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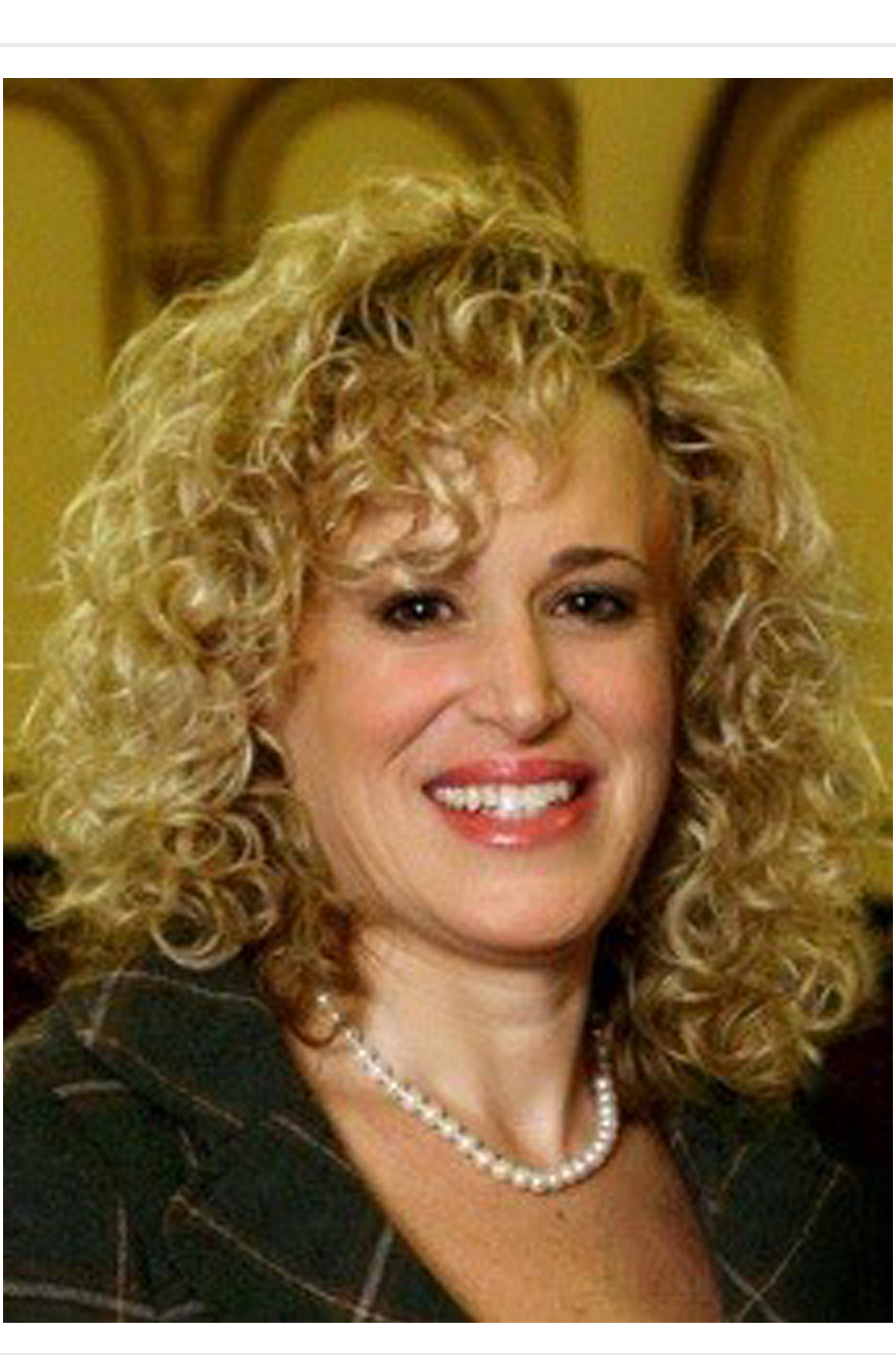

An Interview with Adriann Sax, Biotech Executive & Entrepreneur

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This week, Jason Colodne, Managing Partner at Colbeck, spoke with Adriann Sax, co-founder and CEO at Vetigenics, a prominent innovator in animal health that is one of the first companies to produce antibody-based immunotherapies for canines. She formerly served as CEO of Orsenix, a clinical stage biotech company focused on developing novel therapies to treat hematologic cancers.

With nearly three decades of pharmaceutical and biotech experience, Sax has overseen the global launch of leading oncology and immunotherapy drugs. She has held executive roles at Roche, BMS, Merck, King Pharmaceuticals, and Kadmon, and is continuously recognized for her commitment to the advancement and professional development of women within the pharmaceutical industry. Sax is a passionate advocate of the One Health movement, and believes it is our best hope for tackling animal and human disease challenges of the future.

Human and Animal Health are Converging

Colodne: Early on in your career, you started out with a background in animal science. How did you transition into pharmaceuticals?

Sax: I wanted to be a veterinarian since I was very young. I worked for a veterinarian starting at the age of twelve just cleaning out cages and doing all the grunt work. I really developed a passion for health, and animal health in particular, and so I went to undergrad for animal science with the hopes of going to vet school.

At the time, there were only 9 vet schools in the US and female vets from out of state were not a high priority, so it was difficult to get in. Instead, I pursued a job in veterinary pharmaceuticals and that's where I got a better understanding of the pharmaceutical industry and how drugs to treat animal diseases are developed. While in this job, I met a human pharmaceutical sales rep, and realized that there were tremendous opportunities on the human side of the business. As much as I enjoyed animal health, pharma was appealing because it seemed like I could really help people by treating disease.

I touched on most aspects of large pharma—sales, marketing, business development—before moving into startup biotech. I transitioned into biotech when the first antibodies to treat cancer hit the market and the science of antibody therapeutics was exciting to me. I also wanted to have more direct influence and hands-on experience with building companies and influencing the development path and commercialization of drugs. My primary expertise was in cancer, but I worked in other specialty therapeutic areas as well, predominantly with antibody therapeutics.

Over a year ago, I was recruited to transition Vetigenics from an academic startup to an independent animal health biotech. It was a wonderful full circle moment, because I could bring what I've learned in biotech to benefit pets suffering from cancer and other chronic diseases with very few treatment options.

Colodne: How has the distinction between human health and animal health changed over the course of your career?

Sax: Historically, most of the drugs that have been used to treat animals—with the exception of things like flea and tick treatments—were really repurposed drugs or generic drugs used in human medicine, and then used to treat those same diseases in animals. Now companies are much more focused on developing species-specific drugs. These drugs are clinically tested in the intended animal species with disease to ensure meaningful efficacy and safety of the drug for the animal patient. These drugs are specifically developed to address the individual needs of animals based on their underlying disease mechanisms versus trying to take human medicines and repurpose them.

Vetigenics actually started out as an initiative to develop fully canine antibody drugs for translational research using pet dogs with cancer as pre-clinical models of cancer. Humans and dogs have lived and evolved together over thousands of years with the same environmental exposures and genetic susceptibilities. So, it is not surprising that canine cancers occur spontaneously with similar presentation, molecular makeup, pathophysiology and natural progression of human cancers. By using pet dogs as parallel patient populations to accelerate human cancer drug development, we can reduce the high failure of drugs that may show efficacy when tested in a mouse but fail when tested in humans.

Vetigenics works very closely with the National Cancer Institute to ensure canine antibodies are available to advance human translational research. At the same time, we further develop these same antibodies as animal therapeutics to treat cancer and other chronic conditions. Thanks to the pandemic, the whole pet industry has seen a huge boost, so the timing is really optimal right now to introduce these types of therapies because the market is primed to consider them and to pay for them.

Is Pharma R&D in Decline?

Colodne: Since the 1990s, the return on investment in pharma R&D has steadily fallen, leading many to predict the industry's "terminal decline." Despite this, the past decade has seen a number of record-breaking years in terms of new drug approvals. Last year, the FDA approved 53 novel drugs. How are companies remaining productive?

Sax: I think that pharma is just as productive, but there is a change strategically. At one time there was a holistic focus on treating chronic diseases with millions of patients such as hypertension, diabetes and high cholesterol. These drugs enabled patients to live long, productive lives with chronic disease, but they were disease specific, not patient specific. There were a lot of "me too" drugs, or similar molecules offering incremental benefit compared to the innovator drug. Payers no longer reimburse patients for new drugs with minimal benefit when a cheaper generic alternative is available which can get the job done safely and effectively for MOST patients.

Now, pharma is really focused on meaningful innovation and patient-targeted therapies where new treatments cure disease, extend survival, substantially improve treatment outcomes, and reduce overall cost to the healthcare system. Although these innovations may treat smaller groups of patients, their impact is significant and pharmaceutical companies can recoup their investment in risk, time, and cost with higher prices. Payers have had the greatest effect on biopharma innovation. Despite the transformational role pharma and biotech have played on changing the course of lethal and rare disease, payers still make it exceedingly difficult for patients to receive these novel therapies and create obstacles for physicians to prescribe them. Payers have evolved to control drug pricing, making it much more difficult for pharmaceutical companies to bring to innovative products to market.

The decline in productivity is still high, but much of it occurs in early translation from animals to humans. There is a lot of work being done to validate the right target, to understand underlying disease mechanisms, and to select clinically relevant animal models of disease that can more accurately predict how different patients will respond to treatment. Identifying specific biomarkers of disease and response to treatment has also helped improve the productivity and cost of drug development, but for some disease areas the process is still very time consuming and costly.

The Growing Power of Insurers

Colodne: The price of drugs has attracted increasing scrutiny in recent years. Last month, as part of a Congressional investigation into the pricing practices of twelve pharmaceutical companies, Representative Katie Porter questioned the CEO of AbbVie for its pricing of Humira, the most expensive biologics drug on the market.

"The Big Pharma fairy tale," Porter said, "is one of groundbreaking R&D that justifies astronomical prices." How do pharmaceutical companies respond to claims of price gauging?

Sax: This is where I will stand on my soapbox for a minute because I get so angry when I hear about the rising cost of drugs. It is prevalent, and the media has made heyday out of it. But nobody has discussed the impact of insurance companies and pharmacy benefit managers (PBMs) on drug pricing.

Let's take Humira. The drug started development in 1991 and was approved in 2002 for indication in RA (rheumatoid arthritis). It took the company eleven years and millions of dollars to bring the drug to market. It was one of the first biologics of its type, so there was a lot of technical complexity in the manufacturing of the new biologic drug. Since then, AbbVie has gotten the drug approved for thirteen additional indications, three of which are pediatric specific. It has conducted over one hundred clinical trials all over the world, treating over a million patients. They even improved the drug formulation based on patient feedback. Patients experienced some burning on administration, so they spent the time and money to develop citrate free, less burning formulation.

AbbVie's been so responsive to the needs of the market, and it is expensive to show such dexterity. They should get some return on that investment. I mean, they have invested billions of dollars into that drug, billions.

Now, Humira's a specialty drug. It has to be distributed through specialty pharma most of the time. They have a list price for it. AbbVie has to pay fees to specialty pharma for the distribution of their drug, and then pharmacy benefit managers (PMBs) and insurance companies take their piece, and at the end of the day, those costs can be up to 30% off "the list price" before it gets to the consumer.

What people should focus on is the net price, not the list price, because consumers need to understand what happens from the time a pharmaceutical company sets a price for a drug, and all the people it has to pay along the way before it gets to the patient. Most of those rebates and fees go directly to insurers and PBM's—none of those offset the price to the patient. It just escapes me that nobody has really looked into the control, influence, and profits of third-party payers. Sadly, the government is one of the worst offenders due primarily to the inefficiencies in the system.

Colodne: What are some of the biggest changes in the industry you've encountered over the course of your career?

Sax: One of the major flaws in the system today is that insurance companies dictate what treatment a patient should get. When I first started, health care providers—physicians, nurses, and medically trained personnel—made the treatment decisions. Now you have companies, bureaucrats, and people with no medical training telling doctors which drug to use.

It's hard for doctors to take full advantage of the latest trends, medications, and procedures because insurers and PBMs wield incredible influence. A doctor might want to try a more suitable therapy, but they can't because an insurance company dictates a different drug they should use or a PBM prefers the patient be given a generic. A lot of this is caused by the proliferation of generic drugs, which are driven by managing and reducing drug cost. Instead of allowing doctors to choose the best drug to treat disease for a particular patient, insurers demand and only pay for what drug is best for managing costs.

Colodne: Do you anticipate governmental regulation of drug prices?

Sax: It's coming. It's very scary and unfortunate because it's going to negatively impact innovation and severely limit drug access for patients.

You know, nobody's out there right now—in the news or on social media like Twitter or Facebook —thanking the incredible work of those biopharma companies who delivered a COVID-19 vaccine in record time. They not only discovered the underlying mechanism of SARs Cov2 and created a vaccine, but they tested it in animals and patients for efficacy and safety, manufactured it to the highest quality standards, and distributed it to patients globally for a nominal cost—all in record time.

But those kudos never really happened in a big way, and with the government controlling innovation and access, situations like that are going to be much more difficult in accomplish.

Advances in Understanding Disease

Colodne: Besides the production of COVID-19 vaccines, what do you consider to be pharma's biggest accomplishment in the last few decades?

Sax: There are so many. I don't know any other industry that has had the same impact on human and animal health as the pharmaceutical and biotech industry.

We can treat severe infection. People with HIV are living long, healthy lives with undetectable disease. We have a cure for hepatitis C. We have changed how cancer is treated, and people with deadly cancers are living longer, quality lives. New therapies for treating cancer are much more targeted, they're less toxic, and they use the patient's own immune system to help defeat the disease, which has been one of the greatest accomplishments in our time.

The fact that we're able to transplant all different kinds of organs into people, and they can survive with those organs for extended periods of time, is nothing short of a miracle. We are also able to treat smaller populations of people that have all kinds of rare diseases, especially children. We are able to cure these diseases and help them live normal quality lives.

Colodne: The FDA has had a number of record-breaking approval years, especially in terms of orphan drugs that might never have come to market. What's causing this?

Sax: Since the human genome decoding in 2003, our understanding of disease and the underlying biology and causes of disease has allowed us to go after targets more intelligently. We now have the benefit of automation to screen thousands and thousands of drugs against those targets that could potentially influence them.

The FDA has also worked with pharma and biotech to really give them a bit more flexibility in developing these drugs in smaller patient groups. They've expedited the approval process significantly: it doesn't take thirteen plus years anymore for an orphan disease. That's a wonderful example of a partnership between government and industry working in tandem to really focus on combatting rare disease.

The government, foundations, and advocacy groups have also helped to secure funding to develop some of these orphan drugs. This has been critically important for pharmaceutical companies because it can be very challenging to conduct these trials when the patient populations are small, but the costs are very high.

New Areas for Growth & Cross-Fertilization

Colodne: Which subsectors of therapeutics are most primed for growth?

Sax: The aging population and its accompanying diseases are ripe for innovation. The greatest number of new drugs in development is in oncology and neurology. There are diseases in both categories that we've made a tremendous impact on. Just last week the FDA approved Biogen's Aduhelm, the first new treatment for Alzheimer's in nearly two decades.

I think we're going to see more examples of focused, hyper-targeted drug development going forward. In the past, we looked at broad categories of disease. Now, our enhanced understanding of disease, patients, and the journey they go through after diagnosis allows for more focused innovation at different points of disease progression.

Colodne: Are there any market or regulatory changes investors should be attuned to in the near future?

Sax: Investors should look very closely at the growing interest in the concept of "One Health." There is a convergence of worlds occurring, with pathogens, vectors, animals, and plants moving across the planet at unprecedented speed. The interface between human health, animal health, and environmental health is collapsing.

In recent years, 70% of new emerging diseases have come from animal reservoirs… West Nile. SARS. Zika. How can we silo the two any longer? Animals and humans can learn tremendously from each other, and I think a more integrated approach to dealing with disease challenges will be a real driving factor behind efficient drug development of the future.

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