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LEADERSHIP & BUSINESS PODCAST

EPISODE 126: JOHN OSBORN – PRESCRIPTIONS, PRICING & POLICY

Ken White

From William & Mary in Williamsburg, Virginia, this is Leadership & Business. The podcast that brings you the latest and best thinking from today's leaders and subject matter experts from a variety of businesses and sectors. We share the strategies, tactics, and information that can make you a more effective leader, communicator, and professional. I'm your host Ken White. Thanks for listening. Americans like their prescription drugs. According to Web M.D., the number of prescriptions filled for Americans rose 85 percent between 1997 and 2016. That's four times the population growth during that same period. While many Americans count on their prescription drugs, many also have an unfavorable opinion of the pharmaceutical industry. John Osborn is a senior advisor with the Washington office of the international law firm Hogan Lovells. He's spent over 20 years with leading life sciences and healthcare companies. Osborn recently visited William & Mary as a guest of the Schroeder Center for Health Policy. He spoke with students about the pharmaceutical industry, drug pricing, and health policy issues. Afterwards, he spoke with us. Here's our conversation with John Osborn, senior advisor, Hogan Lovells.

Ken White

Well, John, welcome to William & Mary. Thanks for joining us this morning.

John Osborn

Thanks, Ken. Thanks for having me.

Ken White

What brings you to campus this time?

John Osborn

Well, I went to William & Mary as an undergraduate. My daughter graduated in 2013, and I've become involved with a public policy program, I'm on the advisory board, and one of the professors here asked me if I would talk a little bit about health policy. And that led to a lecture yesterday.

Ken White

Yeah, and I attended it away. It was absolutely fascinating, and it's why we ask you to be on the podcast, so thank you for being here. I thought one of your first questions was interesting. You asked the audience, do you have a favorable opinion of the pharmaceutical industry? What kind of a response do you get from people when you ask that?

John Osborn

Well, you know most of the time, and perhaps you know not surprisingly it's not they're not a lot of hands that go up when you ask whether you have a favorable impression of the industry. And the specific topic that I was focused on yesterday had to do with the life sciences industry, the business model that that industry uses and the concerns that are headline issues right now, around the high price of drugs, and what hits me although I do kind of know that there's been a lot of negative headlines over the years and that their reputation is not great. But what hits me and what I then remind the audience is that you know at the same time that people are frustrated with what they see as a high price of prescription drugs. They also should remember that this is an industry that has over the last quarter-century made incredible breakthroughs and that we now have patients who are able to live and to live reasonably healthy and happy lives when they have HIV or rheumatoid arthritis or breast cancer or other kinds of cancers. The industry's played an instrumental role in doing that. So it's striking to me that given the role that it plays, which may not be well understood that you know people generally still have a largely unfavorable sense of it.

Ken White

People tend to it seems to me jump on the pricing issue, is there a pricing problem in the United States?

John Osborn

You know it's there is a pricing problem in several respects. I think for me anyway there's a pricing problem you know to use the economist phrase in a microeconomic sense that even after President Obama's Affordable Care Act there are still many people in this country who don't have insurance, there are many people who have health insurance, but they might have a very high deductible, or they might have fulsome you know widespread coverage for drugs. There are people who really have they just have an illness where the particular remedy is so expensive that it is backbreaking. And so I don't deny any of that. I also think the industry has done some things that you know we can get into that in a little bit that hasn't helped its cause and has led to really hurt its reputation. But I would say at the same time I try to highlight if you look at the macroeconomic trends the larger trends over let's say 50 years you've been going back to the 1960s the number of prescriptions that are filled with low-cost generic drugs is strikingly high. It's close to 90 percent overall

the amount of coverage notwithstanding what I just said about some people lacking coverage the vast majority of Americans do enjoy drug coverage whether that's through the relatively new Medicare Part D for retirees whether it's through Medicaid for low-income folks whether it's just through their employer-sponsored insurance plan. So most people do have coverage, and most of the expense of drugs is paid not out of pocket but by these plans. And the other thing I guess to keep in mind is that while there are headlines around these very expensive innovative new cures things like gene therapies and immunotherapy to treat certain kinds of cancers, I mean these are things that have taken decades to develop. They're often for a very limited number of patients. And so the price is high when it's first introduced. But they also represent truly extraordinary biomedical innovation. So I think if you think about all of those larger trends you would look at the big picture and say wow this isn't a this is not a bad picture.

Ken White

Innovation costs money and in it. And is it difficult to get investors in the pharmaceutical arena compared to other businesses?

John Osborn

Yeah, I mean, I think it is it remains a challenge for early-stage life sciences companies. You know a compound will often get developed perhaps with government funding at the NIH or with the university research grant, but it needs to be developed. It needs to be studied with patients in the clinic, and that's done by companies. I don't think that we should spend a lot of time shedding tears for the likes of Merck and Pfizer and the well-known old large companies, but I just saw this week a piece that's out with reference to a lot of the early-stage biotech companies some of whom themselves make these great discoveries all this stuff doesn't come from the Mercks and the Pfizers of the world and it is hard for early-stage companies to get funding. It's become harder in the last let's say 10 to 15 years just because of the rise of Silicon Valley, the opportunity to invest in software companies, perhaps even in-app companies for your phone. They don't have the regulation; they don't have the expense. And so if you're a venture capitalist and you're looking at where to put your money, it's not that we don't still have specialty Life Science venture firms investing in early-stage biotech, but you know dollars. You know there's a competition for those dollars, and it is difficult in relative terms, and so the specter if you will of a kind of you know relatively significant change that would limit the prices that companies can charge is probably going to have an adverse effect at least on the early-stage companies we're looking for capital.

Ken White

And failure rate. I mean, this is this takes a while. Failure rates fairly high to get to something that's successful correct?

John Osborn

It is part of the equation. I mean, that's also part of that dynamic about why is it hard to get money well because it's really expensive and it's really risky, and it's hard. I mean fundamentally even with all the advances and even with people referring to the 21st century as the biology century. We still don't know as much as you might think about the fundamentals of human biology is probably most evident when you study a neurodegenerative disorder like Alzheimer's which is afflicting so many but in big-picture terms, Ken, we've got let's say there's a thousand compounds that get identified in the laboratory is perhaps having some utility either inhibiting something or fostering something in the body in the biochemistry that would be useful as a drug. Only a small number of those are going to go into the clinic even into Phase 1 to see if there's a safety or toxicology issue. And from Phase 1, only a third of those make it to the large scale study that you need to get approval and only 10 percent actually become drugs, so you're probably going sort of on the order of you know a thousand to hundred to thirty to ten. And so if we could reduce the cost if we could get better at that process that that would be a very good thing.

Ken White

We'll continue our discussion with John Osborn senior adviser with Hogan Lovells in just a minute. Our podcast is brought to you by the Center for Corporate Education at William & Mary's School of Business. For the second straight year, Bloomberg Businessweek has ranked William & Mary as the number one MBA program in America for learning. The faculty who teach in the MBA program are the same faculty who teach in the programs offered by our Center for Corporate Education. If you're looking to raise your game, consider the center's upcoming programs. The Certificate in Business Management and Business Analytics for Strategic Leaders both programs taught by the faculty ranked number one for learning by Bloomberg Businessweek. To learn more, visit our website at wmleadership.com. Now back to our conversation with John Osborn of Hogan Lovells.

Ken White

You mentioned generics. I think people assume there's a generic drug for every brand name drug. Is that close? Is that accurate?

John Osborn

There are a lot of generics. I think of you know to the extent that you're a skeptic about the value of the industry. And that's certainly fair. One of the things that I try to emphasize to people is that as a society, we've kind of made this implicit bargain, which is to say you know we support and have patent protection and regulatory exclusivity for a brand new innovative drug. And after about 10 to 12 years, that exclusivity goes away, and generics are entered. And that's the bargain we make that you pay a lot in the early years. But the presumption is that there will be relatively cheap generics that will enter the market. And

that presumption was then made more explicit in 1984 statute that Congressman Waxman and Senator Hatch develop, which gives specific incentives under the law for generics to challenge branded companies and to then enter the market with a limited amount of exclusivity themselves. You know all that said it is also true as you, as your question suggests is also true that there are a lot of off-patent branded drugs that still don't have generic competition. Sometimes they've had generic competition, but the company making the generic version doesn't stick with it. Sometimes there are supply problems and quality issues. The FDA identified under former commissioner Scott Gottlieb's tenure, which ended recently. This was one of the initiatives that I did you know I'd give credit to them for highlighting about 500 commonly used drugs that are off-patent and that do not enjoy generic competition. So it's a real opportunity. And it goes against this kind of fast hidden bargain that I describe this is the assumption that well OK we're going to kind of put up with these high prices for a while because we really do value biomedical innovation but also because we know down the road there's real consumer advantage in all these generics. Well, of course, that only happens in our system. You know if there is a company out there willing to step up and get the generic approval, so that's kind of what's going on in that space.

Ken White

Are we taking you pointed out 1960 as sort of an interesting time to benchmark? Are we taking more prescriptions as Americans today versus 1960?

John Osborn

Yes, absolutely. And of course, there's been extraordinary innovation there. There's so many new medicines, both biologics, and small molecule pharmaceuticals, then we had then. There are many more medicines. The overall rate I mean what's often cited as a genuine concern is the percentage of our overall health care spend that goes to drugs. And then the percentage of our total GDP that goes to health care. So the latter number is a real concern, and I think those because it's approaching 20 percent even after the ACA I would say this even with the amount of overall the aggregate spend on drugs there is a relationship between the investment as a society that we're making and the spending that we're making on drugs and the overall spend on health care for a long time just worth mentioning that the Congressional Budget Office which does a lot of good analysis on all kinds of things including health care spending by the Federal Government, of course, they came out I think it was at the end of 2012 CBO for the first time recognized formally. And one of their estimates that if you're evaluating different proposals to cap spending on drugs into you know effectively limit the use of drugs, you should also recognize the relationship between spending on medicines and spending on other health care hospitalizations and other services. And that kind of I guess that really in a way ratified what the industry has been saying forever, which is wait a minute. OK. We do things, but we're part of a larger ecosystem of health care, and we should think about the use of

prescription drugs in the context of wellness and in the context of total spending on health care.

Ken White

What's happening on Capitol Hill? What's being discussed? What are lawmakers trying to do in terms of pharmaceutical and drugs?

John Osborn

Well, the focus right now is on a bill H.R.3 that's in the House of Representatives that was introduced as you can tell by the number three introduced very very early in this Congress at the beginning of the year. And of course, we're heading into an election next year. And I guess by congressional standards in the calendar time is running short to do much. And there's also, of course, a continued division between the House of Representatives and the Senate but all that said H.R.3 is a bill that Speaker Nancy Pelosi supports. And it's really been labeled the speaker's bill although there are a number of people that are in favor of it. There are some interesting provisions, one of which would seek to undo the prohibition in Obamacare that doesn't allow the government to negotiate directly with drug companies to reduce their prices. This would, in fact, allow that, and it would direct HHS the Department of Health and Human Services to negotiate for up to 250 pricing on up to 250 drugs. I think there's a target now of 35, which I guess doesn't sound like a lot of drugs; it's targeting the very high price drugs to make sure we're getting good value for those. It would also buy some mechanism, apply those government negotiated prices to private-sector plans that qualify. And then there are different aspects of it to sort of make this work. There are there is a debate going on as to if companies decide that they're not interested in negotiating. Do we compel them by forcing a discount upon them? Do we have reference pricing, and other provision would actually look at a basket of prices for drugs that are available in this in half a dozen other countries outside the U.S. and would reference our price to them? And there are provisions around limiting the amount of price increase that you could put on on a drug and having that be rebated back as you now do under Medicaid. So you know the industry, I think, is genuinely concerned about some of these provisions. I think it understands that they need to be responsible. And there have been a number of industry initiatives themselves about you know limiting price increases. There have also been industry initiatives around value-based contracting. Some companies have started to negotiate provisions in which if a drug isn't effective. If it turns out that it doesn't work as intended that the price would be refunded. So it's not that the industry is insensitive to the Ferber and the political winds out there we'll see if some of these things get traction. But you know my sense is you're probably going to have to wait until the results of the election in November 2020 to really see how this plays out.

Ken White

That's our conversation with John Osborn of Hogan Lovells. And that's our podcast for this week. Leadership & Business is brought to you by the Center for Corporate Education at the William & Mary School of Business. The Center for Corporate Education is offering programs to help you raise your game. The programs are taught by the William & Mary MBA faculty ranked number one in the nation for learning by Bloomberg Businessweek. For information, visit our website at wmleadership.com. Finally, we'd love to hear from you regarding the podcast. We invite you to share your ideas, questions, and thoughts with us by emailing us at podcast@wm.edu. Thanks to our guest this week, John Osborn, and thanks to you for joining us. I'm Ken White 'til next time have a safe, happy, and productive week.