FUTURE OF MEDICINE

BIOMEDICAL NANOTECHNOLOGY

The smaller the thing, the bigger the challenge for nanotechnology, for medical treatment, for packaging, and for regulatory.

BY DR. MICHAEL DRUES, CONTRIBUTING EDITOR

Nanotechnology? It involves really small stuff, but it's all science fiction, and it will be 50 or 100 years before we have any real products. If this is your view of nanotechnology, then it's time to take another look. Nanotechology and nanomaterials are already used in consumer products such as paints, cosmetics, sunscreens, and even foods.

So why don't we hear more about products that already contain nanomaterials? One reason is the negative connotation of the word nanotechnology. Another reason is that companies are often not required to tell us. Like the word "nuclear," nanotechnology is still scary to many and as a result, companies don't want to scare off their customers—not if they don't have to.

Technically, nanometer means one-billionth of a meter. But more importantly, size is a continuum. How long until we talk picotechnology (one-thousandth of a nanometer) or femtotechnology (one-millionth of a nanometer)?

In medicine, one advantage of nanomaterials is that because they are so small, they can get everywhere in the body. One disadvantage of nanomaterials is that because they are so small, they can get everywhere in the body. For my packaging friends, here's a question to ponder: Since nanoproducts can move through virtually anything, how do you plan to keep your nanotechnology-based products in a package? And how do you ensure there is a barrier that keeps nanoproducts either in or out?

From a medical device perspective, there are many materials we've used to make medical devices for decades that are perfectly safe at the macro level. Yet some of these same materials at the micro or nano level can become extremely cytotoxic. We must face new technology challenges with our eyes open and not be biased by the way we have done things in the past.

From a regulatory perspective, our current model was not designed for revolutionary technologies like nanotechnology, and that holds us back. True, both the U.S. and E.U. regulatory authorities have issued guidance in these areas, yet more regulation will neither solve nor prevent problems. In fact, maybe we need a completely new, even revolutionary regulatory model.

Last year FDA Commissioner Hamburg announced she was forming a Program Alignment Group to look for ways to bring better alignment between FDA's different centers.

Carl Sagan once said, "Science is a way of thinking much more than it is a body of knowledge." Similarly, regulatory is a way of thinking much more than it is a body of rules and regulations—or at least it should be. This is what all of us must do to reap the benefits that biomedical nanotechnology offers while simultaneously avoiding the potential dangers it poses. **[HCP]**

DR. MICHAEL DRUES is President of Grafton, MA-based Vascular Sciences, an education, training, and consulting company. He can be reached on Linkedin®, by phone at 508/887-9486, and by e-mail at mdrues@vascularsci.com

Read an expanded version of this column online at hcpgo.to/171