Elie Dolgin

Straight talk with... Donna Ambrosino

In the 1890s, a diphtheria epidemic was killing thousands of children across the US, prompting many state health departments to create laboratories to start extracting antiserum from horses' blood. More than a century later, however, only one of these public labs is still in operation: the Massachusetts Biologic Laboratories, known simply as MassBiologics. Established in 1894 as the Massachusetts Public Health Laboratories, it is now the only nonprofit, licensed vaccine and biologics manufacturer and research center in the country—which gives the lab a unique position to tackle diseases that 'big pharma' isn't willing to touch. Leading the charge is Executive Director Donna Ambrosino, who took the helm in 1998 after a 20-year career at the Dana Farber Cancer Institute in Boston. On a snowy day in January, **Elie Dolgin** sat down to chat with Ambrosino at MassBiologics's brand new research center, opened last summer in the outskirts of Boston.

What's the role of MassBiologics compared to traditional drug companies?

Our research now is focused on monoclonal antibodies, but we're picking primarily the infectious disease targets—the unmet medical needs—because although these aren't as big a market they still represent a significant public health need. That's our role: to take the technology, take the great science and target it to diseases and markets that matter but maybe aren't large enough for the other companies in this field to have interest in.

Can you give an example of MassBiologics stepping up when private companies didn't?

Our involvement with the response to the 2003 SARS [severe acute respiratory syndrome] outbreak is a good example. After the agent was discovered, we had a monoclonal antibody to it and showed it worked in animals in less than a year. We spent our energy there to develop antibodies to get it ready, but the disease went away—thank heavens, we were totally pleased! However, now we've got an antibody if it ever returns.

Why has no other institution copied the MassBiologics model?

We're unique because of history, and I'm not sure that history can be copied. There's a history here of having licensed products, being a manufacturer, being a research facility and having funds from royalty streams. We can put all that together and then go after unmet medical needs. But to duplicate that in other places is hard because you'd have to start in the middle.

Why did you choose to leave an academic clinical position to lead MassBiologics?

What appealed to me was the idea that one could marshal all the capabilities here for the full spectrum of product development, from basic discovery to clinical studies and hopefully on to approved medicines. I wanted to actually take ideas to a product and see it work in patients. We've done that here, and it's a thrill. Moreover, I wanted to do that for unmet medical needs, and that's the unique part here. We're able to choose targets that are important to public health, both here in the United States and in the developing world that might not have enough market to interest big pharma or biotech to actually develop those products. And that's what's unique about having the public nonprofit entity doing this.

More than a century after its inception, is MassBiologics still funded by the state?

We're self-funded. We have two general sources of revenue: manufacturing, which is selling tetanus diphtheria vaccine, and royalty income from past inventions. There's a product called Cytogam [licensed to CSL Behring], which is an immune globulin isolated from human blood product against cytomegalovirus, an infection associated with disease in organ transplants. And there's a newer product called Synagis [manufactured by AstraZeneca's MedImmune], which is a monoclonal antibody to protect babies from respiratory syncytial virus. A newer royalty stream is our experimental *Clostridium difficile* product [licensed to Merck].

In 1997, MassBiologics was transferred from the state health department to the University of Massachusetts Medical School. What impact has this transition made?

It's been an important and positive step for the lab. Product development and thinking about how you partner with other collaborators is not what a public health department does. But it is what a medical school can do—and they've got great scientists we now collaborate with and an infrastructure that allowed us to take what was a very successful model and move it forward to the new era. It's allowed us to build these new facilities, make discoveries, have an intellectual property system where we patent our discoveries, and then collaborate with both public entities and pharma. That structure allowed the operation to grow from around 100 employees then to 300 or so now. It also gives the medical school students opportunities to train here at the lab and participate in the development of our clinical trials.

Do you have a favorite project that has developed under your watch?

I don't think it's wise to have pet projects, but my heart is in the rabies trial we are working on in collaboration with the Serum Institute of India. The most impact we'll have, I believe, is for this monoclonal antibody against the rabies virus to be available to the world—and that wouldn't be available if it hadn't been for us. We're just about to submit the trial to the regulatory agencies in India, and we're hopeful that, because there are hundreds of patients that can be enrolled once it starts, it shouldn't take many months to complete. Our expectation is that we'll have licensure in 2012. And if it's licensed and sold, then it can also become available to other countries.