LETTERS

Are Drug-Safety Concerns Endangering Drug Benefits?

The best way to avoid draconian restrictions on consumer and doctor access to the world's most innovative medicines is to strike an appropriate balance between benefits and risks.

— Rob Norton

A Congressional overreaction

For starters, I'll tell you that I am shocked — absolutely shocked — that some members of Congress appear to be overreacting to drug safety concerns. Believe me, as a service provider that helps pharmaceutical and biotech companies manage the safety and minimize the risk of medicines, we have every reason to want drug safety to be on the front burner. But (sarcasm aside) many of us who help serve the pharmaceutical and biotech industries see a very real danger in overreaction that could keep valuable medicines from consumers.

We took a look at the drug-safety legislation recently introduced by Senator Chuck Grassley and Senator Christopher Dodd. The bill addresses some common criticisms of the drug-safety system, including drug manufacturers that often fail to complete the drug-safety studies requested by the FDA; manufacturers that cannot be relied upon to disclose safety information, especially if it would threaten sales; and the FDA's current organizational structure that discourages aggressive drug-safety enforcement.

Among other things, the bill would create a new FDA center for drug safety, require completion of postmarketing study commitments, and mandate public disclosure of product risk data.

Here's the problem: the legislation doesn't adequately address the essential question of how regulators, doctors, and consumers should balance product benefits versus risk.

Yes, some drugs have very serious side effects, but a laser focus on drug safety alone should not completely eclipse a drug's benefit. For some patients, the potential benefits of certain drugs will far outweigh the risk. Congress is well-intended, and well-justified, in attempting to improve the management of drug-risk information, but this effort must account for the benefits that drugs — even some risky drugs — provide patients.

The fact is, advanced information technology, modern postmarketing surveillance, and late-stage clinical research allow for "smarter" benefit-risk assessments of prescription drugs. The key to identifying and monitoring risks, and balancing this information with a sufficient consideration of benefits, is to encourage postmarketing research and surveillance programs to optimize the use of medicines. These efforts can be facilitated by industry cooperation, proactive regulatory attitudes, and legislative restraint.

If not, the current overreaction could create an imbalance where drug benefits are needlessly overshadowed by potential safety risks.

The best way to avoid draconian restrictions on consumer and doctor access to the world's most innovative medicines is to strike an appropriate balance between benefits and risks. Let's hope we see more of this balance as Washington considers this critical issue.

Rob Norton
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What's Your Opinion?

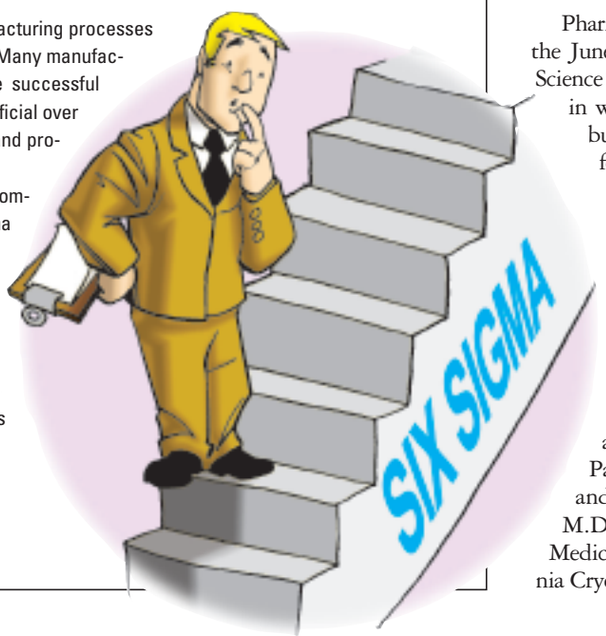
SIX SIGMA — A PROCESS STRATEGY

Six Sigma was first implemented in the manufacturing processes of electronics, according to Uniworld Consulting. Many manufacturing-oriented companies continue to apply the successful techniques but the efforts have become less beneficial over time since the focus has been on cost reduction and productivity improvement.

The vision for Six Sigma is not only about bottom-line savings. Within the last few years, Six Sigma programs have begun focusing on stimulating top-line growth by addressing critical aspects of company-centric design processes.

PharmaVOICE wants to know: Does your company have a Six Sigma program in place? If so, what are the pros and cons? If not, is your company evaluating the implementation of Six Sigma as part of its corporate strategy?

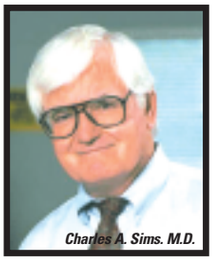
WHAT'S YOUR OPINION?
Please e-mail your comments to feedback@pharmavoice.com.



Pardon us ...

PharmaVOICE apologies for the errors in the June article, Ideology vs. Science The Stem Cell Battle, in which the photo attributions were incorrect for Kirstin Matthews, Ph.D., Research Associate, Science and Technology Policy, James. A. Baker III Institute for Public Policy, Rice University; Patrick O'Shea, Senior VP and Managing Director of Palio Communications; and Charles A. Sims, M.D., Cofounder and Medical Director of California Cryobank Inc.


Patrick O'Shea


Charles A. Sims. M.D.