

## Biotech & Tech

### At BioAgenda, spirited debate is the rule *1st East Coast event by institute confronts difficult questions*

KAREN BUCKELEW

Daily Record Business Writer

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SILVER SPRING — The role of the U.S. Food and Drug Administration is a delicate balance and a bit of a conundrum, agreed experts at the BioAgenda Institute's first-ever East Coast conference.

"It's necessary to be regulated to a certain point so we have the public confidence," said Nancy Bradish Myers, a former senior strategic advisor in the FDA commissioner's office.

"But if we're overregulated, we will not be able [to keep] the U.S. as a leader in science," she added.

The complicated, crucial role of the FDA made it perfect fodder for debate at BioAgenda East on Thursday in Silver Spring, the first East Coast event sponsored by the San Francisco-based BioAgenda Institute. The event drew about 125 scientists, investors and entrepreneurs to the American Film Institute Theatre and Cultural Center.

Confronting difficult questions in life sciences is a critical part of the institute's mission, said founder and director David Ewing Duncan, as is holding seminars that foster spirited debate on controversial issues.

"We're getting some sparks flying," Duncan said during a break in the action Thursday. "That's so important."

Bradish Myers' panel discussion, examining the role of government in regulating life sciences, was just one of a series of debates that packed the day's schedule.

A morning panel weighed the impact Bush administration policy would have on the future of life sciences, and even the lunch break featured a heated debate on the genetic manipulation of embryos.

Bradish Myers sat on a five-person panel on the importance federal regulations, a discussion that confronted fundamental issues of human health and the future of science.

The FDA is saddled with the task of ensuring the safety and efficacy of the nation's drugs and medical devices, as well as much of the food consumed in America, noted panel moderator David Hamilton, a former Wall Street Journal bioscience reporter.

But with a budget of \$2 billion, compared to the National Institutes of Health's budget of \$30 billion, Hamilton questioned whether the FDA has the resources to do its job.

"That's a substantial difference there," Hamilton told the panel, assembled in a row of chairs in the front of the institute's theater, just beneath the towering big screen.

And the FDA's role could pose both a burden to its resources and to the industries it oversees, suggested panel member Gregory Stock, an author, CEO of Signum Biosciences and director of UCLA's program on Medicine, Technology and Society.

"The current regulatory environment ... places huge burdens on early stage drug development and moving drugs into humans," Stock said.

For regulators, "there is no reward for getting things to market a year earlier, and you're penalized if you make mistakes," Stock added.



M. James Barrett, a general partner for venture capital firm New Enterprise Associates, warned that too much regulation can stifle the wild ideas that offer the biggest payoffs.

"The craziest, most frightening science is what gets funded by us," Barrett said. "Consider carefully the consequences of regulations ... on the companies that get formed."

Dr. Michael Zasloff, a pediatrician and senior consultant in life sciences banking at Ferris, Baker Watts Inc. in Baltimore, said he would like to see a more efficient way of determining the risk/benefit balance of a drug, maybe using the new fields of proteomics and genomics.

The future of the FDA lies in those new technologies, agreed Merrill Goozner, director of the Integrity in Science project for the Center for Science in the Public Interest.

"What [the FDA] needs to do now is modernize so it can bring these new tools to bear," Goozner said.