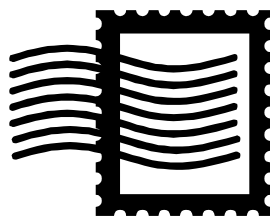


Letter from Washington**Changing behavior vs. changing minds****By Peter Pitts**

When the Food and Drug Administration talks, industry listens and obeys. That's called "compliance." But while mandates change behavior, they do not necessarily change minds. And as FDA enters its second century, minds need to



be changed both inside and outside of the agency that regulates over 30% of the U.S. economy. Nothing less than the health of America is at stake.

During my recent tenure as FDA's Associate Commissioner for External Relations, I worked with then-Commissioner Mark McClellan

to expand the agency's mission from protecting to protecting *and advancing* America's health. For that to be more than rhetoric, we had to move from changing behavior to changing minds.

The most important internal mind change was a sea change — a shift from purposeful ambiguity to practical clarity. That's harder than it sounds because regulators love ambiguity. Ambiguity is power. That's why interpretation of FDA actions is such a vibrant cottage industry. Industry, on the other hand, seeks clarity. They want bright lines. They want to know the rules. They want predictability. This may sound simple, but it has proven to be a fractious bureaucratic *kulturkampf*. "Change is not required," as management guru W. Edwards Deming once said. "Survival is not mandatory."

There have been successes. Last November, the agency's draft guidance on pharmacogenomic data submissions helped to encourage drug and biologic developers to conduct pharmacogenomic tests during drug development by clarifying how FDA will evaluate the resulting data. Bright lines. As Commissioner McClellan said at the time, "pharmacogenomics is a new field, but we intend to do all we can to use it to promote the development of medicines. By providing practical guidance on how to turn the explosion of pharmacogenomic information into real evidence on new drugs, we are taking an important step toward that goal."

And there have been failures. Some FDA regulators continue to prefer ambiguity to clarity when it comes to direct-to-consumer advertising. Despite new draft guidances that attempt to draw bright lines, what is and is not "in compliance" remains more art than science. Industry is confused, and the public health is not served.

Perhaps the most important example of FDA working to provide industry with clear direction is the agency's recently announced "Critical Path" initiative. This commits the agency to work in partnership with both industry and academe to develop new tools to improve the predictability of the drug development cycle and lower the cost of research by helping identify product failures earlier in the clinical trials process. To fulfill the promise of the "biomedical century," FDA can — indeed must — be a bridge over the widening canyon between

bench and bedside.

Regulators change industry behavior by changing the rules of the game. But changing the minds of regulators, having them embrace bright lines rather than broad definitions, is a distinctly more challenging proposition, because changed minds must begin with change agents within the agency itself. FDA's Critical Path initiative, under the direction

of Acting Commissioner Lester Crawford and Acting Deputy Commissioner Janet Woodcock, is a promising example of the agency's desire to embrace change (see *Online Links*, A5).

Going forward, the agency's stakeholders will be looking for other "surrogate markers" to gauge FDA's willingness to continue the McClellan era's aggressive determination to both protect *and* advance the public health.

For example, these should include a forceful and long overdue physician labeling rule that explicitly states what labeling information is in the best interest of the public health, rather than for liability protection.

FDA also should be pursuing prudent and appropriate efforts to enforce its federal preemption powers, making it clear once and for all that the agency's determination of "safe and effective" *means* safe and effective.

Robust pursuit of e-labeling would help offset anxiety about off-label reimbursement.

In the area of unfinished business, FDA should issue new guidance on DTC advertising, using solid social science research to determine whether consumers are getting useful information in an understandable way, replacing the current "I know it when I see it" approach. Industry needs an evidence-based regulatory framework that provides predictable standards for their communications efforts with consumers. Bright lines.

Predictability is power in pursuit of the public health. It is the result of creative, forward-thinking leadership that rises above bureaucratic ambiguity. It won't be easy, because swimming against the tide of an entrenched bureaucracy never is. But as the agency's change agents demonstrate that their efforts lead to public health successes, the tide will turn. As Winston Churchill said, "Ease is relative to the experience of the doer."

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