AN AUDIENCE WITH…

Frank Torti

Principal Deputy Commissioner and Chief Scientist at the Food and Drug Administration in Rockville, Maryland, USA. Prior to joining the FDA in May 2008, Frank Torti was the Charles L. Spurr Professor of Medicine, Director of the Comprehensive Cancer Center, and Chair of the Department of Cancer Biology at Wake Forest University School of Medicine, USA. He is an active and well-known basic as well as clinical investigator, widely published and has designed and executed clinical trials that have become standards of care in genitourinary oncology.

Why has there been a need for the FDA to appoint a Chief Scientist?

The US Congress recognized that the job of the FDA has changed dramatically and permanently in the twenty-first century. For example, the number of foreign manufacturing facilities that produce products that the FDA regulates will equal in 2008 the number of domestic facilities. If you add to this the overseas production of FDA-regulated products and the congressionally mandated FDA responsibilities related to bioterrorism — and superimpose over these the enormous underlying change in the rate of technology development — then the FDA is a different place than it was just a few years ago.

Therefore, there needs to be an overall scientific vision and a plan for the agency that is proactive and informed by these changes, particularly the rate of scientific advance. The FDA science advisory board published a report that further pointed out that some of the deficiencies in scientific expertise were in areas of rapidly developing science (http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_00_index.html). This re-enforced the wisdom of having a chief scientist to look at these issues across the many FDA Centers, to create a scientific plan, to reach out to stakeholders and to develop and modernize the workforce.

Could you outline the key issues that you, as Chief Scientist, prioritized to address during your first 100 days at the FDA?

Two weeks after I arrived at the FDA I was asked to present a vision for science at the agency. This was an opportunity to conceptualize some of the problems and commit to the first steps towards implementation. So I presented a series of deliverables for the first 100 days that were focused around three principles.

The first principle is that the FDA cannot do it alone — we need to think of new ways to engage all of the stakeholders in science at the FDA. For example, I proposed that we identify — through a competitive process — academic centres of excellence in regulatory science that would have substantial capabilities in areas such as food and product safety or drug development. Then, when the FDA has a specific need or question to ask, the mechanisms will be in place to quickly engage this research. With respect to the pharma, device and food industries, I felt that although the FDA is already doing a lot in terms of public–private partnerships, it could do more. One has to be very careful because the FDA regulates the products of these companies, and so, certain types of FDA–industry interactions are not appropriate. However, there are areas of basic regulatory science in which we could and should collaborate productively.

The second principle is that the FDA must maintain its core scientific expertise because there are many functions that the FDA performs from a regulatory standpoint that cannot be distributed to external parties.

Finally, the third principle is that the entire scientific strategy must be pre-emptive. A major element of this is to bring new, well-trained scientists to the agency; partly through the new commissioner's fellowship programme, the pilot of which will begin in the fall. Fellows will be exposed to regulatory areas across all FDA Centers but their major experience will be scientific, whether in a research project or participating in a drug application review. The hope is that we will get the best and brightest people, some of whom will stay and become future leaders at the FDA.

Which key areas of internal expertise at the FDA need to expand as a priority?

First of all, one of the reasons I am here is that I am extraordinarily impressed with the people and the quality of the science. Nobody should forget that FDA funding has been relatively flat in the past 20 years while the mandates have increased substantially and the science has become more complex. Inevitably, there were specific areas identified by the science board that need to expand. For example, we need more expertise in genomic large database acquisition, evaluation and interpretation — that includes everything from classical biostatistics to systems biology approaches. Obviously we also need to build the informatics infrastructure for this and that's a big ongoing effort at the FDA. Another example is innovative clinical trial design to help bring drugs to the market safely but also faster; in all aspects of what the FDA does there needs to be risk-based approaches to science. In addition, we would like to see, where appropriate, more interdisciplinary teams such as the ones we have already established for combination products that bring together cell-based product and tissue-engineering expertise. We are beginning to think more and more about interdisciplinary teams at the FDA to ensure that when these products come down the line we have the right teams in place.

How will the FDA work with the Reagan–Udall Foundation and what will be the aims of that relationship?

This is a great opportunity and represents a very important part of the future of the FDA. The Reagan–Udall Foundation is a non-profit foundation for the FDA and was established to identify and address unmet scientific needs in the development, manufacture and evaluation of FDA-regulated products and they are just beginning to set up their by-laws. The Foundation has identified two initial issues to address that it views as critical to the future of the FDA. The first is the commissioner's fellowship programme that will bring new regulatory science and scientists to the FDA and the other is post-market surveillance of FDA-regulated products through the recently announced Sentinel Initiative (http://www.fda.gov/oc/initiatives/advance/reports/report0508.pdf). I'm now setting up an FDA-wide process so that the issues that the FDA Centers want tackled by the Reagan–Udall Foundation can be discussed and prioritized.