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Financing Innovation: Investment in Development and Marketing of New Technology, Venture Capital, and Other Aspects of Innovation

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UNITED STATES SPEAKERS

*Theodore C. Theofrastous** & *Dr. Joseph J. Jankowski†*

MR. THEOFRASTOUS: Actually, I invited Dr. Jankowski to join me here today, in part, because he has an excellent insight on the issue we are going to talk about here. We have sort of worked both ends of this angle of financing innovation.

One thing I will just clarify, what we are talking about here is the financing of innovation itself as opposed to financing the commercialization or the long-term commercialization of innovation.

For instance, if I were going to talk about the venture capital aspect of financing an innovative company or an innovative concept, frankly, that's a fairly straight forward discussion, and it would, you know, it would take maybe ten minutes.

The issue that we want to talk about is who is funding innovation in the United States, to the extent that you have the federal, private, and institutional funding of this process. As the process goes forward toward commercialization, we see an emerging conflict of interest really wreaking havoc, to

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some degree, on the process of innovating in the first place. There is a definite need for a solution.

We cannot offer the solution. It is actually something that Dr. Jankowski and I will be studying over the next several months to put out an article, particularly industry perspectives on this issue. We will offer a couple of ideas, but the main thing is to raise your awareness just to the fact that the issue is there and where it comes from because I think where it comes from is kind of interesting.

So this was an e-mail that Dr. Jankowski actually received a couple days ago. Maybe you want to walk us through it.

DR. JANKOWSKI: Yeah. It made for a wonderful Monday morning. But it really was timely because this view still exists and is probably, I believe I would say, is growing due to the exposure of the interface between industry and the academy, and it is interesting because, as you will see throughout this talk, that interface has always existed.

In fact, interface does not exist out of necessity or just because it happened to emerge, but was strategically put in place by the U.S. Government.² Although I typically do not like to read the slides as I go through this, I did want to read this quote because of the errors or misperceptions that this view represents.

Personally, I think the results of federally funded research started about two decades ago and has been a destructive conflict of interest for universities. Again, we will touch on this as we go through it.

It was two decades ago when the Government said well, there is nothing less efficient than the Government trying to commercialize this; let's give the universities a shot, and in order to do that, we will let them own the IP. Previously, the Government owned the innovations and the intellectual property.³

So this author said this did not happen during the first half of his career and scientific communication was more open. I can't speak to that. It is possible that it was. It is also possible that it wasn't. Collaboration was freer of inappropriate motives.

I would say that is far from the truth. We do not think that the potential upside fiscally for a researcher necessarily has led to any inappropriate motives. In fact, it is a motive that we want to help drive innovations. Universities were less avaricious. Universities have always needed money, and they have always been greedy.

² See generally Bayh-Dole Act, Pub. L. No. 96-517, § 6(a), 94 Stat. 3019, 3019-28 (1980) (Act paving the way to allow research institutions to license their inventions to corporations).

³ *Id.*

And there was a lot less money wasted on administrators to shovel paper and waste of time of administrators. That is me, so I guess he is right in that point.

But it is interesting because in the first few slides we will talk about conflicts of interest, but you will see by the end of this we wanted to really say just the opposite. People do now view it as a conflict of interest. In fact, it is a convergence of interests, and it is again intentionally structured by the United States Government as a way to help bring innovation to the people.

Do you want to take this?

MR. THEOFRASTOUS: Yeah. So just to set up the discussion, primarily, there are three sources of funding for innovation in the United States at this point.⁴ One is from the public, from the federal government, from state governments, from the various covers of Government administrations.⁵ There is the private funding of innovation. Obviously, within the corporate context, you have formalized R & D programs that may or may not then leak into this area, which is the institutional side.

You have got universities, academic medical centers and others that are using portions of their budget to create innovation. We will talk a little bit about the law on policy framework governing this, but essentially, we see the nexus of these three very compatible, frankly, very similar missions as something that is now sort of beginning to create a problem in the commercialization of the science that is out there.

So if we look at individuals, you know, what do you think is the sort of perceived problem in terms of the individual and the conflict of interest?

DR. JANKOWSKI: The real issue, of course – and it certainly has been proven at times with a few bad actors – but the motivations for research are no longer pristine. The ivory tower is gone. Academia is now in the pocket of industry and, more importantly, individual researchers; the scariest thing to the public is that individual clinicians and clinical researchers have motivation of dollars rather than advancing the field of medicine and patient care.⁶

The public's awareness is certainly an incredibly strong factor. Anybody in Northeastern Ohio has certainly taken note of the national press that we have received, particularly focused on The Cleveland Clinic. But there is the perception of the public that there is a wrong intention, and it is always difficult and dangerous to speak to intent.

⁴ See generally NAT'L SCI. FOUNDATION, SCI. AND ENGINEERING INDICATORS 2004, available at <http://www.nsf.gov/statistics/seind04/c4/c4s4.htm>.

⁵ *Id.*

⁶ See generally Bayh-Dole Act, *supra* note 2 (the bill allows researchers to keep a portion of the fruits of their labor).

But certainly when people do speak of conflicts of interest, they are basically saying is that person on the take? Are they no longer peer in their analysis?

MR. THEOFRASTOUS: Well – and so, fundamentally, I think the issue that we have to keep track of is institutions do not innovate. Governments do not innovate. Companies do not innovate but people do innovate. It is always a person that is innovating somewhere.

Ultimately, even the patent law, I think some people are surprised when they start getting into the commercialization process to see that companies can own a patent. Certainly, a company can have the assignment of a patent or an institution can have that as well. It is a person who invents things.

So the question is, as that is the genesis of innovation itself and these other players come in to provide potentially millions of dollars to take this innovation forward, how can you keep the line clear between personal interest and all the good things that you want for well validated science?

We talked just quickly about the institutional side. I think the perception is that there is a lot of money or prestige involved, and potentially, it could sway the institution away from its primary mission. Frankly, the societal tension here is sort of interesting, and to some degree, we want to say in the scope of all of this great technology is that we need it. I want a replacement hip that I can go mountain biking with. I want to have personalized medicine that will keep me alive as long as possible, so just bring it on as quickly as you can and fund it, and do not tell me about all this rigmarole between the outcome and I.

So if we were going to frame it, I guess, it would be in an objective sense that the primary issue is that the people that are involved in this and to some degree the institutions, that there may be a motive to falsify or taint results in order to speed this new innovation through the process of validation and proving that it is safe and effective.

Obviously, from the public perspective, we care about safety. From the finance side, we – or from the private side, we care about the huge investment we are going to make in this technology, and we do not want it to fall apart at the end, and from the institutional standpoint, at least we care about standing. From the individual side, you know, there is profit. There is funding. There is ego. There are all kinds of things that come out from having great science.

And let us be clear, this is not related, specifically related, to biomedical science. Biomedical science is fun to pick on because it is expensive, and it takes long to get to market, and the safety issues are more dramatic. As you can see, for instance, in the outcome of Merck – anybody here have, either directly or indirectly, during this period an interest in Merck through your pension plan or otherwise? This was not a very satisfying outcome.

We have the FDA coming back and saying that they have received information that, in fact, Vioxx may not have been as pristinely, as objectively reviewed as it might have been and, in fact, it is not safe.⁷ So if you look at the relative drop in share price – and this is half, I mean, half share price for the company, and we will not say it is entirely Vioxx – but it is a very dramatic drop between this first data point, which is where you see the above news headline.

DR. JANKOWSKI: It was about, I believe, a \$29 billion-dollar hit in their stock price, and it was a very short period based on Vioxx.

MR. THEOFRASTOUS: So from an institutional perspective, you would say yeah, fast is good, but if we are going to spend all this time and money getting a product to market, we need to make sure that it is, in fact – that it has been treated appropriately. Look at other outcomes and, again, not only are we not picking on biomedical science, we are not picking on The Cleveland Clinic. The Cleveland Clinic is the largest employer in the region.

It is a power house of academic medicine, and yet, if you read the Wall Street Journal and sort of follow Cleveland issues here, you have the chairman of the board of trustees, Mel Mixon of The Cleveland Clinic Foundation, and the newly appointed CEO of the Clinic [Toby Cosgrove], getting raked over the coals for institutional and perceived individual conflicts of interest that have a dramatic effect on the institution's standing.⁸

And I can tell you from my tenure there, there is absolutely nothing wrong that happened, nothing wrong happened here. There was no scandal. There was no ill act. Everything was done according to law and, frankly, according to ethics. Yet, here is a little blood in the water, and all of a sudden the institution has a very serious problem, and the ramifications of this are still being sort of rolled down into the process of innovating and moving products to market.

So as we look at these three, we will just talk quickly about where we see this conflict coming and something I think is a fundamentally United States phenomenon, but I believe other areas of the world, including Canada, may, in fact, hit parts of this [conflict]. So, as we frame up the three sectors, we are talking about industry, federal, and medicine, ultimately, we are all aimed at this in the context of biomedical and healthcare science.

We are aimed at better, safer, more effective products going to market. We all want the same thing. We have got from the industry perspective shareholder return as something we are very focused on, which obviously

⁷ FDA Statement, U.S. Food and Drug Admin., FDA Statement on Vioxx and Recent Allegations and the Agency's Continued Commitment to Sound Science and Peer Review (Nov. 17, 2004).

⁸ David Armstrong, *Clinic Toughens Policy After Conflict Flap*, WALL ST. J., May 10, 2006, at A3.

was a problem with Merck. We have got economic advancement on the federal side, and let's be clear, the federal side of the equation is obviously not just, you know, the greater good of humanity; it is the greater good of the American economy.

And on the medical side, it is much more in an objective sense delivering the highest quality care and outcomes to the sick. So as we look at each of these, just talk a little bit about where the innovation is actually funded from, when we look at the federal side, if we call this the continuum of commercializing medical innovation, this is a very long process.

And so when we get all the way to the far end of the spectrum to the commercial sales, we have spent a lot of money and we have taken a lot of time. The question is: who is going to fund basic research? Who is going to fund that innovation itself? And I will tell you, it is not the venture capital community, and to some degree it is less and less going to be corporate America.

So we have got here the National Institutes of Health (NIH) and agencies like the National Science Foundation, to some degree NASA, certainly the Department of Defense, Homeland Security, these are all places that are deploying large amounts of money to basic research.⁹ If we talk about the NIH, you know, the NIH is to some degree the largest engine of funding for life sciences research.¹⁰

And I think it is just important to note that, among other things that you would expect to see here is, as well this is enhancing the nation's economic wellbeing, and so to some degree, how are we going to do that? We are going to commercialize the results. It is a fairly straight forward outcome if you think about it. When you look at the sheer amount of money that is going into bio—frankly any federal funded research, both sides of aisle at Congress want to see outcomes. They don't want to just see this money going into a hole, so the outcome is an economic outcome for the nation.

DR. JANKOWSKI: It is interesting as well because, as Dr. Rosen showed on the previous presentation, that the United States is still by far and away the leader in research and development.¹¹ Meanwhile, the federal government's role, including the private sector, is largely the NIH [National Institutes of Health], and the NIH serves as the engine who takes blame or credit for medical innovation.¹²

⁹ See Sci. and Engineering Indicators, *supra* note 4.

¹⁰ See About NIH, Nat'l Inst. of Health, <http://www.nih.gov/about/> (last visited Nov. 1, 2006).

¹¹ See Sci. and Engineering Indicators, *supra* note 4.

¹² See About NIH, *supra* note 10.

And the medical spending in the United States is somewhere in the 15 to 23 percent of the gross domestic product.¹³ It is a huge, huge portion of the economy, and, in fact, the NIH is charged with making that work. I was surprised when I first read the NIH charter that they have an economic mission, but they do, and it clearly makes sense in terms of the math.

MR. THEOFRASTOUS: So when you look at the amount of funding that is dispensed by the NIH and essentially where it is deployed, you can see it is a major driver. North of \$25 billion dollars a year is going into this basic research and back into that lonely blue cylinder that needs somebody to move it forward.¹⁴

On top of that is the Bayh-Dole Act, which I think is unique to our country.¹⁵ In essence, the federal government for many years funded research but was never particularly good at commercializing it.¹⁶ So, the concept here was that you would push the rights, frankly, and the incentives back to the universities and eventually back to the researchers themselves so that there is a property interest. There is some skill in the game and, ultimately, an obligation to move forward with the commercialization process itself.

Now, if you think about it, the problem here is that what you have done is you have taken that person who used federally funded research dollars to invent something they have innovated, and now you have sort of pushed the economic interest right back to them. You have now sort of empowered them to go forward and make those millions of dollars. So how can we possibly be surprised that we are running into this conflict of interest?

Add to that the issue that most academic medical centers are tax-exempt institutions and are encumbered as part of their deal with the federal government.¹⁷ They don't pay tax on their income and they have to responsibly and fairly dispose of these new assets that they have from the Bayh-Dole Act, and now you've got a new layer of responsibility that comes back to the institution.¹⁸

¹³ See generally Press Release, Ctr. for Medicare and Medicaid Serv., Ctr. for Disease Control, Health Spending Reaches \$1.6 Trillion in 2002 (Jan. 8, 2004) (indicates that health spending in the United States is 14.9% of GDP).

¹⁴ See About NIH, *supra* note 10 (stating that the current NIH funding is approximately \$27 billion).

¹⁵ See generally Ashley J. Stevens and John Fraser, *Judging the Bayh-Doyle Act*, EUROMONEY INSTITUTIONAL INVESTOR, Dec. 1, 2005, at 36 (discussing the Bayh-Dole Act as changing United States law regarding title of patents resulting from federally funded research).

¹⁶ *Id.* (discussing how in the United States universities fund commercialization without government support).

¹⁷ See generally Harold Orlans, *Potpourri*, CHANGE, May 1, 2004, at 6 (discussing the Bayh-Dole Act's tax breaks for industry research).

¹⁸ See generally Ted Agress, *Intro Course in Selling Drugs*, DRUG DISCOVERY AND DEVELOPMENT, Oct. 1, 2003, at 15 (cautioning universities to keep their roles as universities and companies clear, especially since they are nonprofit organizations that enjoy tax benefits).

DR. JANKOWSKI: But two points there again: it goes back to the government for once and the NIH knew what it was doing. It wants its for-profit center to make money off of its public funded research. It is not an unfortunate circumstance that the nonprofits will be creating technologies and will be conflicted. It is expected. It is needed.

There was a wonderful one-page article in *Science* a few years ago by an author named Kennedy.¹⁹ It really compared the three great frontiers of the United States, and it said the first was the Homestead Act in which the government recognized we cannot develop everything west of the Mississippi, but people can, and if we are going to give it away, we are going to allow people to take ownership of this land, and they will farm it.²⁰

Of course, that was a wonderful thing to do, and it worked. The Government could have never had that build out, and at the same time it caused unforeseen problems, similar to our conflicts of interest. People wanted to do logging and cattle ranching rather than farming, which originally was not the intent or expected, and there was that moral and was that the intent?

After World War II, somebody had the audacity to suggest that we take the money being spent on the war effort and put it all into basic sciences, again as an economic engine, and that is exactly what the Government did and then in the mid '80s realized, okay, we need Homestead Act Part 2.²¹ We can't do anything with this IP. We are spending hundreds of billions of dollars with no return. Let us allow the institutions to take a crack, and let us allow them be put in direct contact with the private sector that has a mission to make money for its shareholders, again very, very strategic, very intentional. And it certainly has put the U.S. biotech sector and state of medicine at the top of the world.

MR. THEOFRASTOUS: So just to jump through this because I know we are limited on time, I guess what I would say you understand now the federal momentum of moving and funding innovation and what it sort of tees up. The sector of this that needs to run with that innovation is industry, and if we look at industry, I think it is easy to summarize that essentially what industry is faced with is what America faced with Vioxx, at least, as a potential downside.

There is huge potential. There is an incredibly high risk. It is going to take a long time and money to run through anywhere near the potential of the market that you see here, and ultimately, as you see in this sort of very long process of moving something one compound, taking between \$1.1 and \$1.7

¹⁹ Donald Kennedy, *Enclosing the Research Commons*, *SCIENCE*, Dec. 14, 2001, at 2249.

²⁰ *See generally Id.* (discussing the Homestead Act of 1862).

²¹ *Id.* (discussing the push to reallocate resources that had been disposal to the war effort to support basic research).

billion dollars to take to market, they want to make sure also that the science itself is as it should be.

If we roll forward – and I apologize, I know this is hard to keep up with – if we roll forward to the institutional side, internally the institutions are struggling with their own digestion of these potential conflicts. Part of it is just the very fact that the institution has a stake in the outcome, a product that is going to be tested on human beings, and part of it is acknowledging that the only way industry can run with a product is to run with the actual investigator.

What I will say is that, you know – let me pull this down to something like a close – what I will say is that the problem itself beyond the sort of headlines in the Wall Street Journal, beyond the new sort of – I guess what is sort of surprising to me given this backdrop is that this all appears to be a very unanticipated bear trap when, in fact, if you think about the history and policy behind it, it is really not.

What has yet to be determined is how far industry can go in policing itself. You see here this is a series of subpoenas that were issued to orthopedists who were interacting with industry. I just yesterday received the new NASS Guidelines, the National Academy of Spinal Sciences, guidelines for handling conflicts of interest, and it is incredibly rigorous.

The jury is still out as to exactly what the industry, academia, and federal government should do about it. I think from our perspective we just have to acknowledge this is something we have got to be very clear headed about and very sober about, acknowledging that the tensions will not allow us to slow down.

They will not allow us to back away from the innovation mission and, frankly, making the use of these federal funds that we are supposed to, and simultaneously, you have things like what I am showing here, the clinical and translational science awards, which are even upping the ante further, saying that we want that basic science interaction with industry.

As an outcome, there has got to be something else. There has got to be another arbiter, another dialogue between industry and these various sectors so that as the funds are applied, they are applied intelligently, and frankly, just as we deal with safety, we deal with conflicts throughout acknowledging that it is difficult, but we are going to have to weigh in.

The one thing I will say without telling any tails out of school is I watched what academia did with this issue, and I do not think it was handled particularly well. I think it was viewed as another administrative task, something else that needs to be done by committee. Oh, my God, we need to put together the committee. Who should be on the committee?

By the time the committee is actually there, you end up with a group that is actually very ill-equipped to actually drill into what's going to happen with this particular science and this particular business context and make reason-

able decisions. In essence, I think there is a great tendency really just to back away from the issue and say it can't be managed. We need to move on.

DR. JANKOWSKI: Yeah. And in closing, I would say Ted quickly showed the CTSA grant. By the way, that was a March 2006 grant. The Government needs to actually build that interface and that conflict if people want to call it that, even more. The population is aging. We need more drugs. We need more devices, and we need them faster.

And the only way to do it is to have the academic world even come closer to the patient and to the company. As Ted said, well, then what's that going to do? That's going to put more emphasis on the legal and political world to accept in and make sure that that machine, which is needed, is running okay.

CANADIAN SPEAKER

Mark Romoff[‡]

Well, I am thinking back to Dr. Rosen's presentation when he slipped in that one line about innovation being a contact sport, and it is very much that, and the remarks I am going to make really turn on my organization and where it applies, which is right at that level of contact between all the players that make a difference on the innovation agenda.

Just to situate things a little bit, I am obviously in the province of Ontario, and the Ontario Centers of Excellence is at the heart of the innovation agenda, and there are a couple of things that, obviously, are the context for my organization and why the Government, in part, funds it.

Clearly, it is driven by that growing concern about economic impact of global competition. It is easy to say. I think everybody understands that. In the case of Ontario, that's a significant issue right now because major industries that are critical to the economy of Ontario have already been considerably downsized.²² The obvious ones are the textiles industry, electronics, and

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²² See generally Peter James, *Abitibi Boss Expected More Mill Closures*, DAILY MINER