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Report of a Workshop

TRAINING AND PROFESSIONAL SUPPORT OF MEDICAL REVIEWERS AT THE FOOD AND DRUG ADMINISTRATION

Forum on Drug Development and Regulation
Division of Health Sciences Policy

Institute of Medicine

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This meeting summary was prepared by J. Richard Crout, Chair, Workshop on the Training and Professional Support of Medical Reviewers at the Food and Drug Administration, Institute of Medicine, and the staff of the Institute of Medicine's Division of Health Sciences Policy. Major themes are reported to provide highlights of the conference discussions; however, they do not represent policy statements by the Institute of Medicine.

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TRAINING AND PROFESSIONAL SUPPORT OF MEDICAL REVIEWERS AT THE FOOD AND DRUG ADMINISTRATION

Introduction

On February 4-5, 1988, the Forum on Drug Development and Regulation, a project of the Institute of Medicine, National Academy of Sciences, sponsored a workshop on Training and Professional Support of Medical Reviewers at the Food and Drug Administration. The purposes of the workshop were (1) to bring together a small group of current and former FDA medical reviewers and managers and scientific leaders in academia and industry, and (2) to ask these participants to recommend an educational program for the training and professional support of medical reviewers at the Food and Drug Administration (FDA).

This report is the proceedings of the workshop, which was concerned with a few specific questions. Participants recognized that salary and funding levels, physical facilities, and congressional inquiries have an impact on the FDA, but chose not to concentrate on these issues specifically. The intention of the workshop was to evaluate and determine the appropriate professional environment, including training and support, for FDA medical reviewers.

Background

The medical reviewers involved in the drug review process at the FDA perform a unique function. These professionals are full-time federal employees who form the backbone of the FDA review process, and are responsible for review of all applications for drug approval. Medical reviewers at the FDA evaluate the clinical data on specific drugs, judge whether such data meet the scientific standards prescribed by law for the approval of these drugs for marketing, and provide leadership to the overall drug review team. These tasks carry enormous responsibility. Their evaluations not only determine the availability of new drugs for patient care, but also, their criteria and scientific recommendations influence the spending of billions of dollars for clinical research conducted worldwide.

However, little attention has been paid to the precise nature of this scientific review work. Much discussion has been devoted to the mechanics of the review process and to the roles of physicians, statisticians, pharmacologists, and other scientists in this process. But prior to this workshop the intellectual character of review work and the training and continuing education of reviewers were relatively unexplored topics.

The emphasis at the workshop was on medical reviewers at the FDA because of their critical importance to the technical review of individual drugs, and to the management of the whole review process. The workshop did not specifically address the training of FDA scientific review personnel in other disciplines (e.g., statisticians, pharmacologists, pharmacokineticists, and chemists) or the training of industry physicians and scientists involved in drug development.

Organization of the Workshop

The participants in the workshop are listed in attachment 1. The chair of the workshop was J. Richard Crout, the discussion leader for Group I was Alfred P. Fishman, and the discussion leader for Group II was Marcus Reidenberg.

Prior to the workshop the participants were given the specific questions to be addressed (listed in the agenda, attachment 2). Two speakers were selected to give their points of view on each question, and their remarks were followed by an open discussion in plenary session. The workshop was then divided into two groups: Group I was given the assignment of drafting answers to questions related to recruitment and training (questions 1, 2, and 5) and Group II drafted answers to questions related to personal talents and professional growth (questions 3, 4, and 6).

The two groups worked individually and their preliminary answers were then presented to the workshop in a plenary session. (Because of time limitations the plenary session review of answers to questions 5 and 6 was not held).

This report was prepared in draft form by the workshop chair and circulated to all workshop participants and the members of the Forum on Drug Development and Regulation for comment. After emendation, the final report was submitted to the Forum. The intent was to report consensus views.

The workshop is indebted to the participants who served as speakers for their thoughtful and stimulating presentations, to the rapporteurs for their careful drafting of replies to the questions, and to Steven J. Bongard and Kyung-Sook Lee of the Institute of Medicine for their excellent staff assistance.

Terminology

Medical Reviewer:

In the course of discussion it became clear that clinical reviews of certain new drug applications are currently done in part by non-physicians. The example cited was the review of applications for psychotropic drugs by Ph.D. psychologists who are experts in the rating scales and techniques applied in this field. In this instance the Ph.D. reviewer serves as the clinical reviewer for efficacy data, but the data relating to safety are reviewed by a physician.

This is a model that some FDA divisions have found successful and would like to consider expanding in the future. The participants noted that a related model is widely used in the drug industry where much of the work in organizing and conducting clinical trials, reviewing data, and writing reports is done by non-physician scientists. The workshop participants agreed that the term "medical reviewer" should properly include any scientist who reviews the clinical data in a new drug application. Nevertheless, the major focus of the workshop discussion was on physician medical reviewers because of the complexity of their roles, and the fact that most medical reviews are currently done by physicians.

Drug Evaluation Science:

There was additional discussion of whether the term "drug evaluation science" describes a medical discipline or a career path, with most participants favoring the latter. The distinction is not crucial for the purposes of this report; the term is used here to identify the complex set of professional activities performed by FDA medical reviewers for which specialized training, relevant experience, and professional skill are necessary.

Phase I, II, and III Clinical Trials:

The clinical investigation of a potential new drug is divided into three phases. Phase I is the initial testing of the substance in humans and is primarily designed to determine safety. Phase II studies are concerned with the product's efficacy and short-term safety. Phase III trials involve more patients, occur over longer periods of time, and are designed to provide data on optimum use, long-term safety, and less common side-effects.

The questions posed to the workshop, and the participants' answers, are as follows:

QUESTION 1. WHAT IS THE NATURE OF THE WORK THAT FDA MEDICAL REVIEWERS DO?

Medical reviewers work to carry out the FDA's responsibilities to the public as a regulatory agency. Reviewers are supposed to determine three things about a drug: whether it is effective; whether its benefits outweigh the negative effects; and the conditions under which it may be used. Reviewers play a pivotal role in the development of therapeutic agents by applying scientific and legal standards to a review of the data developed by drug manufacturers during the drug development process.

The reviewer's work on a new drug begins with the review of the Investigational New Drug Application (IND). This review must be completed before the drug can enter Phase I trials. During the early clinical pharmacology studies conducted under an IND, the medical reviewer, often working as the leader of a team that includes a chemist and a pharmacologist/toxicologist, is responsible for assuring that these early studies are carried out as safely as possible. Later in the drug development process, the medical officer and statistician provide advice on clinical study design and on the ultimate requirements for marketing approval to the drug company sponsors. This advice helps assure that the definitive clinical trials are properly designed and capable of providing the evidence on side effects and effectiveness that is needed for marketing approval. An important point in this process is the end-of-Phase-II meeting, and other meetings held with the sponsors and consultants, to help plan the large scale clinical trials conducted in Phase III.

When the marketing application (New Drug Application or NDA) on a new drug is submitted, the FDA medical reviewer is responsible for evaluating the clinical section of this substantial document (often 100 volumes or more). The reviewer is also commonly responsible for leading the review team (i.e., the chemist, pharmacologist/toxicologist, and medical officer) within the division handling the application, and for collaborating with the reviewing statistician, biopharmaceuticist, and outside consultants to recommend to the FDA whether the drug meets the scientific and legal

standards of safety and effectiveness required to permit marketing. Unlike a reviewer for a scholarly journal, who only sees a final manuscript, an FDA medical reviewer has access to the original data in each clinical trial.

The reviewer provides a written description of the design and results of each trial based on the sponsor's description and the reviewer's own review of the case records. Then, as the resident expert in the drug and disease area relevant to the drug, the reviewer brings expertise and judgment to bear in a critical analysis of these trials, including an evaluation of the adequacy of the database, the accuracy of the drug sponsor's analyses and conclusions, and an evaluation of the risks and benefits of the drug's anticipated conditions of use in the target patient population. This analysis requires a broad background of training and experience in the relevant medical specialty and expertise in the scientific method, clinical trial design, and data evaluation. General knowledge of drug regulatory law and public health policy is also needed.

Ultimately, in conjunction with other FDA scientists and outside advisors, the medical reviewer plays a key role in determining whether the drug is demonstrably effective for its intended use, has been properly evaluated for its risks, and is acceptably safe -- i.e., the benefits outweigh the risks. In reaching conclusions on these matters, the medical reviewer not only considers the adequacy of the clinical trials but also whether information crucial to proper use of the drug has been obtained, including data on associated adverse drug reactions, proper dose and dose-interval, and results in special patient populations such as children and the aged.

An important final responsibility of the medical reviewer is evaluation of the data to determine the conditions of use to be outlined in the label, such as the indications, directions for use, dosage, precautions, warnings, listing of adverse effects, and other information necessary for safe and effective use of the drug by physicians.

QUESTION 2. WHAT IS THE DESIRED TRAINING AND PROFESSIONAL EXPERIENCE FOR INDIVIDUALS AT THE TIME THEY ENTER A CAREER IN DRUG EVALUATION SCIENCE?

Excellent FDA medical reviewers have been recruited from a variety of different medical and scientific disciplines, and have a variety of prior professional experiences. Although a significant portion of the training is acquired on the job, there are certain backgrounds that are particularly beneficial.

It is desirable for reviewers to have advanced training or practical experience in the relevant subspecialty area of medicine and, in selected instances, clinical or laboratory research experience or special training in epidemiology, public health, biostatistics, and pharmacokinetics. For example, infectious disease training is valuable for someone reviewing antibiotics, and psychiatry for someone reviewing psychoactive drugs. Clinical pharmacology training is highly desirable in any drug review area.

Educational settings that may provide this training (beyond the M.D. degree) include internship/residency, medical subspecialty fellowships, postdoctoral clinical or laboratory research experience, and master's degree programs in public health.

Certain types of employment can provide the requisite educational training. These include academic or industry experience in designing, carrying out and evaluating data from clinical trials or laboratory research.

QUESTION 3. WHAT ARE THE DESIRED TALENTS AND SKILLS OF THE EXPERT MEDICAL REVIEWER?

A successful medical reviewer must possess a variety of native talents and acquired skills, some of which can best be attained at the FDA. Ultimately, the expert reviewer will have a thorough working knowledge of the current published world literature on one or more classes of drugs relevant to the drug under review, will have carefully reviewed the available unpublished data provided to the FDA, and will bring a broad understanding of the drug and the disease to each drug review.

Talents and Other Personal Qualities

The underlying talents needed by the expert reviewer are the same as those needed for success in other areas of biomedical science. First and foremost, a high natural intelligence is essential. In addition, the reviewer needs a scholarly temperament: a combination of intellectual curiosity, the desire to learn, open-mindedness, and an orientation toward the detailed evaluation of large quantities of complex data. He or she should be able to analyze information logically and critically, and form well-reasoned conclusions.

Self-motivation, self-confidence, and a commitment to high standards of excellence are also critical. FDA reviewers must be able to cope with the stress and demands associated with a powerful and responsible role in affecting patient care, the drug industry, and medical practice. Debate is frequently robust, and individual judgments may be challenged or rejected. Finally, personal integrity, fair-mindedness, and sensitivity to real or perceived conflicts of interest are necessary qualities of the expert reviewer.

Medical Knowledge

Most expert drug reviewers possess general medical training and often specialty or subspecialty training in the area in which they work. However, a medical degree is not always essential; in particular areas, other types of advanced professional training and appropriate clinical experience can be as useful. The expert reviewer is also sufficiently well-acquainted with pharmacology and toxicology, pharmacokinetics, biostatistics, and epidemiology to be able to interact with specialists in each area. Furthermore, each reviewer must be sensitive to issues of medical ethics and public health policy.

Biomedical Research Skills

Expert medical reviewers should understand the evolving biomedical and clinical research concepts in their disciplines, and participate in the disciplines by attendance at scientific meetings and consultation with experts. Expert reviewers also understand the process by which drugs are discovered and developed, the structure of drug developmental programs, the principles of design of individual studies, the integration of

information from multiple studies, and the ethical requirements for clinical trials.

Drug Evaluation Process Skills

Unlike most scientists, medical reviewers work under specific legal constraints and obligations in a public and often politicized arena. The expert reviewer should have a working knowledge of the history of drug regulation, the current law and regulations, and the interrelations of regulation and science. Medical reviewers also need to be sensitive to the concerns of FDA constituencies who are affected by, but are not immediately involved in, drug research and evaluation.

Communication Skills

The expert medical reviewer should communicate effectively. This requires more than proficiency in English and the ability to write clearly. It also means being able to articulate questions and observations precisely, to listen to others, to respond carefully, and to engage in scientific debate comfortably and confidently.

Administrative and Work Skills

The medical reviewer works as a member of a review team that includes a chemist, pharmacologist, statistician, and biopharmaceuticist and is usually the designated team leader. The entire review team evaluates massive amounts of data, and the review process requires extensive written documentation and supervisory concurrences. The expert medical reviewer therefore has managerial and negotiating skills, is able to manage his or her time and workload efficiently, and is tolerant of the administrative demands of the system. Increasingly, the expert medical reviewer must also understand computer applications in word-processing, data base management, and statistical analysis.

QUESTION 4. WHAT IS AN OPTIMAL PROFESSIONAL ENVIRONMENT FOR MAINTAINING THE SKILLS OF MEDICAL REVIEWERS?

An optimal professional environment would provide initial orientation to the specialized skills needed for drug evaluation and ensure maintenance of each reviewer's competence, efficiency and motivation. To this end, the following elements and associated programs would contribute to such an environment.

- Top-down management support of a collegial, scholarly environment, defined as one in which there is encouragemnet of scholarship along traditional academic lines, intra- and extramural learning, teaching, critical inquiry, and research. Outside professional/academic affiliations should be encouraged and attendance at relevant professional meetings is necessary.
- Opportunities for continuing professional development. These are essential, and up to 20 percent of duty time should be allowed. Such opportunities might include intramural or extramural research, teaching, writing, and/or clinical practices.
- Formal, individualized training programs, including initial orientation to the FDA and the job, mentored on-the-job-training in unique FDA medical officer skills, and continuing professional education.

- A relevant educational leave program for career medical officers for the acquisition of job related experience, and a reciprocal program for academic scholars to spend their sabbatical time at the FDA.
- The continued development of drug evaluation science as a discipline with its own unique combination of methodology, research problems, and policy issues.
- Adequate office space, conveniently located conference rooms, and research space with modern air-conditioning. Optimally, these would be located on or near an academic campus with adequate parking.

There must be adequate physical facilities and support services to perform professional duties. Implementation of the above conditions may well require additional resources for direct costs and to maintain review activities.

QUESTION 5. WHAT IS A RECOMMENDED TRAINING PROGRAM FOR INDIVIDUALS WHO ENTER DRUG EVALUATION SCIENCE?

It is almost always necessary that individuals entering the career field of drug evaluation science have postgraduate training. Two strategies are proposed to address this.

A training experience or program could be developed as part of an orientation program within the FDA. Newly hired medical reviewers who have strong training in specific areas but deficiencies in others might be targeted for selected training and exposure to those areas in which additional training is needed. Thus, for example, a medical reviewer with a strong clinical background in infectious disease might get needed academic exposure to the pharmacokinetics of antibacterial agents, or to current immunological concepts of AIDS, through a 2-3 month paid educational leave. Similarly, if it was deemed important for a medical reviewer in psychopharmacology to have greater training in biostatistics, that might be accomplished with a 2-3 month leave within the agency or at some external training site. Additional experiences could be arranged in clinical pharmacology, pharmacoepidemiology, management skills, and the like.

Another strategy for a postgraduate training program after medical residency and subspecialty training is an organized fellowship environment. Such a program should be aimed toward the career path of a medical reviewer in drug evaluation science and be sponsored by academic and industry efforts as well as the FDA. The fellowships could be set up as part of a clinical pharmacology training program with a specialty in drug evaluation science.

A two-year program, for example, could include 18 months outside the FDA and 6 months within it. The first year would take place in a clinical pharmacology division of an academic center that is actively engaged in clinical research and that has a clinical pharmacology consulting service. This would enable the fellow to have hands-on involvement with all aspects of the conduct of a clinical study: obtaining approval of the Institutional Review Board (IRB), recruiting subjects, planning and conducting the study, dealing with adverse drug effects, analyzing the data and publishing the results. The fellow might then spend two months in a Phase I/early Phase II clinical pharmacology unit in the

pharmaceutical industry, and two months in a later Phase II/Phase III medical investigative group in industry.

Additional training outside the FDA should include periods of training in (a) pharmacoepidemiology at the FDA or in a specialized center, (b) management skills and writing skills pertinent to report writing and (c) legal issues specific to the regulatory process. The final 6 months of the formal program would provide a training, orientation, or apprenticeship experience within the FDA.

These strategies are ambitious, and would require a large commitment from both the candidates and the institutions affiliated with the program. The workshop participants felt that, under either strategy, appropriately trained medical reviewers could be educated to carry out their important function. It was also felt that the proposed clinical pharmacology fellowship was sufficiently lengthy and demanding that federal fellowship support would be necessary to attract qualified applicants.

QUESTION 6. WHAT IS A RECOMMENDED PROGRAM FOR FOSTERING THE PROFESSIONAL GROWTH OF PHYSICIANS AND SCIENTISTS WITH CAREERS IN DRUG EVALUATION SCIENCE?

Those recruited to careers in drug review medicine will come to the Food and Drug Administration with a wide variety of potentially useful professional backgrounds, skills, and attitudes. To be certain that all reviewers initially are prepared to carry out their duties, they should take part in a formal orientation program that will ensure the cultivation of working knowledge in disciplines necessary to their task.

The orientation program should include the history of drug development and regulation, the relationships between science and administrative law, the legal basis of drug regulation, and the role and function of the FDA and its drug review offices. In addition, the orientation program should begin to make up for any gaps identified in the reviewer's educational background. Thus the orientation program should offer training in the planning and conduct of clinical trials, biostatistics, epidemiology, pharmacokinetics, the scientific method, etc.

To encourage all reviewers to improve their knowledge and skills throughout their careers, the FDA must develop a formal professional development program in which all reviewers participate. The program should provide individual counseling and monitoring, to insure careful evaluation and planning of each review officer's career in drug evaluation science.

Ideally, such a program would consist of both intra- and extramural activities. These activities should bring agency personnel together with leading scientists from academic and industrial settings in settings conducive to continued learning.

The intramural activities would include a variety of lectures, seminars, conferences, workshops, journal clubs, and research opportunities both for agency personnel and visiting scientists. Particular attention should be devoted to research and policy studies related to drug evaluation science. The formation of a "staff college" within the FDA that would serve as the organizational vehicle for the intramural program is encouraged.

Extramurally, drug reviewers should have regular opportunities to expand their learning environment beyond the confines of the agency. Each reviewer should attend at least one major scientific meeting each year, and have the opportunity to participate in other seminars, conferences, and meetings.

Each reviewer should be encouraged to take advantage of opportunities for professional development within the agency, in other governmental entities such as the National Institutes of Health, and in universities, research institutes, and hospitals. The agency should allow at least 20 percent of duty time (e.g., one day/week, 6 weeks/year or 3 months/2 years) for such activities as part of the individual reviewer's career plan.

The ideal program would encourage reviewing officers to take leave for purposes of continuing education or research. Selected reviewing officers would be eligible for 3-6 months leave after each three years of service, or 6-12 months of leave after every six years of service.

The physical setting of the intramural activities must be conducive to breaking down barriers to communication both among agency personnel and with the outside world.

Finally, a mechanism for securing private funding to help support the professional development program should be considered. A private foundation might be established to serve as a receiver of funds that could be used to support research, education, research scholarships, visiting professors, and trainees.

Summary

The following picture emerged of the characteristics of expert medical reviewers. They are intelligent persons with a keen interest in the evaluation of data from clinical trials. They are scholarly, interested in learning, and detail-oriented. They have the discipline to adhere to appropriate scientific and legal standards in reviewing data, the judgment to reach sound conclusions on the basis of evidence, and the capacity to work under stress. Finally, the medical reviewer must be a person of high integrity and balanced judgment.

The medical review of a new drug application was described as having as its first essential element a critical description of the database, i.e., a systematic, succinct description of each clinical trial with the essential findings. It is this critical and penetrating assessment of the actual data behind the figures and tables that distinguishes an FDA review of a clinical study from the typical review of a paper submitted for publication in a peer-reviewed journal.

The next step in the medical review is a thoughtful evaluation or analysis of the significance of each clinical trial, an exercise in judgment that is similar to the peer review of a research grant proposal or publication manuscript. The final step is a conceptual synthesis of the evidence from all studies in the New Drug Application with a recommendation on whether the legal standards for drug effectiveness and safety have been met.

The medical reviewer is responsible for ensuring that the wording in the package insert (the labeling) is both adequate to guide physicians in prescribing the drug and is supported by the evidence in the application.

It was emphasized by FDA officials that successful completion of the first step in the process -- namely, the creation of a systematic, concise description of the clinical database -- is essential for subsequent handling of the application. If this is done well the FDA management, advisory committees, and others can bring their own judgment to bear in a global appraisal of benefit-risk issues related to the drug. However if the clinical trials are poorly described no one else can bring thoughtful consideration to the evidence in the application.

The personal and professional rewards of medical review work include intellectual stimulation in an intense problem-solving environment, continual on-the-job learning, a sense of responsibility and excitement in bringing new therapeutic agents to the public, the opportunity for contact with medical and scientific leaders in the field and, as one FDA official expressed it, "the chance to see everyone's breakthroughs a year ahead of time."

On the negative side, the actual mechanics of conducting a review can be tedious, the Parklawn Building (housing FDA offices in Rockville, Md.) is unattractive and crowded, the workload is heavy, many of the freedoms and rewards of academic life are missing, and there is a potential for reviewers to become isolated from the mainstream of medical practice and biomedical science. Special attention to these issues is needed to assure that the negative aspects of the working environment do not overburden the fundamentally challenging and intellectually rewarding character of drug evaluation.

In considering the ideal educational background for medical reviewers, the workshop noted that successful reviewers have come from a variety of medical and scientific backgrounds. The ideal training was considered to be postdoctoral training in the relevant subspecialty of medicine and a user's knowledge (not necessarily expert knowledge) of clinical pharmacology, clinical trial design, pharmacokinetics, statistics, drug epidemiology, and regulatory law. Excellent writing skills were considered essential and computer literacy helpful. Experience in either clinical or laboratory research is valuable, though experience in clinical practice beyond that acquired in specialty training was not considered necessary. Because medical reviewers commonly function as the leaders of the review team for each drug, leadership, management and negotiating skills are highly desirable.

In considering the optimal professional environment for medical reviewers, the workshop recognized the unattractive physical facilities and geographic isolation of the Parklawn Building, the work overload, and the special limitations on FDA employees with respect to consulting and outside employment. Nevertheless, the workshop participants felt that, under the proper conditions, both drug evaluation science and medical reviewers can flourish in less than optimal surroundings. These conditions include management support of a scholarly environment, opportunities for work-related and/or extramural research, the availability of training programs, the opportunity for extended educational leave to an outside medical center or laboratory, and strong support for scientific seminars and for travel funds so that each reviewer can attend at least one major scientific meeting per year. The idea of funding some of these activities through a private foundation was raised, and the workshop encouraged further exploration of this possibility.

Specific ideas discussed at the workshop were as follows:

1. The FDA could establish a set of courses targeted to the needs of individual reviewers. This program might cover such content areas as clinical pharmacology, pharmacokinetics, clinical trial design and biostatistics, drug epidemiology, and drug regulatory law and review policies.

Each content area could be covered by a course sponsored by a local university, the Foundation for Advanced Education in the Sciences (FAES) or the proposed FDA staff college. These courses would provide a general training program suitable both for newly recruited and current reviewers, depending upon individual needs. These courses could present practical, usable information, and ideally would be given at or near the Parklawn Building during work hours or in the evening. All medical reviewers would be expected to master the content of these courses, and additional courses in management skills and computer skills could be made available.

2. To fulfill special needs, the FDA could encourage selected medical reviewers to take 2-3 month paid educational leaves to selected medical centers or laboratories for specialized training. This training could be in a medical subspecialty or one of the areas noted above.

3. The FDA could also consider supporting an organized two-year post-doctoral fellowship program that would train particularly promising individuals for a career in drug evaluation science. Such a program might be structured as follows: one year in clinical pharmacology at an academic medical center, six months in the clinical pharmacology and clinical development groups of a drug firm, and six months in a mentored training experience at the FDA. Fellowship funding for trainees would need to be provided.

4. To assist in maintaining the quality and professional growth of its staff, the FDA could establish a formal professional development program for its reviewers. This program would provide for individual counseling and monitoring and require a professional development plan for each reviewer. Possible activities might include:

- Extramural research or clinical experience (up to 20 percent of duty time) spent internally at the FDA, at a local university, or at the National Institutes of Health.
- Participation in a clinical research unit and/or an Institutional Review Board at a local hospital or the National Institutes of Health.
- Teaching at a local university, FAES or the proposed FDA Staff College.
- Short (2 weeks to 2 months) visits or guest worker experience in clinical pharmacology and/or clinical development departments of drug firms.
- Writing scholarly reviews or research papers on topics related to drug evaluation science, such as clinical trial design and analysis, the detection of adverse events, or drug regulatory policy.
- An extended (3-12 months) educational leave experience for research and continuing education at a university.

5. A continuing well-organized program in the Parklawn Building is essential to keeping FDA reviewers in communication with their scientific fields. The basic essentials of such a program are:

- Regular seminar programs.

- Providing financial support and time for each reviewer to attend at least one major scientific meeting per year.
- Management encouragement of research and publication, particularly on technical and policy matters in which FDA staff has unique expertise and experience.

6. The FDA might consider the possibility of supporting some of these activities through a private foundation.

In making these observations, the workshop participants did not want to imply that none of these activities currently exists at the FDA. Indeed a number of these ideas stem from the experience of the FDA in training its personnel and reflect ongoing programs and policies. The intent was simply to outline a comprehensive framework for the training and professional support of scientists who have careers in this small but extremely important medical field.

Two themes that repeatedly appeared in the discussions were not fully addressed by the questions. These deserve highlighting in this summary:

1. Concern was expressed that the overall compensation of FDA medical reviewers is increasingly noncompetitive in comparison to similarly trained physicians in academia, the drug industry and medical practice. Many workshop participants felt this issue is at least as important to the recruitment and retention of an excellent staff, and perhaps more so, than the training/professional development issues before the workshop.

2. There was considerable sentiment that an effective training and professional development program must go beyond formal courses and passive learning opportunities (e.g., seminars and meeting attendance) and include ongoing "reality-based" clinical research experience. This could be done through participation in clinical studies at local universities and/or short-term guest worker experience in the clinical development departments of drug firms. It was recognized that implementation of such activities would require special management attention to resolving potential conflict of interest problems and relieving productive reviewers from overburdened workdays so they could participate. Nevertheless, the advantages to the FDA of reviewers having firsthand knowledge of the clinical research process, in both medical clinics and the drug industry, was felt worth the effort.

The workshop participants recognized that any increased implementation of training and professional development programs would require resources -- not only money and personnel, but also management attention, vision and long term investments by the agency and the Congress.

Attachment 1

Workshop Participants

William B. Abrams	Merck Sharp & Dohme Research Laboratories
William T. Beaver	Georgetown University
Leslie Z. Benet	University of California at San Francisco
James M. Bilstad	Food and Drug Administration
Gregory P. Burke	Food and Drug Administration
Christine K. Carrico	National Institutes of Health
J. Richard Crout	Boehringer Mannheim Pharmaceuticals Corporation
Alfred P. Fishman	University of Pennsylvania
Edward J. Huth	Annals of Internal Medicine
Leonard S. Jacob	Smith Kline and French Laboratories
Marvin E. Jaffe	Merck Sharp & Dohme Research Laboratories
Ruth L. Kirschstein	National Institutes of Health
Ronald L. Krall	Lorex Pharmaceuticals
Thomas P. Laughren	Food and Drug Administration
Louis Lemberger	Lilly Research Laboratories
Robert T. O'Neill	Food and Drug Administration
Carl C. Peck	Food and Drug Administration
Paul H. Plotz	National Institutes of Health
Marcus M. Reidenberg	Cornell University
Alexander M. Schmidt	University of Illinois
Barrett Scoville	Otsuka Pharmaceutical Co.
Edward Tabor	Food and Drug Administration
Robert J. Temple	Food and Drug Administration
William W. Vodra	Arnold and Porter
Raymond L. Woosley	Georgetown University School of Medicine

Attachment 2

Agenda

Thursday, February 4, 1988

10:00 am	Introduction and Charge to Workshop - J. Richard Crout
10:15 am - 12:30 pm	Plenary Session I
	Question One - What is the nature of the work that FDA medical reviewers do? Speakers - Robert Temple, Edward Huth Rapporteur - Raymond Woosley
	Question Two - What is the desired training and professional experience for individuals at the time they enter a career in drug evaluation science? Speakers - Barrett Scoville, William Beaver Rapporteur - William Vodra
12:30 pm - 1:00 pm	Lunch
1:00 pm - 3:00 pm	Plenary Session II
	Question Three - What are the desired talents and skills of the expert medical reviewer? Speakers - Louis Lemberger, Robert O'Neill Rapporteur - Edward Tabor
	Question Four - What is an optimal professional environment for maintaining the skills of medical reviewers? Speakers - Marcus Reidenberg, Alexander Schmidt Rapporteur - Carl Peck

3:00 pm - 6:00 pm	Working groups retire to different rooms for discussion and drafting of replies to questions 1, 2, 3 and 4.
6:00 pm	Reception and Dinner

Friday, February 5, 1988

Plenary Session III

8:30 am - 11:00 am	Discussion of replies to Questions 1 to 4
11:00 am - 12:30 pm	Question Five - What is a recommended training program for individuals who enter drug evaluation science? Speakers - Raymond Woosley, Leslie Benet Rapporteur - Louis Lemberger Question Six - What is a recommended program for fostering the professional growth of physicians and scientists with careers in drug evaluation science? Speakers - Marvin Jaffe, Carl Peck Rapporteur - Alexander Schmidt
12:30 pm - 1:00 pm	Lunch
1:00 pm - 3:30 pm	Groups I and II answer questions 5 and 6
Omitted	Plenary Session IV
	Discussion of replies to Questions 5 and 6
3:30 pm	Adjourn

Attachment 3

Discussion Groups

Group I	Group II
William B. Abrams	William T. Beaver
Leslie Z. Benet	James M. Bilstad
Alfred P. Fishman*	Gregory P. Burke
Edward J. Huth	Marvin E. Jaffe
Leonard S. Jacob	Ronald L. Krall
Thomas P. Laughren	Carl C. Peck
Louis Lemberger	Marcus M. Reidenberg*
Robert T. O'Neill	Alexander M. Schmidt
Paul H. Plotz	Barrett Scoville
Edward Tabor	William W. Vodra
Robert J. Temple	
Raymond L. Woosley	*discussion leader

(Drs. Carrico, Crout and Kirschstein served as resource persons to both groups).