I interacted with a lot, as you saw from the emails probably, was Ashley Noland who I believe was the scheduler for Collins. So at that point it was similar to how I planned other visits. We reached out to a number of our MS researchers, including Dr. Bielekova, found out who had availability for times that the Congressman, that his staff had suggested. And we sort of went from there in terms of identifying a date and a time for them to come.

Paul Solis: Okay, okay.

Jeff Brown: I think it might actually be helpful to walk through this with some of the documents.
NIH Employee 1: Sure.

Jeff Brown: If that works for you. But before I get there, you sent over a variety of emails, did you have communications that were not via email with any of the Congressman's staff? In other words is there any sort of communications that we're not aware of via the production?

NIH Employee 1: So I imagine I may have talked to them on the phone at some point. And I think in one of the emails you'll see, you probably saw, that Jeff asked me to call him.

Paul Solis: And what did you talk about?

NIH Employee 1: So in that call actually he told me, he said he wanted me to be aware of Collins involvement in the Innate Immunotherapeutics company, and that it was a company that was developing, trying to develop, a drug for MS.

Paul Solis: So let's, as best you can, describe that conversation. So he wanted you to be aware? How did he bring it up, and what occurred?

NIH Employee 1: That is my recollection of the conversation. Now I will tell you, that he didn't, from my recollection, he didn't tell me anything in that conversation on the phone that I did not already know. Because in preparing the individuals at NIH who were going to participate in this visit, I had pulled together information on Representative Collins and his involvement in this company was one thing that I was able to find out from internet searches basically.

Paul Solis: Did you pass that information on to the individuals who'd be meeting with him?

NIH Employee 1: I did.

Paul Solis: Okay, did they have any reaction, or did they say anything when you passed that on to them?

NIH Employee 1: No, not that I remember.

Paul Solis: Okay, okay.

Jeff Brown: And when Mr. Freeland said involvements, did he elaborate on that at all?

NIH Employee 1: You know I don't remember, but I don't think so. I recall it being a pretty brief conversation.

Jeff Brown: About how long?

NIH Employee 1: I honestly could not say.

Jeff Brown: Two minutes, five minutes, ten minutes.

NIH Employee 1: I honestly couldn't say.

Paul Solis: Why don't we show NIH Employee 1 that email.

Jeff Brown: See if this jogs your memory as well. Here you go.

NIH Employee 1: Right.
Transcript of Interview of NIH Employee 1
May 19, 2017

Jeff Brown: Just for the record, I’ve handed NIH Employee 1 a copy of an email from Jeff Freeland to her. Dated November 18th, 2013 at 10:23AM. Subject line is, "Regarding Monday’s visit to NIH".

Paul Solis: And so in it Jeff writes, "Just had one quick thing I wanted to tell you over the phone," is this, soon after this in time is when you had the phone call with him?

NIH Employee 1: Right, again I couldn’t tell you when I called him after this, given this was almost four years ago now.

Paul Solis: Totally understandable. Just want to make sure even apart from the substance of the conversation, whether that phone call would have been connected to this statement by Jeff, or this request.

NIH Employee 1: Yeah so I call, in response to this email, I called Jeff.

Paul Solis: Did you have any other phone calls with Jeff about the Congressman’s visit?

NIH Employee 1: It’s possible, but I don’t know for sure.

Paul Solis: But you can definitively say that the phone call you’re referencing just now with us is in response to this email?

NIH Employee 1: Correct.

Paul Solis: Okay.

Jeff Brown: I wanted to hand you another document... And just for the record I’ll identify this as an email chain from, that begins with an email from Jeff Freeland to yourself dated Tuesday, August 20, 2013 at 2:39PM. Again the subject line is, "Regarding NIH intramural labs". I’ll give you a chance to flip through it before I ask you any questions.

NIH Employee 1: Right so I probably did, I mean I remember now from one of these emails. I probably did have a conversation with him on the phone about scheduling.

Jeff Brown: Yeah take a minute. Just look back through the chain and then I want to ask you a couple of questions about it.

NIH Employee 1: Okay.

Jeff Brown: Okay. At the bottom of page two here, and this is 4:30 pm email between Jeffery Freeman and, it looks like, Richard Yamada. You know Richard?

NIH Employee 1: So, Richard was the staffer who organized the hearing that I mentioned that Dr. Landis testified at.

Jeff Brown: Okay, what was Richard’s role in ... Can you tell us a little bit about his title, and his role here at NIH?

NIH Employee 1: Richard? Is not a NIH employee, he’s a Congressional staffer, I believe it was the House Science Committee. So, he organized the hearing ... the health science committee hearing that ...
Jeff Brown: Okay

NIH Employee 1: Dr. Landis, our institute director at the time participated at ... testified at.

Jeff Brown: The title here is "NIH Intramural Labs." For the Non-Scientists or doctors in the room, can you tell me a little more about Intramural Labs, what that mean?

NIH Employee 1: Sure, the NIH Intramural Program is the program of research that goes on, on the campus here at NIH. The other part of NIH, or is the NIH Extramural Program and that is the research that we fund at all the university and medical schools around the country.

Jeff Brown: Okay. Looking back at this email, if we follow the string up ... I was confusing Richard with Mr. Chol –

NIH Employee 1: Right. Pak is his last name.

Jeff Brown: Correct, oh excuse me, Pak is his last name. Can you tell me Mr. Pak's role here –

NIH Employee 1: Sure –

Jeff Brown: At NIH –

NIH Employee 1: So, he's no longer at NIH. At the time he was in the Office of Legislative Policy and Analysis.

Jeff Brown: And he has since moved on?

NIH Employee 1: Yes.

Jeff Brown: Could you tell me a little bit about what his role would have been? I suspect it was very similar to what you described earlier?

NIH Employee 1: Yes.

Jeff Brown: Okay. Both you and Mr. Chol say something along the lines of "we'd love to have your boss come out –"

NIH Employee 1: Mr. Pak.

Jeff Brown: Mr. Pak, sorry. "We’d love to have your boss come out and visit –" Can you tell me why you and he might love to have him come out and visit?

NIH Employee 1: Yeah, sure. Similar to the other members of Congress, we like to showcase what we’re doing in terms of research on the campus here at NIH, as well as take that opportunity to talk about research that we fund elsewhere. It’s a way for us to highlight NIH.

Paul Solis: Dr. Landis, it's a she?

NIH Employee 1: Yes,

Paul Solis: When she was testifying the subject ... you may have referenced that a little earlier, what was the subject of that hearing?
NIH Employee 1: It was on, I believe, it was on brain research in general.

Paul Solis: Okay. And ... again, my shortcomings in the science and medical fields, does MS research have anything to do at all with that ...

NIH Employee 1: Yeah, so, MS is a neurological disorder. And so, neuro-scientists and people who work under the neurological study ... It's one of the many neurologic diseases they study.

Paul Solis: So, would that be something, when you prepped her for testimony ... would that have been something she would have talked about as research on MS?

NIH Employee 1: Absolutely! You know, I don't remember exactly what prep went into that hearing, but it is one of the disease areas we devote a lot of resources to and study and again, we have an intramural program, but it would have been one of many other topics that would have been part of that hearing prep.

Paul Solis: Do you recall her actually, other than maybe in her response to the question by Congressman Collins, do you remember recall her discussing MS or MS research with anybody else, anybody else at the hearing?

NIH Employee 1: I don't

Paul Solis: Again, to the best of your recollection –

NIH Employee 1: To the best of my recollection, I don't.

Paul Solis: Is that the only request she received regarding MS?

NIH Employee 1: I believe so, but you know I'd have to go back to the transcript to be sure.

Jeff Brown: Who else testified at that hearing? Do you recall?

NIH Employee 1: I do not remember.

Jeff Brown: Okay. Nobody else that you had any involvement with –

NIH Employee 1: Not that I remember.

Jeff Brown: And therefore probably nobody else from NIH?

NIH Employee 1: It's possible there were other NIH witnesses because there are other institutes at NIH that fund and are involved in neuroscience research, we're not the only one. Yeah, I don't remember who the other witnesses were at that hearing.

Jeff Brown: Okay. I'd like to pass over one other document, and again for the record, this is an email string that begins with an email from Jeff Freeland to yourself and copies Ashley Noland. It is dated Friday, November 15, 2013, 9:29 am. The subject is 'Regarding Representative Collins' visit 11/18.' I'll give you a minute to look at it.

NIH Employee 1: Okay. Okay.
Jeff Brown: The email references, the string I should say, references a draft agenda ... the draft agenda that is referenced, does that look like it is included at page three, here? The third page of this document I handed you.

NIH Employee 1: Yes.

Jeff Brown: You referenced this earlier, but you said you may have had some other conversations with Mr. Freeland ... I'm curious, how you decided that this draft agenda was most appropriate for Representative Collins' visit.

NIH Employee 1: So, given that his main interest was in MS we chose Investigators at NINDS who work in MS research or see patients with MS.

Jeff Brown: Okay.

NIH Employee 1: The last part of the agenda, about the NIH Undiagnosed Diseases Program, was not MS specific and was a, I think at that time, a relatively new program, that I think we and OLPA wanted to highlight.

Jeff Brown: Okay. And you said you became aware of his interest in MS at the hearing. Did you have any further conversations with either him or his staff about his interest in MS?

NIH Employee 1: So, I never had any conversations with him directly.

Jeff Brown: Okay.

NIH Employee 1: And the only conversations I had with the staff were either Jeff or Ashley. And again, most of those conversations were, as I said, I don't recall all the phone calls I had with them. If I had to guess most of them were related to scheduling questions.

Paul Solis: You just told us his main interest was in MS, where would you have developed that understanding?

NIH Employee 1: From his questions and comments at the hearing.

Paul Solis: Then that's it?

NIH Employee 1: That's correct ... yeah.

Jeff Brown: Can you walk us through this draft agenda? We've met with NIH Employee 2 as you're aware of. Can you just walk us through the remainder of the schedule and it might be helpful to walk us through it with any recollections that you have about that day with the Congressman's visit.

NIH Employee 1: Yeah, so I really don't have much recollection about the specifics of the conversations.

Jeff Brown: Would you have been present –

NIH Employee 1: Yes.

Jeff Brown: For all the communications between the Congressman and these doctors?
NIH Employee 1: Yes. Yes. So, he met with Dr. Bielekova. I believe she talked to him in a
classroom, gave him an overview of some of the research and some of the
clinical trials that she was involved in running ...

Paul Solis: Why don’t we stop you right there ... specifically, in references to NIH Employee 2,
you mentioned a conference room. Was it just the two of them in the room?

NIH Employee 1: No, it was myself. I believe Lauren Mullman from OLPA was part of the visit
as well, and to the best of my recollection, Jeff Freeland was also in the conference
room. I was certainly there.

Paul Solis: And that’s with just NIH Employee 2? There was no other doctor’s or investigators
present from NIH in the room?

NIH Employee 1: It’s possible. I don’t recall for sure. It’s possible that since Dr. Nath, who is
the next person on the agenda and is our clinical director, it’s possible that he was
present as well. But I don’t know that for sure.

Paul Solis: And in that meeting with NIH Employee 2 that possibly Dr. Nath also attended, what
is the best you can do with regards to that conversation? What they talked about in
the room and what specifically Congressman Collins talked about?

NIH Employee 1: So, I really cannot recall specifics. I mean, I can tell you that I’m pretty sure
Dr. Bielekova gave an overview as I said, of the research she’s doing here on campus
and the clinical trials that she either was currently running or was planning.

Paul Solis: Did Congressman Collins bring up Innate Immunotherapeutics in that meeting?

NIH Employee 1: I believe he did, yes.

Paul Solis: Why do you believe that?

NIH Employee 1: Well, to the best ... I mean, that’s what I remember. That he brought it up. I
think he also asked Dr. Bielekova during that meeting if she would be willing to
meet with some of the people from the company.

Paul Solis: Okay. Did he, in that meeting at all, identify his position with Innate or his
involvement with Innate?

NIH Employee 1: I don’t remember for sure. Yeah.

Jeff Brown: To the best of your recollection, did this meeting last from approximately 3:15 to
3:45 as it says it did on the schedule?

NIH Employee 1: To the best of my recollection. We try to keep things on schedule.

Jeff Brown: And to the best of your recollection, about how much time was spent discussion
Innate versus NIH Employee 2’s research?

NIH Employee 1: I really couldn’t comment on that. I would say ... I mean, if I had to surmise, I
would say probably most of it was spent her presenting her research, which was the
purpose of the visit.
Transcript of Interview of NIH Employee 1  
May 19, 2017

Paul Solis: Do you know if, upon Representative Collins making his request that she meet with an employee or person affiliated with Innate, do you know if she acquiesced to that request?

NIH Employee 1: She did. But I was not aware of that until recently. I was not aware of that until a couple weeks ago.

Paul Solis: And how did that happen? How did you become aware of that?

NIH Employee 1: Well, it was because of your request to meet with her. She mentioned that this was the visit she had been involved in and then she mentioned that she had subsequently met with people from the company.

Jeff Brown: Did she provide any more details on those meetings?

NIH Employee 1: Not to me.

Jeff Brown: So, we sort of, we’ve touched on NIH Employee 2, can we keep walking through the schedule?

NIH Employee 1: Sure. So I do not have a great recollection of the rest of the schedule. But I would have been present at all the visits. Dr. Nath, as I said is our clinical director. He studies neuro, the interaction between the nervous system and the immune system is the focus of a lot of his research. So, MS is one of the areas that he works on but not the only area of research focus for him.

And then we took them to our imaging facility.

Jeff Brown: Before you move on to that, I’m sorry. To the best of your recollection, did this last about 15 minutes?

NIH Employee 1: Yes. I mean, yes.

Jeff Brown: And did Dr. Nath make a presentation similar to NIH Employee 2?

NIH Employee 1: Yes. I believe, and I’m not positive, that this, well, I guess we could tell from the room number. It may have been in Dr. Nath’s office, where he … it was more of a conversation about, you know, this is some of the areas of interest of my lab.

Jeff Brown: Okay. Did Innate come up in any of those conversations with Dr. Nath?

NIH Employee 1: I don’t recall. I don’t recall.

Paul Solis: So you went to the imaging unit next?

NIH Employee 1: Right. So we went to the imaging unit so we have a research program that is using imaging to try to better understand MS and to help diagnose MS earlier in patients by detecting lesions in their brain through MRI imaging.

Paul Solis: And when you leave to go to that section at the 4:00 pm part of the meeting, is NIH Employee 2 or Dr. Nath with you?

NIH Employee 1: I don’t believe that Dr. Bielekova was with us. Again, I don’t remember for sure but I think she may have just given her presentation and that was her role in
the visit. Dr. Nath, I believe came to the imaging facility with us. I don't recall if he
was present for the last, for the presentation on the undiagnosed diseases program.

Paul Solis: And throughout this agenda, Representative Collins was present for each of these, I
assume?

NIH Employee 1: Correct.

Paul Solis: What about Jeff Freeland?

NIH Employee 1: I believe Jeff was there as well. I don't recall Jeff ever leaving the visit.

Paul Solis: And is Lauren with you at this time as well?

NIH Employee 1: Yes, I believe so.

Paul Solis: And it's just ... So the consistent group of people throughout these meetings is you,
Lauren, Jeff, and Congressman Collins?

NIH Employee 1: That is my recollection.

Paul Solis: Okay.

Jeff Brown: Are Dr. Nath and Dr. Sati, are they still employed at NH?

NIH Employee 1: Dr. Nath I know is for sure. I believe Dr. Sati is. I'm not positive.

Jeff Brown: Again, to the best of your recollection, did the meeting in the NRM center, did that
last about a half hour?

NIH Employee 1: Yeah. To the best of my recollection.

Jeff Brown: And at any point in time did Innate come up in discussions with either of those
doctors?

NIH Employee 1: I don't remember.

Jeff Brown: It looks like up next was the undiagnosed disease program?

NIH Employee 1: Mh-hmm (affirmative). Right. So again, this is not a program that is
specifically focused on MS. It’s a program at NIH where patients come in who have
diseases that have not been able to be diagnosed by other doctors. And I believe at
the time, this was a relatively new program and we thought it would be of interest.

Jeff Brown: Again, did you guys spend approximately a half hour?

NIH Employee 1: I think so.

Jeff Brown: Okay. And did Innate come up in any of the conversations with Dr. Gahl?

NIH Employee 1: Again, I can't be positive. I can't be positive. But I don't think so. Again,
because the focus of that discussion was not on MS at all.

Paul Solis: But you can say definitively that Innate was discussed at the meeting with NIH
Employee 2?
NIH Employee 1: Yes.

Jeff Brown: Did Representative Collins have any follow up with any of these doctors at the conclusion of the program?

NIH Employee 1: So, I know that Ashley had contacted me and asked for Dr. Nath’s address because she said he wanted to send him a thank you note. That was the last I –

Paul Solis: You’ve already forwarded to that. After you wrapped up at 5:00 pm did he go back and meet with any of the doctors or did he leave the campus?

NIH Employee 1: I’m quite, I’m pretty sure he left the campus. Usually, the way these visits work is we escort them back to the entrance of the clinical center that they came in through where their vehicle is parked.

Paul Solis: I’ve got another document that I want to hand you, give you a chance to look it over.

NIH Employee 1: Okay. Okay.

Paul Solis: This email references the final agenda and the third page here attached probably should have had this final agenda in front of you when asking all of these questions but did you recollect any changes to the draft and final agenda?

NIH Employee 1: I don’t recollect any changes. This obviously makes clear something that I probably didn’t remember that Dr. Nath met us. The fact that Dr. Nath met Collins and Jeff Freeland at the visit suggests that he may have also been in the room with the ... For the Dr. Bielekova visit, but I do not recall that.

Jeff Brown: I don’t know if it’s worth following up there.

Paul Solis: There had been some initial discussion about a time for him to come ... For Representative Collins to come in September, October.

NIH Employee 1: Mm-hmm (affirmative)-

Paul Solis: Is that correct?

NIH Employee 1: Right, I think it got ... The date got changed at some point. That’s what I recall from these emails.

Paul Solis: Yeah. I’d like to ask you a question at this point.

Jeff Brown: Hand this over to you to look over.

NIH Employee 1: Okay.

Paul Solis: And this is an email chain beginning with an email from Ashley Noland to NIH Employee 1 September 24th, 2013 at 10:27 a.m., and if you could, just flip to page 3.

NIH Employee 1: Okay.

Paul Solis: This is September 4th, 2013 at 3:05 p.m.

NIH Employee 1: Mm-hmm (affirmative)-
Paul Solis: And this is from you? Right?

NIH Employee 1: Correct.

Paul Solis: Okay.

You put, "And then we thought he might be interested in also learning about the NIH, Undiagnosed Diseases Program ..."

NIH Employee 1: Right.

Paul Solis: I think that was reflected in the agenda." Why did you ... Why did you think he might be interested in that?

NIH Employee 1: I think it’s a pretty cool program. Again, it was a new program at NIH, I think relatively new. Often with these visits if the congressman has more time we will occasionally highlight another area. It may not be exactly the area they're interested in, but it’s something we’re proud of at NIH and want to share with them.

Paul Solis: So, that wouldn’t have been based like the MS portion? That would not have been based on anything he or his staff mentioned that they were interested in?

NIH Employee 1: I don’t think so.

Jeff Brown: All right. I have one more document I’m going to ...

NIH Employee 1: Okay.

Jeff Brown: Pass over. For the record, this is an email string that begins with an email from Ashley Nolan to yourself. It’s dated Tuesday, November 19th, 2013 at 3:43 p.m. The subject line is, Regarding Representative Collins' visit on 11/18. I'll give you a second to just look at it.

NIH Employee 1: Okay.

Jeff Brown: Okay.

I think you started to briefly reference this. Are you aware of any follow-up between Representative Collins and any of the doctors that he met with?

NIH Employee 1: No.

Jeff Brown: Does this email help jog your memory at all?

NIH Employee 1: Well, again, as I said, the only ... This is the last I heard of this. Where Ashley Noland asked for Dr. Nath's address because she indicated that her boss wanted to send him a Thank You card.

Jeff Brown: Okay.

NIH Employee 1: I do not know if he sent the Thank You card and I never heard any follow-up.

Jeff Brown: Aside from your follow-up conversations with NIH Employee 2, have you had any more recent conversations with any of the other doctors that met with Representative Collins?
NIH Employee 1: I've spoken to Dr. Nath, but about ... Not about MS or this visit.

Jeff Brown: Okay. So you haven't had any conversations except with NIH Employee 2 regarding Representative Collins' visit?

NIH Employee 1: That's correct.

Jeff Brown: Okay.

Paul Solis: She mentioned that you said, just recently, so in preparation for her interview with us? Is what you're discussing?

NIH Employee 1: Correct.

Paul Solis: Okay. So she said that she had met with individuals from Innate?

NIH Employee 1: Correct.

Paul Solis: Did she say who she met with?

NIH Employee 1: I asked her that question. She said she did not remember the woman's name.

Paul Solis: Okay. Did she say she had met with Representative Collins?

NIH Employee 1: No, she did not say that.

Paul Solis: Did she say if she was contacted by Representative Collins at all?

NIH Employee 1: No. She did not say that to me.

Jeff Brown: Did she say how many communications she had with somebody at Innate?

NIH Employee 1: She told me that some representatives from Innate came and met with her on campus once, was my understanding, and then she said she has interacted with maybe one, I don't know how many, of people from the company at various meetings that she's been to.

Jeff Brown: Various ... Did she give any indication of a number of times that she's met with somebody from Innate?

NIH Employee 1: Again, in terms of on campus, I believe it was just once.

Jeff Brown: And off campus?

NIH Employee 1: My understanding was the other interactions were informal interactions at meetings. You know, you run into somebody at their poster presentation or something.

Jeff Brown: So none of the meetings that she referenced were any pre-planned meetings?

NIH Employee 1: Except for the one on campus.

Jeff Brown: Correct.

NIH Employee 1: That's my understanding, but I did not ask her many specifics about those meetings.
Jeff Brown: We had a phone call, I guess it was a couple of days ago when we were trying to set this up, and at the time we started discussing some of the ways in which Representative Collins was similar or different to other congressional visits that you've handled. We decided we'd table that for today's interview. Would you be able to elaborate on where you were going to go with that and just walk us through, again, some of the ways in which the visit here was similar to any other congressional visits, or in what ways it was different.

NIH Employee 1: I think it was quite similar to previous visits ... Any other congressional visits that we have. When I had mentioned on the phone ... What I was alluding to was the fact that it had come up during this hearing ...

Jeff Brown: Okay.

NIH Employee 1: Rather than .... And that actually has happened in the past as well, but I think it's more typical that we may get a call from a staffer who we've interacted with on something else and have mentioned to them, "Oh, you should come to the campus to visit sometime if your boss is interested." In this case, with Representative Collins, it was that our director, essentially, invited him during the hearing.

Jeff Brown: Okay. That was sort of the difference that you were referring to?

NIH Employee 1: Correct.

Jeff Brown: Was the phone call regarding Innate different than other congressional visits?

NIH Employee 1: The phone call where the –

Jeff Brown: With Mr. Freeland regarding Innate. Have you had anybody in here before that had a specific interest in a certain company that they were involved with?

NIH Employee 1: Not that I would ... Not that I would ... I mean, not that they disclosed or that I was aware of.

Jeff Brown: Okay. Backing up a little bit. When NIH ... How frequently does NIH get involved with private companies either to collaborate on research, or work together, or to fund. How do those interactions between NIH and private companies generally come about?

NIH Employee 1: I can't answer that question because it's not something I'm involved in.

Jeff Brown: Have you had any experience with doctors that you are working with, or aware of that make connections, or work alongside private companies?

NIH Employee 1: At NIH?

Jeff Brown: At NIH.

NIH Employee 1: Again, not that I'm aware of.

Jeff Brown: You've referenced Lauren Mullman a couple of times and we saw her emails. Can you just tell me a little bit about her role and what her title is here?
NIH Employee 1: Sure. So she is part ... I don't know what her exact title is, but she's in the
office of legislative policy and analysis. In the office of the director. The way that
office is arranged is there're number of analysts, and each of those analysts is
assigned to certain institutes at NIH. At the time, Lauren, and currently, Lauren is
assigned to NINDS, so she's our .... My liaison in the director’s office and then one of
their main roles is to interface with HHS.

Jeff Brown: Did she play any day-of role?

NIH Employee 1: I believe she was present at the meetings as well.

Jeff Brown: Okay.

Anybody else that was either present at the meetings, or involved with the
scheduling of Representative Collins' visit?

NIH Employee 1: Not that I recall.

Jeff Brown: Anybody else that, in light of what we discussed today, you think it might be
appropriate for us to have a conversation with?

NIH Employee 1: I don't think so.

Paul Solis: Have you any contact with Representative Collins, or anyone from his offices, or
someone affiliated with him about our review, the fact that we requested to speak to
you?

NIH Employee 1: No.

Jeff Brown: Got anything else?

Paul Solis: Nope. I think that's a ...

NIH Employee 1: Okay.

Paul Solis: All we have for you.

NIH Employee 1: Great.

Paul Solis: Thank you very much.

Jeff Brown: Thank you.
Exhibit 13
Jeff-
We are looking forward to having Rep. Collins and you visit on Monday. Attached is a campus map. You should enter the NIH campus through the entrance marked on the map off of West Cedar Lane. The NIH Police will be waiting for you – they have Rep. Collins’ vehicle information and have also pre-screened both of you through security. They’ll escort you to the Clinical Center (you’ll be able to park right in front) where Dr. Avi Nath, the NINDS Clinical Director, and I will meet you.

I’ve also attached the final agenda.

Please let me know if you have any questions, and if you need to reach me on Monday, my cell # is ...

Thanks,

Heather Rieff, Ph.D.
Office of Science Policy and Planning
National Institute of Neurological Disorders and Stroke
301...

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HR_0195
Exhibit 14
Visit by Representative Chris Collins  
National Institute of Neurological Disorders and Stroke, NIH  
Monday, November 18, 2013  
Agenda

3:00 pm - Arrival at NIH - Dr. Nath and Heather Rieff will meet Rep. Collins and Mr. Jeff Freeland at North Entrance to Clinical Center

3:15 pm - NINDS Neuroimmunological Diseases Unit; Room 5C-103

Dr. Bibiana Bielekova, Investigator, Neuroimmunological Diseases Unit

Dr. Bielekova will give an overview of clinical trials and research in progressive multiple sclerosis, the development of biomarkers for the disease, and how these biomarkers can help in developing effective therapies for progressive MS in particular and neurological diseases in general.

3:45 pm - NINDS Section of Infections of the Nervous System, Room 7C-103

Dr. Avi Nath, Clinical Director, and Chief, Section of Infections of the Nervous System, NINDS

Dr. Nath will describe his ongoing research to understand how the immune system attacks the brain and what his lab is doing to discover new drugs to treat the later stages of multiple sclerosis.

4:00 pm – NINDS Neuroimmunology Branch/NMR Center, Room B1D710

Dr. Nath, and Dr. Pascal Sati, Staff Scientist. The Neuroimmunology Branch conducts basic and translational research to understand mechanisms of multiple sclerosis and has active clinical trials to develop more effective therapies for different forms of multiple sclerosis. The Branch uses the unique resource of the high resolution 7T MRI within the NIH NMR Center to image the brains of patients with multiple sclerosis in order to understand the biology of the disease and the ways in which it attacks the brain and spinal cord.

4:30 pm – NIH Undiagnosed Diseases Program; Room 10C-103

Dr. William Gahl, Clinical Director, NHGRI and Director, NIH Undiagnosed Diseases Program

After a brief tour of the laboratory, Dr. Gahl will describe the work of the NIH Undiagnosed Diseases program, especially as it pertains to neurological diseases. There may be an opportunity to visit with a patient in the program as part of the tour.

5:00 pm – Wrap-Up and Depart NIH campus
Exhibit 15
Rieff, Heather (NIH/NINDS) [E]

From: Freeland, Jeff <Jeff.Freeland@NIH.gov>
Sent: Monday, November 18, 2013 10:23 AM
To: Rieff, Heather (NIH/NINDS) [E]
Subject: RE: Monday’s visit to NIH

Heather – Thanks so much for putting this all together. Looks great. Just had one quick thing I wanted to tell you over the phone. Could you give me a call at the office when you have a moment?

Thanks!

From: Rieff, Heather (NIH/NINDS) [E] [mailto:rieffh@nih.gov]
Sent: Friday, November 15, 2013 12:14 PM
To: Freeland, Jeff; Noland, Ashley
Cc: Torborg, Christine (NIH/NINDS) [E]
Subject: Monday’s visit to NIH
Importance: High

Jeff-
We are looking forward to having Rep. Collins and you visit on Monday. Attached is a campus map. You should enter the NIH campus through the entrance marked on the map off of West Cedar Lane. The NIH Police will be waiting for you – they have Rep. Collins’ vehicle information and have also pre-screened both of you through security. They’ll escort you to the Clinical Center (you’ll be able to park right in front) where Dr. Avi Nath, the NINDS Clinical Director, and I will meet you.

I’ve also attached the final agenda.

Please let me know if you have any questions, and if you need to reach me on Monday, my cell # is:

Thanks,

Heather Rieff, Ph.D.
Office of Science Policy and Planning
National Institute of Neurological Disorders and Stroke
301-
Paul Solis: This is Paul Solis with the office of Congressional Ethics, I’m joined by my colleague Jeffrey Brown. It is May 10th, 2017. We are here for an interview of NIH Employee 2. I have provided NIH Employee 2 with a copy of the False Statements Act, and she has signed an acknowledgment form that I provided her a copy of the law, and we can begin our interview.

So NIH Employee 2 first off I want to ask if you’ve heard of a company called Innate Immunotherapeutics?

NIH Employee 2: I think it’s the company that was mentioned during the congressional visit. I think it’s a company that is maybe New Zealand.

Paul Solis: Apart from hearing it spoken at a congressional hearing, have you ever heard that name in any other context, Innate Immunotherapeutics?

NIH Employee 2: I have met a person who works for the company several times.

Paul Solis: Okay, who is that person?

NIH Employee 2: I don’t remember her name. She’s a chief scientific officer in the company I believe.

Paul Solis: And how many times have you met with her?

NIH Employee 2: I believe I met her three times.

Paul Solis: Okay, could you give me approximate dates, even just the year, of those times?

NIH Employee 2: I met with her once after the visit of Congressman Collins that was organized by him. She visited me at NIH, I don’t really remember I mean it was, I would say two years ago, or more than two years ago, I really don’t remember when that visit happened. And then I met with her again twice on the conferences. So first time was at the Keystone Symposia meeting, that meeting was I think... It was one of the MS Keystone Symposia meetings. So I think the first one was in New Mexico, and the second one was in Big Sky, Montana. But I don’t know which one it was. And most recently I met her just at the American Academy of Neurology meeting two weeks ago in Boston.

Paul Solis: And all these meetings were they, especially at the conferences, were they planned meetings?

NIH Employee 2: No at the conferences it wasn’t planned. We just met.

Paul Solis: How about that first meeting you discussed, was that a planned meeting, an organized meeting?

NIH Employee 2: Yeah.

Paul Solis: Okay, can you tell me about that?

NIH Employee 2: Well the Congressman Collins asked whether I would be willing to help somebody with a trial design for secondary progressive multiple sclerosis, and I said yes I would be, I mean sure we always help people. He asked would it be okay to
Transcript of Interview of NIH Employee 2  
May 10, 2017

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

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

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

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

Paul Solis: That's okay.

NIH Employee 2: Sorry.

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

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

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

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

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

NIH Employee 2: Sure, sure.

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

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

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

NIH Employee 2: Well he came for a congressional visit. This was my second congressional visit I participated in. Usually the congressperson wants to know what we are doing,
and we have very short presentation of what is our scientific program. And they ask us questions, we answer those. Sometimes they bring constituents, sometimes they don’t.

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

NIH Employee 2: I believe he was alone.

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

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

Paul Solis: What is header?

NIH Employee 2: The person that-

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

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

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

NIH Employee 2: Twice.

Paul Solis: Twice? Both times with Congressman Collins?

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

Paul Solis: And who was the other one with?

NIH Employee 2: I’m really bad with names.

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

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

Paul Solis: Was it a senator or a congressperson?

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

Paul Solis: It’s okay, it’s okay.

NIH Employee 2: But he came with, I know he came with constituents. So it was a large delegation. And again we talked about progressive multiple sclerosis because there is no treatment for progressive multiple sclerosis, and at that point NIH was really running the only clinical trials for progressive MS.
Paul Solis: And what you just described, that’s the second meeting with this congressperson from New York. When they brought constituents.

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

Paul Solis: Was the second meeting, okay.

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

Paul Solis: We can cross that bridge later possibly.

NIH Employee 2: Okay, sorry.

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

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

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

NIH Employee 2: Yes, yes.

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

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

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

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

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

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

Paul Solis: And-

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

Paul Solis: Okay, and when you were discussing some of your work and conducting a PowerPoint presentation, what was the topic? What were you discussing with him?
NIH Employee 2: Our work. Basically the kind of rationale for research program. Why are we focusing on progressive multiple sclerosis and how we are tackling progressive multiple sclerosis and what kind of advances we have developed?

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

NIH Employee 2: No.

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

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

Paul Solis: Right, okay.

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

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

NIH Employee 2: Yeah, I can see that.

Paul Solis: And it says “Chris was kind enough to dig up the person's name” and it does mention in this recounting of the events that there was an NIH official who Chris had further talks with and, you know, so-

There is a connection between your name and the NIH official and after you just explained to me that you had met with him, I'm just wondering if this sort of recounts the story you just gave me that you met with Congressman Collins.

NIH Employee 2: Yeah.

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

NIH Employee 2: That's possibility.


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

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

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

Paul Solis: Okay, well we can-
NIH Employee 2: Okay.

Paul Solis: Maybe we can do that-

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

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

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

Paul Solis: Okay.

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

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

NIH Employee 2: About the trial design, right.

Paul Solis: Walk me through what that means.

NIH Employee 2: Well, so basically when you are trying to test efficiency of a drug, you know, you cannot really ... so, the drug development happens in three stages. The first stage is you’re giving it for the first time to humans, that’s called Phase 1. You’re not looking at efficiency at all, you’re looking only on toxicity. Then Phase 2 trials is usually what is ran here, we also run Phase 1, but it’s basically a trial when you are giving a drug to the patient that you really want to treat and you are supposed to ... you’re still gathering some toxicity data, you’re gathering data about the dose, what is the best dose, and you are gathering data that would tell you whether the drug efficacious. Whether, you know, you want to invest into Phase 3, which is this extremely large and expensive trial. In fact, two trials are required for regulatory approval of the drug.

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

For example, we are looking at service spinal fluid bio markers that would be able to tell us in much fewer patients in much shorter time period whether the drug is going to be effective or not.
So, you know, I was telling them about all of these things, right. That, you know, how you need to power, what are the outcomes that you need to look at, you know, whether you want to look at MRI versus clinical outcomes, how long do you need to treat if you want to look at clinical outcome, or all of these things.

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

NIH Employee 2: No, not to me.

Paul Solis: Okay.

NIH Employee 2: Not to me.

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

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

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

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

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

NIH Employee 2: That's correct.

Paul Solis: In some other country possibly.

NIH Employee 2: Yeah, yeah.

Paul Solis: Okay.

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

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

NIH Employee 2: Sure.

Paul Solis: Just sort of the spirit of collegiality?
NIH Employee 2: Yeah. Definitely the other two times I have met with them at the conferences, precisely. I would have answered and they did ask me follow up questions I would answer those.

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

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

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

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

Paul Solis: Okay.

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

Paul Solis: From Innate?

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

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

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

Paul Solis: Jeff, do you have any questions?

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

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

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

NIH Employee 2: I would say weeks or months, I don’t really know exactly. But I knew exactly that this is related to that. Either she told me that it was from him or I definitely was able to put two and two together.
Paul Solis: Directing you back to this email, what is SPMS? Do you know what that stands for?

NIH Employee 2: Secondary Progressive Multiple Sclerosis.

Paul Solis: Okay. And is that what this MIS 416 is attempting to address?

NIH Employee 2: Yes.

Paul Solis: What about this CUBRC? Do you know what that is?

NIH Employee 2: I have no clue.

Paul Solis: Okay, if you look at the top here, this Tom McMahon, that name, do you know what that name?

NIH Employee 2: No. I think Simon Wilkinson is working for Immunotherapeutics and I think his name, the lady was mentioning Simon.

Paul Solis: Okay.

NIH Employee 2: Maybe there were two people who came? No, I think I was just talking to a lady.

Paul Solis: Okay. Is Innate the only one who is developing this MIS 416?

NIH Employee 2: To my knowledge, yes, but I haven't really looked it up.

Paul Solis: When you look down here and you see Phase 2B trial, I know you just talked to me a little bit about-

NIH Employee 2: Yeah, so I just told you, Phase 2B is basically a larger Phase Two trial that really needs to give you understanding whether the drug is efficacious or not. So some Phase 2B trials, like FDA would be able to consider some Phase 2B trials if they were large enough as a first regulatory approval trial.

Paul Solis: Okay. You did touch upon this a little bit, but the paragraph discussing funding from HHS and NIA [crosstalk].

NIH Employee 2: I really cannot help you with that. I don't do anything with the funding decisions. We just don't do that.

Paul Solis: Given that you said that you'd met this Chief Scientific Officer even just two weeks ago at a conference.

NIH Employee 2: I did.

Paul Solis: What did you talk about with her there?

NIH Employee 2: She was presenting [inaudible] and we talked about her work. There was somebody else also with her and then, maybe this was Simon I don't know. I was asking her how is it going and she said the work is going really well.

Paul Solis: Did she mention where they're at with their trials, the position they're in.
NIH Employee 2: No, obviously they haven't gotten the data that would show them that the drug is efficacious so I think that they're still at the funding stage.

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

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

Paul Solis: Again, where was this last conference?

NIH Employee 2: In Boston.

Paul Solis: In Boston.

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

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

NIH Employee 2: No.

Jeff Brown: You wouldn't. Okay.

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

Jeff Brown: Okay, why is that?

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

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

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

Paul Solis: Mm-hmm (affirmative)

NIH Employee 2: So it's their baby and –

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

NIH Employee 2: Yes.

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

NIH Employee 2: Yeah, I mean again I think progressivism is really bad disease and we just have a first approved drug so it's in my interest, interest of NIH and interest of
everybody to help with development drugs for this disease, because the societal need is so humongous right? So, I mean I would feel that it’s part of me being a federal employee to foster such ... to give that knowledge so that companies can develop affective drugs.

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

NIH Employee 2: Yes.

Paul Solis: Okay.

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

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

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

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

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

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

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

Paul Solis: Did he talk about ...

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

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

NIH Employee 2: Not that I can recall.

Paul Solis: Okay, about how long did his meeting with you last or how long was he here for?
NIH Employee 2: I think he was here maybe for 30 minutes or yeah probably not much longer than that. I know that they tell us that the PowerPoint presentation should be five minutes so I...

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

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

Jeff Brown: 30 minutes between the three of you?

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

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

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

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

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

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

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

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

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

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

NIH Employee 2: Yeah Heather is ... so I think somehow we have an office for congressional visits and so I don't know what is her official title. Whether she’s PR for NDIS, but I know she's in NDIS and she always organizes this visits and each time we get any
kind of inquiry, like you have, I forwarded your email to her because I know that we
have official channels for these things.

Paul Solis: You mentioned he handed you something, a stamp or something. What was ... 
NIH Employee 2: Yeah it was this congressional, I don’t know, it wasn’t a stamp, it’s ...
Paul Solis: A coin?
NIH Employee 2: Like a coin, yeah.
Paul Solis: So what did he say when he handed it to you?
NIH Employee 2: Thank you for spending time and gave it to me. I mean, it had some wording
about US congress so I gave it to my nephew and he was very happy with it.
Paul Solis: Well Jeff do you have any further questions?
Jeff Brown: Just real quick, what’s the amount of time you, can you tell us about that first
meeting with the Chief Scientific Officer?
NIH Employee 2: I would assume I spend with her at least an hour if not more. So it was quite
involved, she was really asking me a lot of questions and I really tried to help her
with the design and ...
Paul Solis: And that was here?
NIH Employee 2: That was here, yeah.
Paul Solis: And she had flown in from Australia?
NIH Employee 2: I’m assuming so yes, maybe she was attending some meeting here and did a
side visit here.
Jeff Brown: And what, I think we’ve talked about this a little bit, but the benefits to her is
tapping your expertise?
NIH Employee 2: That’s correct.
Jeff Brown: How frequently do you do that?
NIH Employee 2: Just yesterday I had somebody calling me from Switzerland and so yeah we
do that. Also very often this doesn’t happen ... I mean like the Switzerland was the
person contacted me directly, but very often basically these PR offices get these kind
of requests and then they hand them to us. So, yeah.
Paul Solis: And what if anything do you know about how New Zealand ... I mean do they have a
corollary NIH in New Zealand that does this type of thing?
NIH Employee 2: I have no clue. I have no clue.
Paul Solis: And I’m just wondering because phase to be trial is that universal language? That’s
not particular to NIH?
NIH Employee 2: No that’s universal language.
Jeff Brown: I didn’t want to jump ahead, I wasn’t sure if you wanted to talk about this?

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

Jeff Brown: Yeah, sorry after your ...

Paul Solis: This is TAM 0258.

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

Paul Solis: Mm-hmm (affirmative)

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

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

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

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

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

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

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

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

So maybe that’s what it is about, I don’t know.
Jeff Brown: But in short, in some instances, for lack of a better word, somebody from industry could come to you [crosstalk].

NIH Employee 2: That’s correct.

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

NIH Employee 2: That’s correct, that’s correct.

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

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

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

NIH Employee 2: Yeah, so ...

Jeff Brown: How does that work?

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

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

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

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

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

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

Jeff Brown: US or international?

NIH Employee 2: I believe it’s also international, yes. I believe so. But uh, you know, you would need to ask really grant people, so that’s the extramural.
Transcript of Interview of NIH Employee 2
May 10, 2017

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

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

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

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

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

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

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

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

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

Paul Solis: Do you have any more questions?

Jeff Brown: I do not.

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

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

Paul Solis: Okay, thank you.