Conference Review

FDA at BIO 2011 – Weighing a hefty mission: Where is the balance?

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The mission of the Food and Drug Administration (FDA) is to promote public health by ensuring the safety and quality of food and medical products sold in the United States. At this year's annual Biotechnology Industry Organization (BIO) convention, significant discussion revolved around the appropriate interpretation and execution of that mission.

The BIO meeting hosted 15 646 participants from across industry, government and the nonprofit sector, focusing on the current state of the biotechnology industry, as well as its challenges in seeking to further improve public welfare. Perhaps partly because this year's meeting was held in Washington, DC – the seat of the federal government and of BIO's headquarters – much attention was paid to the US regulatory environment. In particular, attendees debated the quandary faced every day by the FDA: how to enable access to novel therapies quickly, but only once their safety has been certified.

Industry members predominantly noted that the regulatory framework currently in place in the United States constrains their ability to innovate, and thereby to remain productive. Some – such as companies aiming to develop new antibiotics – have seen regulatory guidelines change after clinical trials have already begun, making it hard for them to meet the FDA's standards for approval of a new product. They also reported difficulty obtaining meetings with FDA reviewers during the development process. Company representatives urge that greater access to agency staff before submission of a product application would facilitate more effective trial design as well as earlier detection – and correction – of any problems.

BIO's CEO, former US Congressman Jim Greenwood, said industry needs an FDA that focuses more on promoting new drugs than on postponing them. The problem, though, is that if anything today goes wrong with an approved drug, the FDA inevitably gets the brunt of the blame; as incoming BIO Chair Tom Watkins noted, Congress tends to pay attention to even very rare safety issues that arise, encouraging the agency to become even more risk-averse.

We cannot hold the FDA to impossible standards of approving, and quickly, only perfect pills. Clearly, a balance must be achieved between the FDA's duty to ensure the safety of products it allows onto the US market and its responsibility not to impede access to needed therapies due to potential harm. But that may be feasible only if we relax our dependence on the FDA to guarantee the total safety of all our medical products.

Dr Anula Jayasuriya, a participant in *Scientific American*'s Worldview panel on global

innovation, suggested that Europeans have a more reasonable expectation of their regulators than do most Americans. In Europe, she noted, individuals implicitly agree to take some responsibility for any decision that affects them and understand that benefits come at a price – as indicated even by their willingness to accept some rationing of health-care services in exchange for more universal access. In addition, Dr Jayasuriya pointed out, Americans are much more litigious than people in other societies. As a result, the FDA is simultaneously pressed by those in need to make potentially helpful drugs available and threatened with legal or other difficulties should those drugs have any adverse effect post-approval. By contrast, in places such as the United Kingdom, extraneous lawsuits are seriously disincentivized: those bringing the charges pay all costs if they lose the case. Because of the implied agreement in Europe over what is an acceptable level of risk to pass on to those actually using a product, European regulators can approve products that inevitably bear some risk without as much fear of retribution, as long as the costs and benefits have been reasonably compared and appropriate warning is given for known risks.

The potential for greater partnership to achieve a more productive health-care system is true not only in the case of citizens (as former UK Prime Minister Tony Blair noted), but also in all other realms in which the FDA is involved. For example, the FDA and manufacturers are working to create a better-defined model of risks and benefits. At the same time, the memorandum of understanding signed last year between the FDA and the Centers for Medicare & Medicaid Services (CMS) is a foundation for what will hopefully grow into a more open relationship between the two agencies. Such cooperation, if successful, will help bring new products to market faster by decreasing duplicate work for both sponsors and reviewers; in so doing, it will reduce the burdens currently faced by both the FDA and CMS in fulfilling their missions. Finally, as acknowledged by numerous parties, Congressional recognition that the FDA remains tremendously underfunded for the increasing responsibility it has been assigned, and appropriation of more resources to it, should also help ameliorate its ability to verify safety while speeding access to deserving drugs.

As the various stakeholders in and around the biotechnology sector come together more coherently, questions of how to achieve the proper balance between safety and access may begin to be resolved. A big part of that change will undoubtedly involve enhancing the public's understanding of what the FDA can and cannot do, so that others can take on some of the accountability whose weight is too much for the agency to bear on its own.

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