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. Virionyx needs some money again. We’re out of 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 than some broker out of New York City. There’s no ifs, 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
June 5, 2017

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.

Rep. Collins: I'm confident that it does.

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?


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?

Rep. Collins: 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
Jeff Brown: 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?

Rep. Collins: 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.

Paul Solis: 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?

Rep. Collins: 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.

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


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

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

Paul Solis: Okay.

Rep. Collins: We couldn’t recruit enough patients in Australia.

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

Rep. Collins: 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
Transcript of Interview of Representative Collins
June 5, 2017

1. desperation, we decided – they decided, the board decided to set up two new
2. trial sites in New Zealand that we knew we could recruit because the
3. patients don’t – aren’t taking this relapsing remitting drug. They’re taking
4. nothing and they’re desperate for it, but we had to forgo the 40% rebate on
5. it.

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

7. Rep. Collins: Oh, no. They all ended at the same time. It was last patient in, last patient out.
8. 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
9. we got three over that. 93rd patient ended the trial. So the trial’s over.
10. Paul Solis: In Australia?


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

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

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


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

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

39. 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 filing 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’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.
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 do – 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 1/5th 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 blindered 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?
Transcript of Interview of Representative Collins
June 5, 2017

1 Rep. Collins: It's a lady…Roxanne? Anyhow, she works for Simon. If you rattled off all
2 their employees, I could tell you which one it was, but...

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


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

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

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


15 Paul Solis: To Simon.

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

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


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

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

24 Paul Solis: I should rephrase. I think I didn’t state that as carefully as I should have. In
25 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?

28 Rep. Collins: Oh, yes. Well, we never looked at hard data points. It would just be,
29 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
30 we needed to hear, everything's fine.

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

35 Rep. Collins: He would bring it to the board, but if he and I were talking, because that
36 would happen, I wouldn’t – or I don’t have any exact recollection, it would
37 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 –
Rep. Collins: We’re not going to fund it beyond the end of this. One way or the other, this suckers gone.

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

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

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?

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.

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 –

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 quality for accelerated approval.

Paul Solis: With the U.S. FDA?

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.
Transcript of Interview of Representative Collins
June 5, 2017

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,
Transcript of Interview of Representative Collins

June 5, 2017

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
to 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
conversation 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?
Transcript of Interview of Representative Collins
June 5, 2017

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?

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 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.
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 I 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 Gil, 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.

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?

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

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

Okay, sure.

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

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-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?