

## The US FDA's Medical Device Postmarket Transformation Initiative

*Jonathan Sackner-Bernstein*, associate director for postmarket operations at the US Food and Drug Administration's medical devices centre, updates *Campbell T Hutton* and *Alice S Bailey* on developments aimed at improving the initiative.

US manufacturers of medical devices can expect to see increased scrutiny of their postmarketing reports as the US Food and Drug Administration's Center for Devices and Radiological Health takes action to strengthen its Medical Device Postmarket Transformation Initiative. The initiative, launched in 2006<sup>1</sup>, was designed to increase the ability of CDRH to identify, analyse and act on postmarket information, thereby improving the safety and effectiveness of medical devices and radiation-emitting products. It is focused on execution in four areas: creating a culture of collaboration within CDRH, developing world-class data systems, enhancing risk:benefit communication efforts and collaborating on enforcement strategies and outcomes.

Jonathan Sackner-Bernstein who leads this effort, is associate director for postmarket operations at CDRH. In this role, he is also responsible for postmarket policies and day-to-day strategies for addressing postmarket problems. In this interview, Dr Sackner-Bernstein provides information and insights on how the CDRH postmarketing initiative is being managed and explains the implications for medical device manufacturers.

**CH/AB:** What is your role at the FDA?

**JSB:** I am the associate director for postmarket operations at the FDA's Center for Devices and Radiological Health, with the additional role of champion for the centre's Matrix organisational structure.

As the Matrix champion, I lead a team of 13 Network Leaders who serve to integrate office functions [within CDRH] across the total product life cycle. Each leader has a "network", focused on specific product categories or disciplines. These networks are a new way of doing business for the centre, each one composed of experts from across the centre, from premarket review to compliance, focusing their expertise on identifying, analysing and acting on specific issues.

The Matrix structure is focused on postmarket issues but it also helps continuous improvement, as lessons learned postmarket can feed back into the premarket process.

The processes of integrating the tools within the centre, liaising within the agency and involving outside stakeholders are well under way. Our initial focus includes the development and disclosure of consistent and transparent methods to identify potential issues early, to determine whether the information represents a public health concern, and to communicate with the public clearly and promptly.

**CH/AB:** What is the goal of the Medical Device Postmarket Transformation Initiative? Why is it needed?

**JSB:** The CDRH Postmarket Transformation [Initiative] focuses on improving communication and collaboration across the centre and will enhance our decision making and foster better, more timely awareness of priority issues. Ultimately, it will help refine the centre's postmarket problem identification, problem assessment and public health response, resulting in improved safety of medical devices.

In the private sector, transformative initiatives are launched to keep or gain a competitive advantage. In a government agency, the motivation is based on our mission, to protect and promote the public health.

**CH/AB:** What changes should manufacturers expect in the next 12-24 months, if any?

**JSB:** Now that the Matrix and networks are in place, manufacturers should probably expect an even keener interest from the centre in postmarket reporting. At the same time, the new structure will bring greater consistency and transparency from the centre.

The industry and consumers should expect more detailed communication on an ongoing basis.

**CH/AB:** How will you ensure that all stakeholders are able to contribute concerns, concepts and technology to assist in achieving your goals?

**JSB:** Stakeholder input is critical for the success of this initiative – as it is for most of the centre's

Campbell T Hutton is vice president, Strategic Consulting Group, and Alice S Bailey is a senior consultant at Becker & Associates Consulting in Washington, DC.

*The initiative aims to increase CDRH's ability to identify, analyse and act on postmarket information*

*Lessons learned postmarket can feed back into the premarket process*

*The new structure will bring greater consistency and transparency*

operations. We will utilise a number of methods to garner input, including the solicitation of comment for appropriate documents in the *Federal Register* and discussion at different industry and scientific meetings and conferences.

**CH/AB:** There are many sources of data about the performance of marketed devices (information reported to the FDA by manufacturers and users, medical literature, etc). Do you propose to change the methods used to collect and analyse this information? In what way [will you do this]?

*Decision making is possible even when there is uncertainty over the data sources*

**JSB:** One target in this initiative is the development of quantitative decision making in the postmarket setting. This is an approach based on decision sciences and Bayesian statistics. These approaches are already widely used and accepted, and they have distinct advantages in providing consistent and transparent paths to rational decision making. And with the lack of perfect data sources for postmarket device safety, these approaches incorporate the recognised uncertainty into the models instead of using it as a reason why decision making cannot go forward.

As we apply these strategies, we'll be sharing the results at scientific meetings and other appropriate venues.

**CH/AB:** Do you propose to require a unique identification system for medical devices? If so, when do you anticipate implementing this requirement?

*The FDA is developing a proposed rule to establish a UDI system*

**JSB:** Under FDAAA [Food and Drug Administration Amendments Act], passed by Congress in [September] 2007, the agency must publish a regulation that establishes a unique device identifier [UDI] system. We are in the process of developing this proposed rule, which will improve public health by providing timely and accurate identification of medical devices. However, this is obviously a complex process requiring collaboration with stakeholders and, eventually, careful review of all comments we receive once that proposed rule is published.

We recently held a public workshop on the UDI process, which is an example of how the centre will foster more transparent and open process with industry, consumers and other stakeholders.

**CH/AB:** One of the challenges that the programme currently faces is the limited resources available for inspections. Given the recent attention to problems at food product manufacturing facilities and the FDA's efforts to inspect more manufacturers outside of the US, how, if at all, do you think the resources for inspections at CDRH will be affected?

**JSB:** Based on current funding, we expect that there will be an increase in device-related inspections – both domestic and abroad.

**CH/AB:** One of the stated goals of the programme is to cycle the information gained about postmarket performance of devices into the premarket review process for new devices. How will CDRH keep industry and the public informed about the changing expectations for new devices?

**JSB:** The answer to [your questions about stakeholder input] may be the most direct answer. But I'd also like to add further thoughts.

The industry, public and the FDA all want the same thing – maximum benefit from medical devices with minimum risk. The agency must assess risk and benefit to public health according to statutes and regulations. In this role we are expected to stop unsafe and ineffective devices from reaching the market and monitoring those on the market to be increasingly confident that their safety and effectiveness remain consistent with the premarket assessment.

*Companies need to be confident CDRH will provide appropriate development and review paths*

Companies developing potentially ground-breaking products based on innovation such as nanotechnology, for example, need to be confident that we will provide a transparent and scientifically based path for the development and review of those products. When we do that, we fulfil another component of our mission, that of encouraging the innovation that will help transform healthcare.

*References*

1. FDA press release, 9 November 2006, [www.fda.gov/bbs/topics/NEWS/2006/NEW01506.html](http://www.fda.gov/bbs/topics/NEWS/2006/NEW01506.html)

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