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Now Biopharma
A Catalyst for Successful Drug Development Programs

Q&A with Richard Prince, Ph.D., President and CEO of Now Biopharma, LLC, a boutique Clinical CRO and Product Development Consultancy in the Life Science Space

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CEOCFO: ***Dr. Prince, your tagline is "A Catalyst for Successful Drug Development Programs." How does Now Biopharma fit that bill?***

Dr. Prince: Now Biopharma serves as a catalytic agent for clients, especially small to midsize companies, due to our corporate personality and how we are structured. We don't like to waste time and we value yours! We facilitate useful outcomes and quickly cut through unrealistic or faulty assumptions, often on behalf of entrepreneurs with sterling scientific credentials but who have not yet commercially launched a new company in the life science space. We also don't like to waste clients' money, especially knowing the competitive landscape for new companies and how hard it is to access and to bank capital. As a consequence, we deploy a virtual business model that utilizes a pool of highly qualified, retained consultants to provide *ad hoc* support in product development programs as well as a US-based clinical CRO that relies on an experienced, nationwide team of clinical and regulatory professionals to run clinical trials. Catalysis is also a byproduct of the fact that we possess hands-on, horizontal (cross-functional) experience in industry and in medicine (e.g., service and product firms; small and large molecule programs; consulting, entrepreneurial, corporate environments; multi-disciplinary leadership roles). We de-risk programs by emphasizing the need to thoroughly understand the science behind the invention and its purported attributes (often a fatal mistake made by entrepreneurs in a rush to show progress to investors) as well as to engage upfront with the regulatory authority to discern in written form what is likely to be deemed an appropriate clinical development program that, upon its complete execution, will lead to an actionable, binary result from a regulatory authority standpoint. We counsel companies that the best way to save money (in the long run) is to actually be prepared to spend it, albeit wisely. We also tell companies that if they want to go fast, actually slow down (at least initially) and verify your assumptions. Some of this may sound counterintuitive and, in fact, it is. But, it represents wisdom that too few will learn during their schooling or in their careers. For us, this

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represents business catalysis on the anticipated road to commercialization. It's not my line but I think it says it all. Question: What's the definition of a drug? Answer: A piece of paper handed to you by a regulatory authority. Everything else is commentary.

CEOCFO: ***Would you give us an example of what you are asked to do with a company and how you crafted an approach and the end result?***

Dr. Prince: The very first question we ask when reviewing or contemplating a new product candidate is: "Does the intellectual property support the intended product label?" Most start-up programs, however, don't begin here, but derive from what is a seemingly "good idea" in treating a disease or condition often, but not always based upon some suggestive data. The data may be perfectly reasonable in supporting a publication and supportive of a research grant, but while there's scientific rationale, there may be insufficient consideration of the key factors influencing the marketplace and justification for embarking on the path towards commercialization. Pursuit of the scientific method is not an excuse for sloppy, incomplete planning. A thorough understanding of the marketplace should be explored - including competition, (other products in development), ideal approaches appropriate or logical in treating certain patient populations including cultural idiosyncrasies, reimbursement and pricing sensitivity, IP infringement and freedom to operate, regulatory strategy, marketing, sales, distribution, finance and budget and cost to achieve approval and product launch.

My experience is that entrepreneurs - individuals that are inventors, scientists and/or founders - are brilliant in their respective areas of expertise but may not necessarily know all of the ins and outs and the art of becoming a successful scientific entrepreneur. We try to help them understand the process and the vagaries upfront, and then to shepherd the development and implementation of a clinical development plan. The last thing a company wants to do is that once they are capitalized (initially and then subsequently) -no easy task - is to squander the money because of faulty or unrealistic assumptions about their management team, the product candidate, the competitive space, the regulatory landscape, and/or the relative prospects for successful market acceptance and, ultimately, corporate profitability. Drug programs often routinely cost tens to hundreds of millions of dollars, and that money (which is finite) must be safeguarded.

CEOCFO: ***How do you work with a founder, with the scientist who has created something and cannot give up control of any aspect of it, I and is resistant to having someone tell them a direction they might take?***

Dr. Prince: Inventor-scientists are without exception brilliant. They can also be stubborn. That trait of stubbornness is actually a virtue as inventors routinely smash accepted dogma while establishing new frontiers of thought and practice. It can become a detriment, however, when one believes that they have a (reasonably) complete command of how to create a successful commercial entity. These are entirely different animals.

It is human nature because precisely the confidence that they have in their specialty of science, and which makes them truly great in that area,

can turn into hubris and become a weakness from the standpoint of the fundamental goal, which is to create a successful business featuring a product(s) that improves healthcare outcomes in some way. So few of us are innately able to develop a unified field approach for taking a basic idea and turning it into a successful business enterprise. Another important part of the equation is whether the founder actively seeks countervailing advice. In my experience, the founder will listen and take independent advice if you can substantiate your position with empirical data or some other form of evidence that illustrates your credibility.

I am currently co-editing a biotechnology textbook with two colleagues from Harvard (Dr. Fred Mermelstein; Dr. Carl Novina) that will be published later this year. It will be a practicum on how to establish a company, how to finance it, how to operationalize it, and how to commercialize it. It is intended for students, scientist-inventors, entrepreneurs and seasoned industry veterans who would like to do something different, or bigger, and who have a need or desire to learn content in other functional areas. What the book will do is what we do at Now Biopharma, namely, to partner with scientific leaders and entrepreneurs to facilitate the timely execution of rationally crafted clinical development programs by inserting our resources and capabilities across the development continuum on behalf of these companies. If someone is unwilling to receive and/or accept this type of feedback, that of course is their prerogative.

CEOCFO: ***How do you vet the science, or is it a given that when someone comes to you, they have something valuable?***

Dr. Prince: We are service providers, so our obligation is to provide the relevant services. When a company comes to us and says they need help, we are very likely going to work with them. We don't vet or judge the value of the science per se. Instead, we work with the client to scientifically adduce the native value of the scientific invention (or asset) by deploying a smart product development program. We want to make sure that we provide, in essence, a safe harbor for the company so that through our efforts, in part, the intrinsic value of the asset will be identified, understood, confirmed, approved and ultimately monetized. That journey flows through a highway called 'process'.

Our obligation is also to make sure we understand the science being presented to us so that we can credibly represent it to regulatory authorities or other third parties that have a need to work with us to support the client project (e.g., how to characterize it, how to manufacture it, how to test it, how to store it). One of the exciting things about the business that we are in is the range and variety of innovation coming out of my home state (New Jersey), Boston, California and beyond, in which we get to work with brilliant people in so many different areas such as stem cell regeneration, proteomics, epigenetics, tropical disease. We want to do everything we can to help get the idea to market. If that novel idea is not well thought through from a product development planning perspective, then its conversion into that coveted "piece of paper" received from the regulatory authority becomes problematic and, potentially, unattainable.

CEOCFO: ***Would you tell us about how Now Biopharma is structured?***

Dr. Prince: Now Biopharma is partitioned as follows:

- A US-based Clinical CRO, which is led by Dr. Frank Peacock (Houston, TX, USA). The CRO is a virtual model by design, not bricks and mortar. This allows us to save clients millions of dollars when executing multi-year clinical programs because we do not have appreciable sunk, infrastructure costs compared to competitors, with no diminution in the quality of the generated clinical information.

- A US-based product development consultancy with some 75 consultants that are deployed to support various client needs (e.g., manufacturing, validation, quality, regulatory, medical writing).

- Now Biopharma works closely with *Pollination Ventures Management*, a company that evaluates and advises promising new life science startups on corporate structures and development.

A final thought if I might. Our credo is: *Safeguarding Money and Lives*. We believe companies want to work with companies that provide business value and that also give back to society. We do our part through social justice initiatives and by teaching scientific entrepreneurship to the societally disadvantaged and then connecting these individuals to prospective employers willing to give them an opportunity to succeed in the workplace.

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