BUILDING A HIGH-TECH, 21ST CENTURY ECONOMY*

Panel 2 – Biotech and Healthcare

REMARKS OF DAVID VERBRASKA, ESQ.**

Alright it's noontime so I can officially say "Good Afternoon." I was told no slides, but we can count on the IT[1] guy to show up with slides, which is totally fine. In law school and business school, I always was bewildered by why the professor said to move down to the front, but now I can appreciate it because you all seem so far away. I won't ask any of you to move down to the front. I did want to thank Ray and Victoria and the planning committee for inviting me here, I think it's a really, really important conference. Building a high tech twenty-first century economy, you know at first, I was like of course, this is something we all need to be partnering around, when you consider each of the interdisciplinary nature of the people on these panels. But I will tell you, living in the D.C. environment, building the

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[1] The term "IT" refers to "information technology," which includes "computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources." 40 U.S.C. § 1101(B) (2012).

economy to a lot of folks I have to deal with is the private sector's responsibility. The government just needs to get out of the way, and let the creative, innovative juices of the guy of the garage take us into the future. I am really pleased with the way that this conference is set up, that there is at least implicit acknowledgement that law and public policy matter in creating the ecosystem for innovation and economic growth. Certainly, policy and public affairs as an enabler of business is my livelihood, so I would be a proponent of that. You know, I think law and policy if you are looking at a career or running a business cannot be ignored, really they establish the rules of the game, and if there are impediments, or incentives that are needed, law and policy are the vehicles to creating those. I used to think that law was kind of the rational, and policy was the chaos, and somewhere in between we got the business. I am not sure that it is as clean of a cut, but I like to think that in my head both sides are relevant.

What I am going to do, I am obviously from the biopharmaceutical industry, and when I talk to groups of lawyers and doctors it goes either really well or really poorly. I am going to assume this is a fairly friendly audience so I have hope for that.

I am going to focus on much more of the policy side and probably the regulatory side, in some depth only because our industry is the most heavily regulated industry on the planet.[2] We have actually done the numbers. We used to think it was the nuclear power industry; it is the biopharmaceutical industry. So, regulations really matter. I want to ask a somewhat rhetorical question because we are in law school, because in law school you never really get to the real answer, so all questions are rhetorical, but if you had millions of dollars to invest, and some of you probably do, how would you feel about investing in an industry? How attractive would it look if I told you "the industry you want to sink all of your resources into, or a sizeable amount, has a 95 percent failure rate, and its going to take you about ten

[2] *See* John C. Yoo, *Takings Issues in the Approval of Generic Biologics*, 60 FOOD & DRUG L.J. 33, 43 (2005) (commenting that "the pharmaceutical industry is one of the most heavily regulated of any industry in modern commerce"); *see also* Kragor v. Takeda Pharmaceuticals Am., Inc., 702 F.3d 1304, 1307 (11th Cir. 2012) (noting that "the pharmaceutical industry is heavily regulated by the federal government").

years to figure out if you have a winner or a loser?" That is the pharmaceutical industry, and 95 percent failure rate is probably optimistic. That is our reality. So it is high risk, high reward, and a lot of the determination of whether that reward is realized, is frankly in the regulatory environment that has been established.

Innovation obviously is the lifeblood of a company like Pfizer, although we are a bit schizophrenic because we have innovative R&D,[3] we've got generics, we did animal health, we've got consumer products. But in any of those businesses really coming up with new products that meet customer need is absolutely critical. And I wanted to touch just real quickly on the fact that the model is dramatically different, so if you're a lawyer working with the industry, if you're looking to invest in the industry, I wanted to go through kind of five macrofactors that are playing pretty prominently in the way we develop our business. And it really is a business dramatically different from twelve years ago when I first joined Pfizer as a company. One is R&D. So when I first came to Pfizer, it was not invented in our house. If the science was not created in a Pfizer lab somewhere in the world, then it didn't matter. Our new products were going to come from science, from our (whiz bang?) scientists. Given the failure rate in R&D, given the fact that we really need to de-risk the business, for a whole variety of reasons that has dramatically shifted.

That is why you have a lot of venture capitalists here; you have small biotech companies here, it really moved from an invented inside a pharma, to who can we partner with, what alliances can we build with academic medical institutions, what deals can we do with small groups of scientists who may have a good idea. So it is an important shift in what we do and Pfizer's actually got its own venture-capitalist fund within the company, whose whole purpose is to go out and find next generation science. So, where we get the science is really changing. When I first joined it used to be the "blockbuster," right? The drug that would be available to millions of people. Lipitor® is a perfect example; the world's

[3] The term "R&D" refers to "research and development." 2 C.F.R. § 200.87 (2014). The term "research" is defined as "a systematic study directed toward fuller scientific knowledge or understanding of the subject studied." *Id.* The term "development" is defined as "the systematic use of knowledge and understanding gained from research directed toward the production of useful materials, devices, systems, or methods, including design and development of prototypes and processes." *Id.*

best selling drug, $14 billion a year all around the world.[4] By the way, fourteen billion went to two and then essentially zero in less than a year, as soon as the patent expired,[5] so imagine the chaos within our company when that happened, but fortunately we planned for it.

The third area is really the shift from blockbuster is really within the precision area of medicine now, the right drug for the right patient at the right time, as opposed to these blockbusters, that would really address a whole class of therapeutic need for example. So, its harder, the science around that is harder. Kind of a well-known secret is that a lot of these blockbuster drugs do work for a lot of people that took it. Now, for a variety of reasons, we are really getting into very small indications, smaller populations, so if you can find a drug in that space, that's going to be the sweet spot.

Another big shift is, in the past we had armies of salespeople that went out and sold doctor to doctor, to clinic-to-clinic, maybe hospital-to-hospital. The shift is dramatically to the government payer. So where you get your funding, where you get your research direction, certainly where you get your reimbursement is shifting really from a center of gravity around the individual physician, to the government payor. That's certainly been a shift elsewhere in the world much more dramatically but is happening here.

Transparency. So when first was at Pfizer, again, we held the science very close. But in this era of transparency, you have to register more information than you do clinical trials, you have to disclose the results much more completely, widely, and sooner, so this whole notion of transparency and helping pharmaceutical companies figure that out without giving up our intellectual

[4] *See* Scott Hensley, *As Generics Pummel Its Drugs, Pfizer Faces Uncertain Future*, WALL ST. J. (Jan. 5, 2006), http://www.wsj.com/articles/SB113642962990138315 (labeling Lipitor as "the world's best-selling drug with $12 billion in annual sales"); *see also* Simon King, *The Best Selling Drugs of All Time; Humira Joins The Elite*, FORBES (Jan. 28, 2013, 9:58 AM), http://www.forbes.com/sites/simonking/2013/01/28/the-best-selling-drugs-of-all-time-humira-joins-the-elite/ (noting that Lipitor's peak year sales total was $13.7 billion in 2006).

[5] *See* PFIZER INC., APPENDIX A: 2013 FINANCIAL REVIEW 4 (2013), *available at* http://www.pfizer.com/files/investors/presentations/FinancialReport2013.pdf (stating that "Lipitor revenues were $2.3 billion in 2013, $3.9 billion in 2012 and $9.6 billion in 2011" after Pfizer lost exclusivity on Lipitor in November 2011).

property, is really important.

Then the last thing I'll point to. Again, before we could be very U.S. centric. We could have all of our R&D in the United States; we could go to the FDA[6] first to get approval for drugs, this is a much more global industry now. So in terms of economic development, and fostering innovation in any country, know that we have other markets that we can go to, and a lot of other governments, a lot of other academic medical institutions that are looking for our investment. So before we could be centered in the U.S., now there is a huge incentive to go to the talent, go the science, go to the lower cost elsewhere in the world.

Key for the future in innovation, again I wanted to talk about regulatory authority. Again, if you told me when I was sitting in classrooms in this building that I would do regulatory law, I think I would rather put a gun to my head because it sounded very dull. But if you think about it, its everything; its very exciting, its lifecycle, its global, you know one day you are working with a scientist literally working on a cure for cancer, you know, to the marketing people who want to get the word out that your drug works, you know to D.C. policy makers, to you know, working with the lawyers isn't so bad. We'll say, one of the dynamics too is that the regulatory authority (and this may sound counterintuitive) but as the regulated industry, we want a very strong regulatory authority. So we need our regulatory authority, in this case the FDA, to be strong, to be effective, to have the resources, the budget, the scientific know-how that it needs to do its job. Because if the FDA says your drug has the right benefit-risk balance, that is a key endorser for your drug. So, you are going to hear me talk favorably about the FDA, when you hear me talk to my friends in the Chamber of Commerce, when you hear me talk about the FDA and partnering with the FDA, it took quite a bit of reorientation for them, because you know their mode is big business, corporations, we hate the regulator. And they are at war with OSHA,[7] they are at war with

[6] The U.S. Food and Drug Administration (FDA) is a federal agency within the U.S. Department of Health and Human Services and "is responsible for protecting the public health by assuring the safety, efficacy and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation." *What We Do*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/AboutFDA/WhatWeDo/default.htm (Apr. 10, 2015).

[7] The Occupational Safety and Health Administration (OHSA) is a federal

the EPA,[8] and with the FDA. We have a partner, and that's a good thing. So, real opportunities are ahead to change the rules of the game as I mentioned, around fostering innovation and economic development. We care about the law, the regulation, the guidance, and the review practice. So, all of that matters. You can have a very vague law, but you need the regulatory authority to put very clear guidance in place for it to be important for us.

I'm going to talk about too really quick, again, public policy is our great opportunity to partner with the government. I know a lot of industries have to sort of kick the door open but we have every five years what we call PDUFA.[9] Has anybody heard of PDUFA? I hope you haven't heard of PDUFA. If you haven't heard of PDUFA, you probably haven't heard of GDUFA,[10] BsUFA,[11] or MDUFA.[12] But all of these are not tribal chants, but they are user fee acts. So, unknown to probably most people in the room, is that we as the regulated industry pay over a billion dollars in user fees to the regulatory authority that regulates us.

agency within the U.S. Department of Labor and was created "to assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance." *About OSHA*, OCCUPATIONAL SAFETY & HEALTH ADMIN., https://www.osha.gov/about.html (last visited May 10, 2015).

[8] The U.S. Environmental Protection Agency (EPA) is a federal agency whose mission is "to protect human health and the environment" by developing and enforcing federal regulations, as well as issuing grants to state environmental programs, non-profits, and educational institutions. *Our Mission and What We Do*, U.S. ENVTL. PROT. AGENCY, http://www2.epa.gov/aboutepa/our-mission-and-what-we-do (last updated Oct. 6, 2014).

[9] Prescription Drug User Fee Act (PDUFA) of 1992, Pub. L. No. 102-571, §§ 101–08, 106 Stat. 4491, 4491–500 (codified as amended in scattered sections of 21 U.S.C.). Since 1992, Congress has reauthorized PDUFA every five years. *See* Food and Drug Administration Modernization Act of 1997 (PDUFA II), Pub. L. No. 105-115, §§ 101–07, 111–31, 111 Stat. 2296, 2298–332; Prescription Drug User Fee Amendments of 2002 (PDUFA III), Pub. L. No. 107-188, §§ 501–09, 521–23, 531–32, 116 Stat. 594, 687–97; Prescription Drug User Fee Amendments of 2007 (PDUFA IV), Pub. L. No. 110-85, §§ 101–09, 121 Stat. 823, 825–42; Prescription Drug User Fee Amendments of 2012 (PDUFA V), Pub. L. No. 112-144, §§ 101–07, 126 Stat. 993, 996–1002.

[10] Generic Drug User Fee Amendments (GDUFA) of 2012, Pub. L. No. 112-144, §§ 301–08, 126 Stat. 993, 1008–26 (codified as amended at 21 U.S.C. §§ 379j-41, 379j-42, 379j-43 (Supp. 2013)).

[11] Biosimilar User Fee Act (BsUFA) of 2012, Pub. L. No. 112-144, §§ 401–08, 126 Stat. 993, 1026–39 (codified as amended at 21 U.S.C. §§ 379j-51, 379j-52, 379j-53 (Supp. 2013)).

[12] Medical Device User Fee Amendments (MDUFA) of 2012, Pub. L. No. 112-144, §§ 201–08, 126 Stat. 993, 1002–07 (codified as amended at 21 U.S.C. §§ 379i, 379j, 379j-1 (Supp. 2013)).

And we can talk about the fun around that, but it's our every five-year opportunity to negotiate with the FDA around pharmaceuticals, medical devices, generics, and now biosimilars.[13] That's a huge opportunity that is coming up to us this year, but more closely in front of us is the "Twenty-First Century Cures Act,"[14] which is a huge initiative in Congress right now, started in the House, they picked up some Senate sponsors, but this could change our industry. This could change some real important corners of the healthcare market. We've seen the bill, at least the draft bill, and it's four hundred pages long.[15] Most of it's good. It's been a real partnership with not only the industry but also physician groups, patient groups, insurers, etc.

So in terms of critical drivers for innovation, let me run through a couple stops, because this is what you need to think about if you are playing in this space. So, we want incentives. Our CFO,[16] when we sat with him not that long ago, he said, "Why is policy so important?" Well, he gave us a whole bunch of reasons, one of which was to get incentives to develop drugs, whether they are tax etc., and they work. If you look back at the pediatric exclusivity incentive, the government wanted more drugs for children that were very expensive, small clinical trial populations, a lot of barriers to doing that, but they gave us the nirvana, which is exclusivity, additional opportunity to exclusively sell our product.[17] That works in terms of the amount of drugs for kids now on the market. Tropical diseases, right?

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[13] The term "biosimilar" refers to a "biological product that is approved based on a showing that it is highly similar to an FDA-approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products." *Biosimilars*, U.S. FOOD & DRUG ADMIN., http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/therapeuticbiologicapplications/biosimilars/default.htm (last updated Mar. 6, 2015).

[14] HOUSE ENERGY & COMMERCE COMM., CURES DISCUSSION DOCUMENT (Jan. 26, 2015, 5:26 PM) [hereinafter DRAFT CURES ACT], *available at* http://www.fdalawblog.net/Cures-Discussion-Document.pdf.

[15] *Id.*

[16] The term "CFO" refers to "chief financial officer," which is generally "[t]he executive in charge of making a company's accounting and fiscal decisions." *Chief Financial Officer*, BLACK'S LAW DICTIONARY (10th ed. 2014).

[17] *See* 21 U.S.C. § 355a(b), (c) (West, Westlaw through P.L. 113-296 approved 12/19/2014) (providing a market exclusivity period for patented drugs that are undergoing pediatric studies).

Again, very low returns. They put in a voucher program where if you developed a tropical disease medicine that didn't get approved, you got a voucher to apply to another drug to get expedited approval.[18] That's worth a lot of money. We didn't know how much money until recently, when one company sold a tropical disease voucher for a non-tropical disease review for $60 million.[19] We are like "wow," $60 million for a piece of paper. Another company sold another voucher for $120 million.[20] So, the science was advanced, but it was also a business incentive to get involved.

So in this legislation, potentially, is an incentive to revive dormant therapy.[21] With all of the shifting of the industry, a lot of science has gone on the shelf. We just don't have the money to pursue the science. So as an incentive to get some of those potential therapies off the shelf, there is an additional exclusivity period for any drug developed under that program.[22]

Another thing that is really important in terms of incentivizing the industry is speed. Because we have patent protection that only lasts so long,[23] you know we need to get drugs through the approval process and a huge caveat is that it has got to be safe and effective. That's the public health rationale for what we do is prominent, even though I am kind of talking more in business terms. But speed. So, in this bill is surrogate end point qualification.[24] So, instead of having to take a clinical trial all the way to the end and prove clinical outcome, there are certain scientifically validated checkpoints along the way that can be relied on by the regulatory authorities. But, there needs to be a qualification pathway for that. Antibiotics, again very expensive,

[18] *See id.* § 360n(b) (establishing a priority review voucher program for the sponsor of a tropical disease product application).

[19] *See* Sonja Elmquist, *Drug Industry's VIP Pass Costs $125 Million and Climbing*, BLOOMBERG (Jan. 6, 2015, 12:00 AM), http://www.bloomberg.com/news/articles/2015-01-06/drug-industry-s-vip-pass-costs-125-million-and-climbing (referencing the $67.5 million purchase agreement between Regeneron Pharmaceuticals Inc. and Sanofi for an FDA priority review voucher).

[20] *See id.* (discussing the $125 million purchase agreement between Knight Therapeutic Inc. and Gilead Science Inc. for an FDA priority review voucher).

[21] DRAFT CURES ACT, *supra* note 14, at 101–18.

[22] *See id.* at 102 (providing a fifteen-year "protection period" for dormant therapy medications).

[23] *See* 35 U.S.C. § 154(A)(2) (Supp. 2013) (stating that patent protection expires after twenty years).

[24] DRAFT CURES ACT, *supra* note 14, at 15–28.

very difficult to develop.[25] If we can do it in more limited populations for trials, with an opportunity to do post marketing safety surveillance after that, that is going to get more antibiotics safely on the market.

We talked a little bit about data, but everybody is protecting their own data. Its very difficult not just from a technology standpoint, to share data and to get people comfortable and protected in sharing data that the insurance companies have, the providers have, the pharmaceutical industry has, and so again obviously this data is critically important, particularly real world data that we can get from observational studies that really work in the population and getting it much more clear in how we can get that information into labels, for example, very critical.

A new tool is social media. It's horrible to try to do anything on social media, because, and I've been in on conversations with Google and Facebook, and YouTube in particular, where they don't care. They don't care that we are highly regulated. You know, they have their rule, and I don't want to overstate that too much, but they don't understand the legal requirements that we have to completely communicate about our drugs in the public sphere. So we, you knows those ads that you see in the magazines that go on for pages, with risk information in particular? Well every time we are on social media, we have to print all that. That has to be all there. And we have had problems where we do that in the YouTube text box, and then YouTube changes the policy where if you forward the video it chops off all but I think the first two hundred words. So we are immediately out of compliance, FDA can fine us, and they have as an industry about a billion dollars a year for various marketing practices. And we are not proud of that, but some of that comes from the ambiguity in the rules. So getting some rules around what we can do in social media is really important.

The last thing I'll mention is, again, talent at the regulatory authority. So you can have the best scientists working in your labs, but if they are bringing innovative science to bureaucrats, you know, who haven't been in school for about thirty years and

[25] *See* Eduardo Porter, *A Dearth in Innovation for Key Drugs*, N.Y. TIMES, July 22, 2014, http://www.nytimes.com/2014/07/23/business/a-dearth-of-investment-in-much-needed-drugs.html (explaining that antibiotics "are not only becoming more difficult to develop, but they are also not obviously profitable").

may not be up to speed on the latest in genomics, or whatever the case may be, then you've got delay. And you've got potentially bad decisions. So, part of this bill is around actually allowing the FDA, and this is really boring stuff, but it matters, allowing the FDA to directly hire, and to allow them to offer salaries above kind of base government salaries,[26] because what we have found is people going to the agencies, stay a couple years, get the experience and go into industry. Which isn't so bad, but you know it leaves a big gap in the regulatory authorities.

So, if I haven't completely bored you on regulatory, it is pretty important. How much time do we have left? None? Okay. So if we get into Q&A around state incentives, I don't really work in that space, but there are some pretty important things to be done to keep us here in the capital district. So, thank you.

[26] *See* DRAFT CURES ACT, *supra* note 14, at 140–49 (establishing a "Medical Product Innovation Advisory Commission" to "review Federal policies . . . relating to the discovery, development, and delivery of new medical products and how such interactions influence medical product innovation").