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Health and Life Sciences RX
PODCAST

EPISODE 10:
KNOWING WHEN TO CALL IT QUITS IN DRUG DEVELOPMENT AND HEALTHCARE INNOVATIONS

INSIGHTS FROM THE BDO CENTER FOR HEALTHCARE EXCELLENCE & INNOVATION AND LIFE SCIENCES PRACTICE

INTRODUCTIONS

Steven: So, we all know that the drug development process is laden with risk, it's costly and it's a time-consuming endeavor, and it's made even more challenging with growing and changing demand. In this panel, we're going to explore the oft-overlooked key to success in drug development. That is knowing when to kill it. The time to kill a drug development. We've got a great group of panelists to discuss this topic and they're going to come up onto the podium. First, we have David de Graaf, who's the CEO and president of Comet Therapeutics and brings 25 years of R&D experience to our panel. Secondly, Michael Crandell, he's the senior director of business development for the Allen Institute for Brain Science, which is a leading non-profit medical research institute. And Paul Radensky, partner at McDermott Will & Emery who advises companies at every stage of product development. Our moderator is Howard Levine, who has extensive experience in biopharmaceutical product development and commercialization. So, we welcome all of you and come up to the podium and we look forward to hearing your conversations.

Howard: Pleasure to be here to host this panel. Today's discussion is a little unique at this conference because everybody comes to San Francisco for J.P. Morgan to talk about the wonderful successes that they've had with their drugs and the potential of their drugs and the potential and future for their companies. But the reality is, as we all know, is that at least 80% of them are going to fail at some point along the way and we're going to explore what some people might consider a taboo subject today and that is knowing when to kill a product and when it's time to move on and so we have a great group of panelists here today. We've had some opportunities to discuss some of this beforehand and so I'm really looking forward to the discussion.

TOPICS DISCUSSED INCLUDE:

I hope you all are as well. So, to get things started, let's talk a little bit about the why of development and why most programs end. And so, David, I'll start with you and give you an opportunity to make some comments.

WHY MOST DRUG DEVELOPMENT PROGRAMS END [03:04]

David: Okay. Yeah. I'm a recovering pharma guy. I now do small start-ups and one of the great opportunities we had is actually to do a retrospective analysis of what are the success factors. Because as Howard said for large pharma the failure rate if you start counting from the first idea to a drug to market is on the order of 99%. Fewer than 1% of programs work out. There are some very easy predictors of success. For example, if you have a fast follower. If you have a drug that acts in a similar mechanism to a drug that's already on the market, then suddenly your chances shoot up from about 1% to about 15%. Which still tells you that making drugs and getting them on the market is pretty hard. So, what we looked at is what are the things that you need to have in a program in order for it to be successful in a phase two to phase three transition? That's the moment when you've established that the drug is working, that it's doing what it's supposed to do, and that it's safe and efficacious. And it turned out that there were three very easy lessons and they sound pretty straightforward even to people who may not know all that much about making drugs. The first one was knowing how to test that your drug would actually get to the place where it was supposed to act. That sounds pretty straightforward and simple, and if it's about your liver or your skin it might be. But if it's about your brain, that's not a particularly straightforward question to ask. The second predictive factor is having an essay that told you that the drug engaged its target. That it actually bound to the target that it was supposed to engage in. The third one was that it then elicited the biology that you'd predicted. You didn't need to know everything about what it would do but that the piece of biology that you'd link to disease was effective. And the difference in terms of success and failure, if you even lacked one of those particular factors—which is again, these are not easy things to build in—you go up from a 4% success rate phase 2 to phase 3 transition to 85%. So, there are things you can tell relatively early that will tell you whether you're going to be successful in that transition. And then there are obviously commercial pressures and other reasons why drugs don't develop which I won't touch on right now but they're a part of this.

Howard: Michael?

Michael: Well, I come at it from the small biotech side, emerging biotech side. [I] was lucky enough to start with Immunex back in 1980 and it was just research. We probably spent—in fact, I was telling my father, he said, "How do you have a stock price when you don't sell anything?" I said, "We sell stock." And people bought stock. Back then, you could clone IL2 and you had a couple hundred million market cap. Obviously today, things have changed radically but I've been associated with multiple biotechs, commercial pharma companies, and most recently many, many emerging companies through venture capital. And I don't really, I know your filter makes sense, but you really don't see the filter. People seem to fall in love with something. They push it. And you're sitting there a few years and a couple hundred million dollars later in an offsite hotel room with some person you've never met before who's from the clinical company who's going to un-mess the data and break the randomization code. You're sitting there with three or four people. Piece of paper pops out, .067. You're dead. And no one was prepared for that and you ask yourself why because the numbers that I look at are that of some 17,000 phase ones tracked by bio. It's single digit that make it to market. So, you were $100 million in with all these really smart, passionate people, and believe me, the people are incredible. That's probably why we do this. The people and then what we're trying to do, patients. But you have all this brainpower and they have no clue really why you're still looking at a 90% failure. After $100 million of screening and of expertise and FDA and manufacturing and boards of directors and experts and the numbers keep coming up. I don't know that it's going to get better but it's something we do, and we'll have to continue to do it. And killing it's not, very seldom do you make a decision to kill. Gravity kills it. At a small company, investors kill it because it's, "You're done." One company, if you're familiar with venture capital you have seed and you have Series A, and if you're lucky B, and C. I did one company that had EFG (Enterprise Finance Guarantee) 1 and 2. By the time you get to 2, people have headed for the exits. But that company went on after all the way to the end to come up and get a drug approved. So, it's very hard to dissect this process.

Howard: Paul?

Paul: Great. So, I come at it from a somewhat different perspective. I'm a lawyer, but also a physician by training, and in between my two careers I worked in clinical research for a pharmaceutical company. And I knew I was going to go back to school, so I was doing this to get some experience and then also to learn about drug development. So, I didn't have when I joined the company as much of a long term invested interest since I knew I was going to go back to school, but I did want to learn and understand a lot. So, I was brought in because I had done a fellowship in liver diseases, and they wanted someone who could help dissect and understand about liver-related drug toxicities. And was brought in for some CNS products, and this is a number of years ago. And at that point in time really, we're looking for novel classes of agents for schizophrenia that would not have the

toxicities that the phenothiazines did or the haloperidol which were the products that were in use when I was in training that we had. One of the things that [we] thought was clear was there were some very good biological models and chemical models to look at what caused the adverse events that you would have with phenothiazines, and those models suggested that these products, the new class that we were working on did not have those. But at the highest doses and longer durations in animals you saw some related findings. So, the idea was still to bring this in demand because the thought was that these types of side effects would not likely show up. One of the things that happened though, and this again you really have to not only be thinking about just what you're going to be looking for, for safety, and efficacy, and then also the commercialization issues and dosing issues, the cost of goods issues, all of which may be reasons the products get killed, but you also have to really understand the relationship between the clinical pharmacology and what you're looking at. And these products all had sulfur-related compounds, sulfur bridges. And we all knew, and this is part of the reason that I ended up doing this, was that sulfur compounds often cause liver toxicity. So, we saw some spikes in liver-related enzymes in the first couple of patients. Now because these were for patients with schizophrenia, the early phase two trials were with patients with schizophrenia, the company did not want to kill the products even though we started to see these abnormalities in the first couple of patients in phase two. So, we actually had to devise and get through an IRB, a dose challenge study in patients with schizophrenia. And we set a stopping rule, and the stopping rule was we would re-dose to no more than a half a dozen patients, and if we saw more than 50% have even minor elevations in the liver function tests that we would stop, and that would be it. And part of the thinking was we were seeing some liver-related toxicity, this was going to be difficult to prove the negative. We knew that if we did carry forward, we were going to have some major safety studies that we were going to have to do. But also there was always at least in my mind, at some point in time because of what we saw in the animal models, given enough dosing and enough duration we probably were going to see some of the side effects that we had seen with the other classes before because we did see it at the highest doses. So, we did the redosing trial I think it was two out of four patients did show minor but definite elevations of the liver-related blood test abnormalities. That was our stopping rule and we stopped. I wasn't familiar with the teams. I was relatively new. But I was so surprised at the reaction. When we did decide to kill the drug, I would hear from various folks, "Are you crazy? Look at all of this money that's been spent." But I think the key, at least for me, and I think it was the right decision for the company is you got to know when to let go. If your pharmacology suggests that something might happen and you start to see it, it probably is going to happen, and you probably need very substantial studies to be able to prove that that's not the case. It may be that if you truly are a first in class and you've got something that really, you really think from an effectiveness perspective might be dramatically different, that that would then warrant it. But many, many times, we try and convince ourselves, and that's what I was hearing all over from the company, were people trying to justify, it clearly had the liver-related issue. We had tried the challenge, and it was there. Not necessarily anything fatal or causing acute hepatitis, but it was clearly there. We created a stopping rule, and we stuck to it. It's difficult to do that. But if you are honest with yourself and really looking at the relationship of the pharmacology and efficacy or pharmacology and safety, you can make those decisions.

PRESSURES IN THE MARKETPLACE & PREDICTING HUMAN OUTCOMES [13:24]

Howard: That's an interesting perspective. And we will come back to the question of stopping rules and force disciplining yourself to stop things. But before we do that, I want to just explore another aspect of why companies might kill a drug. We talked about the medical reasons, the scientific reasons, but often there are business and strategic reasons that a company may want or need to kill a particular program. So, Michael, you eluded to this a little bit at the end of your remarks about investors killing a program. Do you want to elaborate on that or add to it?

Michael: I think what you now see is investors and pharma are putting up very tight filters. Used to be, again, you could discover something, and you could get investors to push it through and you could do an A and a B and a C in preclinical. It is very difficult today to get venture capital for a preclinical asset, no matter how exciting or beautiful it is, unless it's AI, and we can come back to that, or Bitcoin. But if you have a preclinical idea today, the VCs have just said, "No. We're not taking that risk." Pharma won't take it. And so, the risk now of stopping is kind of flipped on its head because it's hard to start now. And it's not a good development. But the starting part is really difficult, and investors and every pharma company have 100 people in business development. Okay? Huge amount of people. And you go and pray to that altar and try to get in the door. And the screens are really, really tight. So, investors, they used to feed a company. You could see biotechs that were 10 years old or 15 years old failing but just surviving. That doesn't happen anymore. You pretty quickly get the plug pulled.

David: It's actually because pharma is acquiring earlier, the money cycles have gotten much shorter. And now investors need to be able to recover their investment within a couple of years. And even within 10-year funds, if you tell a story where it's going to take you five years to get clinical evidence, there's a lot of pushback. And that makes it really hard. You have to tell

stories where you can say, "We're going to get into the clinic very rapidly," because ultimately, that's the proof point, is once you're in patients. That's one thing that I would like to add to this. We are really bad at knowing upfront whether a drug is going to work because we're very good at curing mice. And it turns out that mice aren't humans. So, there's not a rampant issue, for example, with oncology, in the mouse community, as far as I've been able to observe in traps in my house. But we're very good at curing that. What you see is that the rewards for passing a particular mouse onto these very tight gates actually have no relationship to the reality of clinical medicine and that some of the commercial gates often have no relationship to the reality of medicine either. So, the example that I have is I worked for a large company, Pfizer, and we developed a version of insulin that could be inhaled. It was a product called Exubera and we were exuberant about the product. People who were afraid of needles would be able to inhale insulin. So, the product was put out and we had spoken to every KOL in the area and they said, "Altogether about a quarter of my patients are needle-averse. They're really afraid of needles and they don't want to inject." So, the marketing people come in, predicted a billion-dollar market. Within the first week, and I don't know if you remember this, there were five arrests for people at airports because it turned out that the inhalation device looked a lot like a bong. And so, people were being arrested left and right. The product did $25 million in its first year. We had not really talked to patients or talked to the patients about their experience. Patients were okay with self-injecting even if they were needle-averse because establishing a protocol for a diabetic patient that works for them takes a while. And now taking that away from them and then reestablishing with completely different dosing and a different way of administering was so disruptive that even patients who were needle-averse weren't actually ready to go and switch. But when we talked to their physicians, the physicians said, "Oh yeah, they're going to love this. They're going to get this done." So, it's really hard to often understand what the ultimate pressures are in a marketplace.

Howard: Is there any way to predict this?

David: Well, actually, talking to patients turns out to be incredibly important. And I think, and I'm doing startups, that you need to do it when you start. So we are, and I'm starting a company right now, and one of the areas of focus is a set of diseases called inborn errors of metabolism. These are very rare, found in children when they're born, and they can't metabolize something specific. And we are now reaching out to patient advocacy organizations, talking to parents to understand the realities of the lives of the parents and of their children.

Michael: Again, the primary reason drugs fail is the models don't predict the human outcome. And some of that is trial design, but the majority of it is the model design. So, what you do see now, and there's the commercial for the Allen Institute. What we have done is created human-based cell lines that are perfect models. Our goal is to push—and we're giving them away, they're completely free to the research community. And the idea is to begin to base models, not a HeLa cell from some person 10 years ago or a mouse model or a monkey model, non-human primate. But actual human cells. Growing up organoids that are biologically the same as the human experience in a kidney or a cardiomyocyte. And that will come, and that will give you a much better predictive outcome. How did the human disease model work? And that's coming in, and genomics are coming in, and epigenomics—and so you do see that coming in, but it's been amazing how long it's taken that to really come forward. And again, FORMA, their strains are set up on models that they like and trust and are invested in. So that conflict is coming or it's underway. And I think you'll get there, and you will have better data to make the decision, but will people decide? That's what we'll keep coming back to. Will you truly make the hard call?

UNDERSTANDING THE INDUSTRY'S 'FAST TO FAILURE' MENTALITY [20:00]

Howard: So, along those lines, everyone obviously wants to be part of a successful, blockbuster, drug development program, but not all drugs are going to be there. And as we've been talking, not all of them are going to make it. And we're starting to hear the phrase fail fast or fast to failure more frequently these days as a means of partially recognizing that we don't have the models to predict, and we have to get into humans to see whether these products are really going to work or not. How can we as leaders of companies and thought leaders in the biotech and pharma industries, how can we help people understand this concept, and get to that failure point quicker to make the decision to cut the drug? Because if we can stop a drug earlier in development, we can save money, and the overall cost of the successful drugs that ultimately make it to market can be lower. So, thoughts, ideas, comments on how we might get to that fast to failure point sooner?

Paul: I think that you have to look at all of the different filters and be honest about it and have stopping rules. One of the things that to me has always been quite difficult especially when I started to work more on the reimbursement side, and the outcomes research side rather than the clinical development side is just as you're saying: the clinical development folks are rewarded or you'll have an NDA filed at such and such a date. Many times, a number of the key pieces of evidence that we need to convince a payer to pay for the product at all or to pay for it at the price we want are substantial pieces of additional information that are well beyond what FDA requires. I get it. I fully understand that as you make clinical trials more complicated, first when you increase the risk,

you increase the time, you increase the cost. And so, there's often a tension between what R&D wants and really what you need to successfully commercialize the product. And that's often where I've seen problems is because a product would get through and then the NDA got in, the folks on the R&D side are rewarded, but then the commercial folks are left, I don't have something that I can really carry forward. And that's often an area where I see that part of it is, especially in larger companies, is due to these almost institutional structures that are set up that really aren't getting to really what's beneficial, is having a product that's safe, and effective, and that we can sell in the marketplace, and we can sell in the marketplace isn't an afterthought.

David: That's the piece that people most frequently neglect. Is that can we sell this product in the marketplace. So, I think the key is to figure out a way to change the mentality of company managements to perhaps change the way scientists and positions are rewarded in the development cycle. But how do we do that?

Paul: I think some of it is, it's like I said, you really have to think through and set up, and they're not necessarily complicated. But what are all the filters, what are the risks for those filters, what are the outcomes that you need to see, what are the dollars that you are going to need to get against that? One of the areas that I struggle with in my work often is the companies have spent the dollars in order to secure the IP. They've spent the dollars to secure on the R&D side, they haven't spent the dollars on the reimbursement side. And then they'll assume that somehow magically that if you are just a really good salesperson, you'll be able to get this through. In today's environment with managed care, with Medicare and other payers really being very smart in a lot of these areas. You can't snow them you need the evidence. I just went with a company to talk to Medicare recently and the R&D folks said to me, "This is all you're going to have." And I said to them, "Medicare's been really clear this is what they want to see. We have other products in kind of similar situation. They are clear on what they want. I'll go in. I'll do the best job I can, but they know that I know what they're asking for." And the answer comes back, "Well, we just didn't fund the studies for this." "Well then, don't expect that the product's going to do that well." And that to me, again, gets back to what the board is told, what the funders are told is actually necessary to get the product through and if you haven't thought of each of these potential issues whether—like I said, one product that I worked on a number of years ago, it died not because it wasn't effective but it was very clear that the cost of goods structure was going to be too high to then have a product that could work. Another turned out it was going to be b.i.d. dosing. We already had enough once-a-day dosing products. So, you really have to be honest with all of these different factors, have rules, understand what you're going to need in order to make those decisions but also understand what you're going to need to fund.

David: It's like for example the pricing structure for curative therapies like gene therapies. This is a huge issue right now because we can see we change people's lives but if we don't know how it can result in a growing company.

WHAT TO CONSIDER BEFORE FLIPPING THE KILL SWITCH [25:27]

Howard: Yeah, okay. Let's move on a little bit and switch tacts a little and talk about what happens once we actually do make a decision to kill a program, stop the development of a drug. You have a lot of people who invested a lot of time and emotion in that product. What strategies can companies use to redivert those resources to new programs and to motivate and incentivize people to really pick up the banner for a new product? And not be too demoralized by the failure.

David: I had an insight in terms of small-company life, or privately held company life, yesterday when I took a Lyft too—Uber, Lyft, it's a gig economy, and it's a gig economy for people who do small companies as well. So, if things don't work out, you're waiting for your next ride. And it's a high risk, high reward. It's probably better to be in biotech than to ride Ubers, but you get the parallels. And we've really changed from that model, from really playing resources internally, to a model where everybody is in a gig economy, including people like me.

Howard: And we touched a little bit about this already early on, but when we look at large companies versus small and the decisions and the impacts of decisions to fail or to stop a program are very different, can be very different in a large versus small organization. So, can you comment on what some of those impacts are and how companies can manage them?

Paul: I think one thing that I would say, I mean, my experience in a large company was in a global pharmaceutical company. And when you're making certain decisions, it's not always easy to translate to a foreign parent why you're making those decisions, especially if any of it is based on things that are unique to the American idiom. And so, some of those are really being able to explain and to translate and continue to explain. And a lot of that has to, again, come from upfront communication and agreement. "This is what we're looking for. This is what we're planning. These are our rules." Or they don't necessarily need to be that rigid. "But this is what we're looking for and this is how we're going to make our decisions. And are you buying off on that? Are you in agreement with it?" But it still can be quite difficult when especially you have different cultural philosophies about kind of working for companies, and where teams are, and what it means to be part of a particular group, and how easy it is to shift to another group.

Howard: Michael? Comments?

Michael: I think in the big companies, clearly, they have the opportunity to reassign and reallocate, and it's a mothership. I know it's still a lot of pain goes down if you're leading a program or your championing something and it doesn't work. It's not a career-ender, but it's definitely painful. And, those people have it a lot easier than your small team, private, where you turn to everyone and say, "Well, we're going in salary deferral." And they're like "What?" "So, we're going to defer our salaries by half for next year to stretch the cash because our investors have told us here's the milestone, the killer experiment." And that happens quite often. And you never really see pharma doing that. But that's the reality of the gig economy. And you have your big pile stock options, and those are interesting. But they're hard to pay. So, it's a fundamentally different effect, cause and effect. And again, in a small company, when you don't hit your number, it's basically you go out to dinner then you move on to the next one.

FROM 'FAST TO FAILURE' TO SUPPLEMENTAL SUCCESS [29:44]

Howard: Can you provide an example where you, either personally in your company or know of an example in another company, where a drug had to be killed but ultimately, there was a success that came out of that failure, whether it be repurposing the drug, or developing a new drug, or some other positive outcome of a failure?

Paul: One thing that I can say, and the example that I gave at the beginning which was the drugs for schizophrenia, because that program failed, it actually opened up a relook at some of the antidepressant products that were in the portfolio. And there had been some early work in obsessive-compulsive disorder with one of those products. There was nothing on the market for obsessive-compulsive disorder. And because there now were resources to allocate, there was a relook there and ultimately did carry forward the first product that was FDA-approved for obsessive-compulsive disorder, which was obviously a major need, and probably would not have dedicated those resources to that if the schizophrenia program had moved forward.

David: So, I've got one great example, as well. I actually was involved in a project for one of the large pharmas I worked for where the drug did the exact opposite of what it was supposed to do. It was supposed to lower the activity of a pro-enterogenic factor effect that made blood vessels and tumors. And what it did is it increased the vascularization of the tumor. The tumor brought in more blood. And I luckily had a really smart mathematician standing next to me, a biomathematician who said, "Well, of course, that's what we expect." And I won't bore you with the explanation, but [we] very quickly realized that this was a generalizable property, that if we modified molecules in a very specific way, instead of stopping something, we could actually increase it. And we've just started a company around this context. We're raising funds for it right now. I hope to close our first round of financing next week. So, that was a failure that led to a big insight, which is going to result into new medicines.

Michael: A trend has evolved over the last few years, so in the old days, it was 'think of an idea, form a company, fill out your org chart, raise some money, and go.' So, you had hundreds of companies, really skinny skillsets, a great idea, but really not the right tiger team, right? So, what really has evolved is virtual companies. And I don't mean you don't do any work. You virtually, you work hard in a virtual company. You don't hire a bunch of consultants. You outsource things, but you tell them what to do. Because your brain trusts that you recruit. So, this virtual company of really smart people who are really experienced, have been through the wars, they're on your tiger team, everything is outsourced. And then most importantly, it's also what they call a 'build-to-buy.' So, you've already got a pharma-acquirer. You've already been through their screen. They're the ones setting your goals and objectives. They say, "You've got the right people. You've got a great idea. Here's your two-year flight path. And if you do it, we'll take an option." So, the build-to-buy virtual company model has evolved rapidly and it's really the only way to go because you don't have the $5 million-a-month overhead. Okay? You're not building, you mentioned $150 a square foot for space and manufacturing and 40 people on staff. You have a virtual company in a build-to-buy. Those can survive failure because you demonstrate, you have the right team, you're capital-efficient, you've hit your marks, and oftentimes that pharma company or that investor group will give you a second chance because you've executed properly. If you've just fluffed it then pull the plug. But those do work, and I think you'll see more of them. And it makes a lot of sense. Tighter screens, the right team, and very clear objectives, and funded properly. And if you win, you win. If you lose, it's biology.

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CONTACT:

HOWARD L. LEVINE, PH.D.
Senior Managing Director, BDO's BioProcess Technology Group
617-697-4033 / hlevine@bdo.com

LANCE MINOR
Principal and National Leader, BDO's BioProcess Technology Group
301-354-0711 / lminor@bdo.com

ERIC JIA-SOBOTA
Life Sciences and National Industry Specialty Services Practice Leader
703-770-6395 / esobota@bdo.com

TODD BERRY
Assurance Partner and Life Sciences Practice Leader
617-239-4125 / tberry@bdo.com

JEFFREY KEENE
Assurance Partner
212-885-8257 / jkeene@bdo.com

JAMIE MASON
Audit Office Managing Partner
858-431-3439 / jmason@bdo.com

STEVEN SHILL, CPA
National Leader, Assurance Partner and BDO Board of Directors Member
714-668-7370 / sshill@bdo.com

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