Research Peer-Review at CDER: Past and Present

At FDA, there are systems for ongoing peer-review of individual senior laboratory scientists in all Centers, and more similarities among the Centers than differences. In contrast, peer-review of research programs at FDA varies across Centers. In general, it is polarized into 2 different approaches.

For the past 20 years, 2 units at FDA have evaluated laboratory research programs via an "academic" model, i.e., through site visits conducted by advisory committees: CBER and NCTR. The other 5 units at FDA with lab programs (CDRH, CFSAN, CVM, ORA, and CDER) have used a "corporate" model, i.e., primary evaluation of research programs via internal Center (or ORA) management.

At CDER, the internal review of laboratory and non-laboratory research programs has been occasionally supplemented by external review. However, external reviews have been episodic rather than formally established and regularly conducted.

Examples of prior Ad Hoc External Reviews of CDER Programs:

FDA Science Board <external advisory committee>. Usually, one topic at a time, rather than full set of programs.

Ad Hoc review by Generic Drug Advisory Committee (predecessor of ACPS).

Information Briefings for the Advisory Committee for Pharmaceutical Sciences (ACPS). Continuing the tradition begun in GDAC, ACPS receives periodic briefings (e.g., October 2004; March 2003) and occasional training sessions (e.g., May 2005; July 2001) regarding OTR laboratory programs. In each case, there are opportunities to comment and provide feedback, but the sessions are not formally organized as a peer-review process.

Ad Hoc review of antiviral labs - actually, part of the charter of the Antiviral Drug Products Advisory Committee was to review the research programs of this lab. (Note: this lab has been abolished.)

Ad Hoc review of cardiovascular lab support (this program was abolished)

Examples of Ad Hoc Internal Reviews of CDER Programs

Annual Presentations to Center Director / Deputy Director.

CDER Research Coordinating Committee, RCC
Mission-oriented research at CDER is not limited to laboratory-based programs. Within OPS, research is also conducted in the immediate office, e.g., by the Informatics and Computational Safety Analysis Staff. When funds are available, extramural contract research is occasionally supported Elsewhere in CDER, research is conducted in various

units, especially the Office of Biometrics, Office of Drug Safety, Office of Information Management and Office of Clinical Pharmacology and Biopharmaceutics. Funding for research of these programs is primarily determined by Office management, with other sources listed below. The RCC has been established in various forms over the last 15 years to provide advice to Center management regarding the full range of internal research programs. The current RCC is chaired by the Deputy Center Director.

In addition to funds from individual organizational budgets, some central funding is available from CDER's "Review Science and Research (RSR)" program. Funding areas are determined by CDER management, and proposals are submitted for review by a committee of CDER scientists. Generally, the funds are not for laboratory research, but foster activities such as database generation within review divisions.

Other FDA sources of peer-reviewed funding for research are the FDA Office of Health Science Coordination and the FDA Office of Women's Health. Priorities for these programs are set by the management of the funding Office, and proposals are peer-reviewed for quality and relevance. Laboratory and non-laboratory proposals are accepted. Only internal FDA staff conduct the reviews.