

US FDA Takes a Pounding

The US Food and Drug Administration cannot fulfill its mission to protect and advance public health. This is the bleak conclusion of a report¹ from a committee of outside experts that FDA commissioner Andrew von Eschenbach asked to be set up to assess whether science and technology at the agency can support current and future regulatory needs.

The document, from the subcommittee on science and technology set up by the Science Board, an FDA advisory body, makes uncomfortable reading. As we report in detail in this issue, the subcommittee found that the FDA's scientific base has been eroded and that its scientific organisational structure is weak. It also found that the agency's scientific workforce has insufficient capacity and capability. As if that weren't bad enough, the agency's information technology infrastructure was found to be woefully inadequate.

The FDA's Center for Devices and Radiological Health escapes some of the worst criticism. The subcommittee, which is composed of three members of the Science Board and experts representing industry, academia and other government agencies, found substantial weaknesses "across the agency, with the possible exception of some drug and medical device review functions funded by industry user fees".

CDRH nevertheless was found to have plenty of failings. The report appendix on CDRH says that "without sufficient intervention the Center will have severe difficulties in carrying out its mission over the next decade"².

The appendix on CDRH lists the device technology areas in which the centre expects significant developments over the next decade. These include: ageing-related devices; artificial organs and organ assists; computerised devices and intelligent systems; early diagnosis/detection technologies; genomics, proteomics, epigenomics; home- and self-care devices; imaging systems; minimally invasive and miniaturisation technologies; portable and mobile devices; robotic devices; sensor technologies; telemedicine; and wireless devices and systems.

The list is impressive. However, the subcommittee goes on to say that, among other things, CDRH lacks the personnel and resources "to adequately support the science needs in the regulatory review process for the technologies of the future". It fears that, unless matters improve, the technologies in the list "may be hampered, or not reach their full potential". The technology forecast performed by CDRH denotes "good planning by management", says the report, but "current plans and resources are not adequate to address unforeseen technologies developed in the future that have regulatory consequences".

The subcommittee calls on the FDA to implement a series of recommendations aimed at tackling the deficiencies it describes. Among other things, it advocates that the FDA's budget essentially be doubled.

US medtech industry association AdvaMed agrees that extra funding is needed. "AdvaMed believes FDA must be given adequate resources so that it can continue its vital work of protecting and promoting the public health," Janet Trunzo, the association's executive vice president, technology and regulatory affairs, said.

In defence of the FDA

The FDA is not commenting on the content of the subcommittee report, not even to issue a broad defence of itself. When contacted by *RAJ Devices*, the agency said only that it was currently seeking public comment on the report [until 4 February – Ed] and that Dr von Eschenbach might testify before Congress on some of the points therein.

There are those outside the agency, however, who think that aggressively written reports such as this one – even if some of the observations they make have merit – can do unintended damage.

It is true that the FDA is facing challenges it has not faced before, says Phil Phillips, formerly a senior official at CDRH's Office of Device Evaluation and now a consultant with Washington-based Becker & Associates Consulting. It is also true that the agency is "not optimally positioned" to meet some of those challenges. Mr Phillips continued, however, stating that some of the views expressed in the report were "a bit extreme and exaggerated" and there was, he said, a danger that the public might wrongly conclude that the agency is not doing its job and that FDA-regulated products are not safe. The agency may have its problems, but, Mr Phillips says, the public can be confident that it does "a tremendous job" fulfilling its mission.

Consultants, especially those who, like Mr Phillips, are former FDA employees, can be among the agency's most vocal critics. In this case, however, Mr Phillips believes the FDA needs defending. He describes FDA employees as "smart" and "committed" and FDA's management as "astute". Mr Phillips has seen agency personnel rise to the occasion in the past and he has every confidence they will continue to do so as required. "When their backs are against the wall, they can be very creative" in meeting important regulatory requirements, he said.

On the issue of resources, Mr Phillips says that extra funding is not always the solution to regulatory problems. While he believes that the FDA should get more resources to enable it to focus on "areas of vulnerability", he argues that over-funding can prompt regulatory agencies to move into areas of low priority. The bottom line, he says, is that FDA is adequately funded to accomplish its core mission, particularly given the strong commitment among personnel to ensure the safety of the products the agency regulates.

The world looks to the FDA as a leader, says the subcommittee report. Today, however, "not only can the agency not lead, it cannot even keep up with the advances in science". Mr Phillips does not agree. "From a global perspective, it is very difficult to conclude that FDA does not give tremendous value for its operating budget," he says.

References

1. FDA Science Board, FDA science and mission at risk, November 2007, www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf
2. Appendix to Reference 1, www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_02_FDA%20Report%20Appendices%20A-K.pdf

Maureen Kenny
Editor

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Contents

Features

Editorial – US FDA Takes a Pounding	1
Combination Products – Patent Issues and Remedies	3
Noël Akers reviews patent laws and practice for protecting drug-device combination products	
Struggling with Science: A Critical Look at the US FDA	9
A report finds that the agency's failure to keep up with science and information systems is threatening public health	
The Role of Medical Devices in the Future of EU Pharma Market ...	13
European industry body Eucomed responds to a consultation on "making Europe a hub for safe and innovative medicines"	
How to Avoid Approval Delays in Japan	16
Neena Brizmohun looks at how best to manage the intricacies of the Japanese regulatory approval process	
Regulatory Developments in 2007	19
Karen Finn reviews the major regulatory affairs events of the past year	

Reference Information

Device-Related Guidelines	65
International Standards	67
Meetings	69
Appointments	70
Directory of Services	72

Worldwide Update

International/Canada	28	Jordan	40
China	29	Middle East	40
Europe	31	Norway/Saudi Arabia	41
France	38	UK	42
Germany/Israel	39	US	46