

**Science at Work in CDRH:
The Role of Science in the
Regulatory Process**

**Presented to the
FDA Science Board**

**By the CDRH External Review
Subcommittee**

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External Science Review Committee

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- **Martin Rosenberg, Ph.D., SmithKline Beechman**

A Note of Thanks

- **My colleagues on the External Review Subcommittee**
- **The CDRH staff members who worked closely with us**
- **All of the CDRH senior management and staff who participated in both the internal and external review**

Objective of CDRH Review

**To assess the quality of science
across the organization and its
relevance to the organization's
regulatory mission.**

Outline of Report

- **Background, Charge, and Objectives**
- **Process**
- **Findings**
 - **Scientific Expertise**
 - **Human Resource Issues**
 - **Organizational and Process Issues**
- **Recommendations**
- **Conclusions**

Internal Review Process

- **Initiated in February 2001**
- **The field of electrostimulation devices was chosen as a representative technology**
- **Ground rules included:**
 - **The review not be an evaluation of individual decisions, but rather an evaluation of the overall role of science.**
 - **Process enters the assessment only to shed light on CDRH's role of science in decision-making.**
 - **The review be reflective of the Center's current practice**
- **This subcommittee commends CDRH for the substantive nature of the internal review and the spirit in which it was conducted.**

External Review Process

- **Built on the foundation of knowledge provided by internal review**
- **Initial preparatory meeting held on June 19 in Atlanta**
- **Three-day review held July 24-26 in Rockville**
- **One-day report writing session on August 8 in Rockville**
- **Final draft by October**

July 24 - 26 Review

- **Case study review teams**
- **Role playing sessions: pre-IDE and post IDE**
- **On-the-spot reviews**
- **Industry interviews**
- **International interviews**

Scientific Expertise

Findings address:

- **Science and the Regulatory Decision-making Process**
- **The Present Level of Scientific Expertise in the CDRH**
- **The Increasing Complexity of Applications**
- **Science and the Long-Term Regulatory Role**
- **The Leveraging of External and Internal Expertise for ODE**
- **Metrics for Quantity, Timeliness, and the Quality of Decision Making**
- **Scientific Expertise for the Newer, Breakthrough Technologies**

Scientific Expertise

Findings:

- The review team reaffirms that good science is critical to good regulatory decision making
- The complexity of applications requiring review has increased and will continue to do so
- The overall high quality of reviewers, medical officers, scientists and engineers was evident
- Even so, expertise across fields is uneven
- The level of expertise among staff about the clinical environment is in some cases limited

Scientific Expertise

Findings (continued):

- There is not enough emphasis placed on the quality as compared to the timeliness and volume of reviews
- There appears to be a strong tendency for ODE to operate primarily “in house,” in fact if not by plan
- The subcommittee was interested in learning about the use of third parties in other countries, e.g. the notified bodies in Europe
- There is a concern as to whether CDRH, and even FDA as a whole, has the right expertise for the evaluation of combination products, e.g. ones that are a combination of a device and a biologic or a drug, products so important to the future

Human Resource Issues

Findings address:

- Recruitment and Retention
- Gaps in Existing Scientific Expertise
- Staff Training and Development
- Workload Issues
- Promotion Opportunities
- Reward and Recognition

Human Resource Issues

Findings:

- The subcommittee was impressed with the quality, professionalism, and dedication of the staff it encountered
- There is a gap between the scientific expertise needed and the competencies of current staff
- There is a woefully inadequate investment of resources and opportunities for staff training and development
- There are too few staff to carry out the necessary activities as CDRH now functions
- For CDRH scientists there is a lack of promotion opportunities

Organizational and Process Issues

Findings address:

- **Structure of CDRH**
- **Office of Device Evaluation**
- **Office of Science and Technology**
- **Combination Products**
- **Communication Within and with Outside Organizations**
- **Regulatory Review Process**

Organizational and Process Issues

Findings:

- CDRH is organized as “semi-porous silos”
- There appears to be no quality metrics about CDRH as an organization
- There is no system of retrospective measurement and analysis of specific CDRH decisions
- There appears to be no effective interoffice communication and coordination
- External experts are seldom used beyond those who sit on existing FDA Advisory Panels
- There is no clear pathway or guidelines for the regulation of combination products

Recommendations

- 1. CDRH needs to communicate, both internally and externally, a clear vision of the fundamental role of science in the regulatory process.**
- 2. CDRH needs to rethink how it carries out its mission, prioritizing its activities, outsourcing those functions it can while still maintaining oversight, and reallocating its resources so as to expand its investment in science; as part of this CDRH should examine its existing organizational structure as well as other regulatory models.**
- 3. As part of its restructuring of activities to enhance the fundamental role of science, CDRH should assess and reconsider the structure of OST to focus on emerging science and technology; this assessment likely will require a separate review of OST.**

Recommendations (Continued)

- 4. CDRH should develop a plan for enhancing cross-office and inter-agency (e.g., FTC, FCC) communication and collaboration.**
- 5. CDRH should establish an electronic database for liaison functions and an internal and external expertise inventory.**
- 6. CDRH should develop and implement a formal process for capturing institutional knowledge so that when a decision is reached it does not only remain in the “mind” of the reviewer.**
- 7. With the large staff turnover anticipated in the next 5 years and in order to fill gaps in scientific expertise, CDRH should expeditiously perform an assessment of the current level and breadth of expertise so as to develop a long-term strategic staffing and recruitment plan.**

Recommendations (Continued)

- 8. CDRH needs to develop procedures and staff development opportunities to ensure that reviewer mandates for such issues as sample size or randomized trials are shaped by realistic clinical perspectives and relevant ethical considerations.**
- 9. CDRH needs to streamline processes that encourage scientific growth within the staff and provide for a more inviting career path and reward structure for scientific personnel.**
- 10. CDRH should encourage and facilitate the use by ODE of internal, but non-ODE expertise and also external expertise, including the development of policies that promote a more liberal use of external experts.**
- 11. CDRH should expand its outreach to and scientific interactions with industry and universities.**

Recommendations (Continued)

- 12. CDRH should develop a plan in collaboration with other Centers for the evaluation of combination products; this plan may require changes in organizational structure and operational procedures**

- 13. CDRH should implement a quality evaluation and improvement program, and as part of this develop metrics for the assessment of quality as well as the timeliness of results.**

- 14. CDRH should implement a quality system with a focus on CDRH as an organization and on the development of activities that contribute to high quality decisions and the most productive use of resources.**

Evaluation of the Review Process

- **The review focused on the role of science in regulatory decision-making, not on the scientific laboratory research being conducted**
- **This subcommittee believes that this was the right focus and recommends it to the Science Board for use in future reviews**
- **The internal self study not only provided a foundation for the external review, but was a significant learning experience in its own right for CDRH**
- **The external review had three separate meetings, each of which was important to the total process**

Components of the Process

- **Case studies:** important to the success of these was the assignment at the initial preparatory meeting of small teams to investigate each case prior to the three-day review
- **Role playing:** for a variety of reasons this was not particularly useful
- **On-the-spot reviews:** did not provide anything significant, but was a very clear signal that any and all information was open to the review team
- **Industry interviews:** these would have been enhanced by these all being face-to-face

Components of the Process (continued)

- **International interviews: the review team was aided by having an individual from Health Canada on the subcommittee and the teleconference with David Jefferies from the U.K.**
- **CDRH management and staff meetings: equally important were our meetings with senior CDRH management and with staff without senior management present**
- **Union management meeting: could have been more useful if the meeting had been planned in advance**

Concluding Comments

- **This subcommittee commends CDRH for the dedication, integrity, and commitment to excellence exhibited by this effort.**
- **CDRH is in many ways doing an excellent job in carrying out its mission**
- **Even so, with new products arising out of the biological revolution and with breakthrough technologies which will be increasingly complex, CDRH will be significantly challenged**
- **This review thus was conducted in the spirit of assisting CDRH as it faces up to these challenges**
- **There clearly are changes necessary if CDRH is to significantly increase the role of science in regulatory decision making.**

Concluding Comments (continued)

- **These changes include a rethinking of how the business of CDRH is to be conducted, including possible alternatives in structure.**
- **Also included must be a reinventing of the CDRH staff through strategic recruitment, the continuous professional growth of existing staff, and policies that reward staff for the quality of their scientific expertise.**
- **CDRH must reach out to external resources to create partnerships that will accelerate making new technologies available that are both safe and effective so as to enhance patient benefit in America.**

Concluding Comments (continued)

- **Finally, the subcommittee appreciates the fact that these recommendations, if accepted, cannot be put into place overnight; the subcommittee suggests that these recommendations be incorporated as explicit components of the CDRH strategic plan.**