

Gary D. Novack, PhD

The Ocular Surface's "Pipeline" editor, Gary Novack, is a highly respected clinical pharmacologist and an expert in clinical trial design and analysis. He has been a key figure in the development of numerous topical ocular medications, including drugs for dry eye disease, ocular allergy, and ocular inflammation. Formerly a research scientist at several pharmaceutical companies, Dr. Novack is now a sought-after consultant, valued for his ability to create a pathway from preclinical findings to an approved product.

In addition to his active role in drug development, Dr. Novack is a frequent author of scientific publications; a peer reviewer for more than 15 ophthalmology journals; and he serves on the editorial boards of both ophthalmology and pharmacology journals.

THE OCULAR SURFACE *What were your circumstances growing up?*

GARY NOVACK I grew up in Northern California, and my parents were the children of immigrants and both the first in their families to go to University. Education opened doors for my parents, who subsequently placed a great deal of emphasis on both academic achievement and acting in an ethical manner.

TOS *Why did you decide to pursue your PhD in pharmacology and environmental toxicology? What were you planning when you decided to go in that direction?*

NOVACK From the time I was an adolescent I knew that I wanted to be a scientist, although I wasn't sure what kind. Then, while an undergraduate at the University of California (UC), Santa Cruz, I took a class in pharma-

cology. Pharmacology is not normally taught at an undergraduate level, nor is it often taught at nonmedical campuses, so this was a rather unusual class—a pilot class, actually—taught by Robert Featherstone from UC, San Francisco. What I learned about pharmacology from Dr. Featherstone had a huge impact on me. And not just me—from a single class of about 40 students, at least five went on to become pharmacologists.

Later, in my PhD program, I focused on neuropharmacology and agents that affect the brain. It was while I was in graduate school that I decided to pursue a career in the pharmaceutical industry, working to develop new compounds.

TOS *How did you first become involved in ophthalmology? What work did you do at the outset?*

NOVACK I began working at Merrell Dow Pharmaceuticals Inc. in Cincinnati and stayed there from 1979 to 1982, before beginning to look for a new position with greater challenges—and a California location. The opportunity arose to join the clinical research team at Allergan in Irvine, CA, where I was hired to work on glaucoma medications. At the time, this meant studying drugs that affected the autonomic nervous system, and my neuropharmacology background came in very handy for working on beta blockers and alpha agonists.

TOS *What people and events were most influential in setting the course of your work?*

NOVACK My undergraduate and graduate professors, both in the sciences



and other areas, influenced me greatly. Although not a scientist, Victor Perera, who taught an undergraduate fiction class, changed my life, teaching me to appreciate the power and the beauty of words. Physicists David Dorfan, Barry

Lieberman, and Bud Bridges taught me the scientific method, thereby laying the foundation for my future career.

In graduate school, my advisor, Larry Stark, and Professor Wally Winters, directed me in my pharmacology studies and gave my work its first direction. Later, Jim McGaugh, a faculty member at UC, Irvine, was a mentor and role model to me. John Urquhart also helped me greatly in the process, teaching me about compliance and how patients use drugs, as well as many other areas.

Within ophthalmology, I had the opportunity to work with Irving Leopold, who was at the time a science officer at Allergan. His perspective, derived from decades of work in ocular pharmacology, was invaluable, as were the many introductions he made, such as to Frank Newell, who was then (as he had been for decades) editor of the *American Journal of Ophthalmology*. Working with Dr. Leopold gave me a perspective that I would not otherwise have had as a junior scientist entering a new field.

TOS *Please describe some of your work relating to clinical trial design and analysis and the development of topical medications.*

NOVACK In any endeavor, I believe that there is format and content. With

respect to format, when I started out in the 1980s, double-masked studies were somewhat new to ophthalmology. There were plenty of observational studies but few ophthalmologists were conducting well-designed masked, prospective, randomized, controlled clinical trials, so I made it my business to learn as much as I could about clinical trial design, and I worked to apply this knowledge to drug testing in ophthalmology.

In the 1980s, I had challenges getting a study I organized on switching glaucoma therapies published. Twenty years later, though, as people started thinking about compliance and its impact on outcomes, study design arose again as an issue and some of those articles had a bit of a renaissance.

In terms of content, part of pharmacology is therapeutics, the goal of which is to be able to treat patients with the best possible treatments. I wanted to work in industry because I felt that was where I could make the biggest difference. I am not a physician and I do not treat patients, but I thought that if I could get new therapeutics to market, I would be doing my part to turn science into something beneficial to humanity.

Of course, it takes an enormous effort to get a new agent to market. No one can do it alone, but I have been fortunate to play a role in bringing a number of products—for both the ocular surface and other tissues and organs—to market over the years.

TOS *In 1989 you founded Pharma•Logic Development Inc. Why did you start the company and what are the primary services it offers?*

NOVACK After a number of years of working for large and small companies, I was seeking another position. But in talking to my colleagues, who said, in effect, “You’ll never find the perfect job; you have to create it,” I thought to start my own company with my wife. I wrote my first business plan and decided to give it a try for 6 months. That was 20 years ago, so the idea appears to have worked.

Pharma•Logic offers services in

the broad area of drug and medical device development. We work with companies who have early stage data showing that a certain molecule may treat some preclinical model of eye disease. We also do preclinical development and follow the drug or device through the steps that eventually lead to human trials and to the final development and approval process.

TOS *What do you enjoy most about being a pharmacologist and medical writer? What are the biggest challenges in these roles?*

NOVACK As a pharmacologist and medical writer, I am constantly exposed to new ideas, and I work with a wide range of fascinating people, from talented young scientists to renowned experts in the field. I enjoy working with these people and creating relationships that last long after the project is finished.

I also enjoy the process of taking data and turning it into information. A typical phase II clinical study can produce thousands of pages of listings and raw data; part of my job as a medical writer is to accurately condense those thousands of pages into a 50- to 100-page report. Sometimes, I then take those 50 to 100 pages and turn them into a four- or five-page manuscript for a peer reviewed journal.

For me as a consultant, the biggest challenge is my lack of positional power within the client organization. If, for instance, I believe that an additional study is needed to support the information gathered so far, I have neither the authority nor the funds to order the study. I can only recommend it.

TOS *What do you consider your greatest professional achievements?*

NOVACK I am proud of the new therapeutics that I have helped get into the marketplace. I am also pleased with my publication record. Although not an academic, I have been successful in getting a lot of papers published, including some key reviews. Obviously my relationship with *The Ocular Surface* is a source of pride. I felt hon-

ored when Michael Lemp called at the founding of the publication and asked me to be involved as a section editor.

I am also, of course, proud that I help my clients to be successful by bringing revenue generating products to market, which then serve to provide funding for the development of new and even better products.

TOS *What did it mean to you to receive the American Academy of Ophthalmology Achievement Award in 2007?*

NOVACK It has always been interesting being a pharmacologist among ophthalmologists. It took a lot of time and listening to understand the field from their perspective. So it was a very pleasant surprise to have the AAO recognize my contributions to their annual meetings and journals.

TOS *As a very active UC graduate, what have your roles as alumni Regent, UC, Santa Cruz Alumni Association Council president, and, most recently, president of the UC, Santa Cruz Foundation meant to you?*

NOVACK While I grew up, my father served on multiple boards and my parents did considerable volunteer work. I recognize that there are many things in the world that would not happen without volunteers—from youth sports leagues, to Boy Scouts, to our professional societies. So volunteering is an important part of my life, a way for me to pay back the people who gave me opportunities.

With respect to UC, my family has benefited greatly from the state of California investing in a public university. My great-grandmother was illiterate; now I have a PhD and at one point, I sat on the UC Board of Regents. Many of the opportunities that I have enjoyed are due to there being a high-quality public university available to my parents and myself. Today, public higher education is threatened by budget cuts and political pressures, so I do what I can to be an advocate for the university. As president of the UCSC Foundation, I am working to get private support for a public uni-

versity that has lost a significant part of its state support.

TOS *When you are not working, what do you enjoy doing?*

NOVACK I love to bicycle, read nonscientific books, and backpack. Being in Northern California, my family is fortunate to be near the beautiful and steep Sierra mountains. I usually take a backpacking trip every summer, where I can really disconnect from the pressures of daily life.

TOS *In your opinion, what are some of the most pressing questions researchers must answer to advance the study of the ocular surface?*

NOVACK A big question has to do with ocular surface disease (OSD) metrics. Unlike blood pressure, OSD can't be measured with a single instrument. Most of the tests we have provide variable results that don't correlate well with clinical signs and/or are highly operator-dependent. So we need to find better indicators of clinical disease.

Additionally, we need to create regulatory precedents so that we know what is required to get an ocular surface therapeutic approved. I think that involves taking scientific ideas and finding testable hypotheses. The research may be clinical, but it is nonetheless science. We still must have a testable hypothesis.

TOS *How is the changing relationship between the pharmaceutical industry and clinicians affecting researchers?*

NOVACK The FDA does not pay for developing new drugs; industry does. Today, for a number of reasons, relationships between industry and physicians, especially academic physicians, are being questioned.

At the same time, it is becoming harder and harder to get new drugs approved, which means greater cost and therefore increased risk for the funding organizations. Government research funding is declining at the same time that pressure is being brought to bear on company profits (which fund research). And restrictions are being placed on how industry works with physicians. I see funding as a huge challenge for future researchers.

TOS *What do you plan to be doing in the next chapter of your career?*

NOVACK I have had great opportunities in my life, thanks to my family and my education. They have enabled me to do many of the things that interest me. I have always been interested in Torah and Talmud study, and I joke that one day I will go to rabbinical school and become a rabbi. I fear that becoming a professional bicycle racer is probably out of the question at this point.

Aside from continuing clinical research, I would like to find a way to increase my academic involvement with the University of California. Right now I am focused on fundraising and administration, but I would be interested in teaching more in the future. ●