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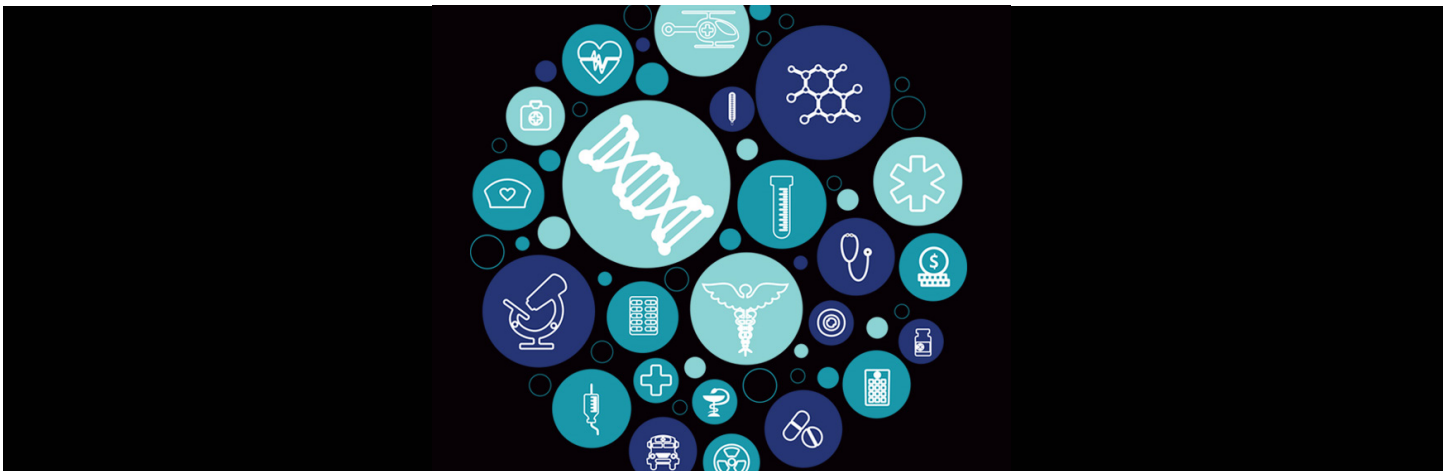

Life Sciences Industry Outlook 2017

What are the trends for US life sciences in the coming year?

Rob LaFrentz: Managing pricing and costs, changing business models, customer engagement, and an uncertain regulatory environment are all part of the shifting landscape facing life sciences companies in 2017. Greg Reh leads Deloitte's global and US life sciences sector practices for consulting, audit, tax and financial advisory services. He has more than 25 years of experience helping clients in the life sciences including multinational pharmaceutical, biotechnology, and chemical manufacturing organizations. I had the chance to speak with Greg about what's ahead for the industry, and I started out by asking him about pricing and how companies can prepare for this enduring trend in 2017.

Greg Reh: IPricing was on the agenda I think regardless of the outcomes of the elections. It's certainly a complex topic. And I think that while at times it's been somewhat of a volatile conversation, I think the level of dialogue both within the industry and within the media has helped heighten some of the awareness associated with the costs of what it actually takes to bring innovative drugs to market. The ongoing challenges of research and development effectiveness, as well as the need to more accurately capture the value that a particular therapy provides.

Interestingly, most of the conversations have been on list prices of drugs. But I think as is becoming more widely known, the reality is that there are quite a number of intermediaries involved. And, frankly, from an industry view, the net price growth of branded products only grew just under 3 percent in 2015.

So with this greater awareness I think the conversations can be had in terms of how to look at overall cost, not just a component of health care, which is made up by the drug component. And it'll continue to be on the forefront as the new administration's policies become clearer. And hopefully the changes in the health care systems that we see down the road will be incenting all the stakeholders in ways to bring overall costs down.

Another element that certainly has changed over time, and I think will continue in 2017, will be the increased involvement of certain advocacy groups in the dialogue. And hopefully they'll continue to be able to shed light on how value can be defined. And just the overall increase in collaboration between the life sciences industry, the payers, and providers will certainly have a positive impact both on outcomes as well as costs.

Couple all of that with advances in science and, this will become a particular important as value of not only treatments but cures as well are brought to market.

Rob LaFrentz: As it relates to value and value-base care, as a pricing consideration there's been a lot of talk about MACRA among health care providers and plans. How do you see MACRA impacting life sciences companies?

Greg Reh: Well certainly the expectation is that MACRA will accelerate the move towards outcomes-based contracting, particularly with some of the decisions that the individual physicians have. One area that might be impacted in particular is the diagnostics space where there may be a potential pathway for some innovative diagnostics to be reimbursed, since it will be a determinant on the outcomes of any particular therapy that a physician prescribes, so it's still speculative at this point, but that could be one of the potential outcomes of MACRA.

Rob LaFrentz: So it sounds like there's going to be a lot of shifting in the way life sciences companies will be reimbursed. What's one capability they should develop to demonstrate value in 2017 and beyond?

Greg Reh: Well, regardless of what any kind of outcomes based models are going to look like, I think the establishment of some end to end evidence management capabilities is going to be critical for any players in the life sciences industry. And whether they use it just to

optimize R&D efforts or start to think about how to shift commercial operations to more effectively participate in those kinds of outcomes based contracts. The need for evidence and the ability to derive insights and also articulate not only insights but the value of the therapy is going be the key to any kind of a sustainable model from a life sciences perspective.

So what that means is the need to effectively collect and manage evidence and share it with health care stakeholders, as well as regulators. You know as the underlying science continues to improve there's going be significant advances to understanding some of the nuances in subpopulations, specific individual behaviors, the various effectiveness of different interventions, and even the ability to sustain adherence to a particular therapy. So overall I think the success is going to be increasingly dependent on, you know as I mentioned, how to use the data for a number of decisions across not just R&D but commercial and manufacturing as well. And implementing these capabilities has got to be a key priority going forward.

Rob LaFrentz: The idea of end to end evidence seems to look at what's effective for certain patient populations. To that end, within the industry, we're seeing an increased focus on patient-centricity. How do you see that impacting what life sciences companies need to focus on in 2017?

Greg Reh: IThe move towards patient-centered models has been evolving now for the last 18 to 24 months. I think the reality is that it's still a model that has yet to be matured fully, and it certainly is different from disease area to disease area. At the end of the day, the level of patient engagement is going to be focused on both determining the effectiveness of a particular therapeutic pathway, it could have an impact on patient adherence, but then also start to enable patient reported outcomes and provide a basis for understanding what to do with those outcomes. There are going to be a number of ways both from a technology standpoint and various channels to engage with patients. As the fidelity from everything from biometrics to the analytics associated with the data improves, it will provide the basis for a more informed view of any key part of the patient pathway through their disease state. In terms of preparation, I think insuring that the appropriate technology enablers are in place, including security associated with the data being collected, as well as the ability to aggregate from not only from a uni-channel kind of a set up, but looking at aggregating and correlating data from multiple sources to be able to derive much more informed insights to the data being collected.

Rob LaFrentz: What can drive increase patient engagement?

Greg Reh: Well certainly the most talked about tool for patient engagement has been the variety of mobile health applications over the last few years. They've come on the market and in some cases been approved as a medical device. And those will continue to be an important part of the links between patients and patient services within our organizations. But, what I think also has been good demonstrated the overall longevity and the effectiveness of many of the mobile health apps. It's still an area that needs to evolve and that can be improved with everything from more accurate metric sensors as well as augmenting the data and using advanced analytic techniques to drive better adoption and creating algorithms that recognize patterns that might predict, behaviors and help actually change behaviors.

But beyond the tools themselves though, I think companies are re-thinking other methods. Whether it's direct engagement with patients in their innovation labs, many of which have been already setup within life sciences companies. And in doing so, service unmet needs or under-met needs. Or furthering engagement with patient advocacy groups to define better quality measures which are going to become particularly important in value based contracts. So I think all these channels will certainly drive increased patient engagement, both virtual and real. And have the potential of yielding better understanding of both the patient experience and how they define value of any given therapy.

Rob LaFrentz: Greg, let's talk about R&D. I know Deloitte recently launched a study that shows annual projected returns on R&D investment continue to decline. How do you see that impacting the sector?

Greg Reh: Well, as our study that we just released showed, unfortunately there has been a decline in the IIR of R&D. and this has been a trend that we've been tracking and regrettably it's at its lowest point now. So the need is loud and clear in terms of changing the R&D model to be more effective. And we'll certainly continue to see the kinds of licensing and acquisition and partnering deals that are out there today. But as they become more focused on specific disease areas and portfolios are restructured to start to focus on the core capabilities, couple that with some of the new approaches like gene therapy that continue to move from clinic to market. That ongoing collaboration with academic and early stage companies will continue.

Rob LaFrentz: You mentioned collaboration. What other opportunities do you see for life sciences companies?

Greg Reh: There's certainly been a continued focus and adoption of translational medicine techniques. That kind of collaborative and directed research is a way to shift the balance of economic and scientific risk and start to look at the broader ecosystem in gaining input from payers, providers, and patients, and regulators themselves. I think the closer that those discussions could be had in the R&D cycle, the better the outcomes will be.

Another aspect of collaboration is the continued adoption of an open innovation model. And this is something that life sciences companies have been increasingly implementing. Whether those collaborators are academic medical research centers or startups, early stage companies, it certainly will have an impact on the R&D productivity. Particularly as the industry continues to focus on some of the precision medicine agendas that have been out there.

But one other thing to add in terms of collaboration is in addition to all the external mechanics that we just talked about, I think there'll be an increased internal collaboration as well. And this will also evolve to help break down barriers between functions within any given life sciences company.

Rob LaFrentz: Life sciences companies have always faced many regulations on both a national and global basis. What needs to be top of mind for executives as they head into 2017?

Greg Reh: There are a number of regulatory standards that are being implemented, the most significant of which, particularly for 2017, is the Identification of Medicinal Products or IDMP, and these are new standards that will enable the unique identification of products throughout their lifecycle to be able to, in a consistent manner, exchange the information, whether it's with regulators or other partners throughout the development, as well as the commercialization and distribution processes. So this has the potential of having a significant impact not only from a compliance standpoint, but for driving some of the collaboration that we spoke about earlier across a number of the functional silos that currently exist by virtue of the need of having data normalized across a product's lifecycle. So preparing for this is an imperative not only from a compliance standpoint, but also in taking advantage of the infrastructure that will be required to drive more collaboration across divisions within any given life sciences company.

Rob LaFrentz: So bearing in mind those global regulations, here in the US, life sciences companies of course need to consider the impacts of the US election.

Greg Reh: Well needless to say, there's still much that is undefined and lots of speculation in terms of what the actual impacts will be. I think it's safe to say that the focus on outcomes and value-driven pricing is going to be a consistent theme regardless of the changes that are being contemplated, be it from a regulatory standpoint or from an overall business environment standpoint, and you know, with that, it makes sense to continue to focus efforts on enabling both from a technology, as well as from an organizational standpoint, all of the elements that are going to be required to continue to operate in an outcomes-based health care environment.

Rob LaFrentz: What do you think are the main opportunities for life sciences companies in 2017?

Greg Reh: Well, as we've touched on, along the way, I think collaboration becomes the key theme. Be it collaboration within the health care ecosystem, with patients, or internally. Many of the pressures that life sciences companies are under, be they cost or regulatory or operational, in somewhere, shape, or form, can be de-risked by creating a platform for information and idea exchange. I think this will truly be picked up more aggressively in 2017. Furthermore with the passing of the 21st Century Cures Act, there will also be increased opportunity to accelerate the overall process from an approval perspective. With new ways of having breakthrough designations and developing quality measures that will really harness the power of real world evidence. The combination of some of the changes from a regulatory standpoint, as well as continued focus on outcomes based contracts, I think will all be opportunities in the long run for companies in 2017.

Rob LaFrentz: For more on trends impacting the US as well as global life sciences and the health care ecosystem in 2017, visit www.deloitte.com/us/lshc-outlooks, and follow @DeloitteHealth on Twitter.

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