CDRH Annual Report
Fiscal Year 2000

OUR VISION:
Ensuring the health of the public throughout a product's life cycle.

CONTENTS

January 16, 2001

Dear Medical Device Manufacturer:

Our Fiscal Year 2000 report again has three tiers. The first is this letter, which will briefly touch on a few of the most significant CDRH activities over the past year. For those interested in more complete coverage of our programs, the next tier is a comprehensive CDRH report, which you will find on our website, see (http://www.fda.gov/cdrh). That report in turn will give you access to the final tier: specific links that provide even greater detail on certain programs and activities. So you can dig as deeply and selectively as you like.

Communicating with the industry

I believe that keeping our lines of communication open and our expectations clear can help avoid needless conflict between our Center and device manufacturers. Towards that end, I've made a strong effort to meet with as many of you as possible over the past year, with 50 talks at industry-sponsored meetings. I'm also glad to report that many of you have communicated concerns and suggestions to me directly via e-mail (Director@cdrh.fda.gov), and I invite more of you to do this.

Good communication notwithstanding, disputes between our Center and individual manufacturers are bound to arise from time to time. To help resolve such disputes, as well as prevent them from occurring, I've appointed the Center's first ombudsman, Mr. Les Weinstein, who reports directly to me. Les has already made himself known to many of you, and this process will continue in the coming year.

FDAMA

We're now in our third year of implementing the FDA Modernization Act (FDAMA), and this continues as a high-priority effort. Over the past year we've expanded the list of devices eligible for third-party review, and, in concert with an industry task force, we're working to translate the "least burdensome" provision of the law into guidance that we can use in all of our activities.

Bringing New Products to Market

"Timely decisions based on sound science" continues to be our goal in this area--a goal we think we met in FY 00. For example, our average review time for 510(k)s was the shortest in over a decade. For PMAs, our average review time was even better than last year's, and represented a 54 percent reduction from the "peak" time registered in 1996. With IDEs, we approved a greater percentage of devices for use in clinical trials during the first 30-day cycle than in any prior year. And of course long "backlogs" remain a thing of the past throughout our premarket program.

Along with outstanding performance came new leadership. In July we welcomed Bernard E. Statland, M.D., Ph.D., as the Director of the Office of Device Evaluation. Bernie's management team was augmented by the addition of a third deputy director, Daniel Schultz, M.D., who will work with existing deputies Phil Phillips and Kimber Richter, M.D.

Assuring Safe Products in the Marketplace

Thirty-eight manufacturers participated in our new Alternative Summary Reporting program, which allows them to submit summary adverse event reports in lieu of full reporting. In the months to come we expect that more will enroll in the program, which saves time and effort for both our Center and the industry.

We also continue to move ahead with the Medical Products Surveillance Network (MedSuN), a pilot project for gathering adverse events information that relies on in-depth information from a subset of user facilities rather than on universal reporting.

Radiological Health

Part of our Center's mission, as embodied in its name, is to ensure the safety of radiation-emitting consumer and industrial products. Because of the need to transfer funds and personnel over the past two decades from radiological health to medical device activities, the radiological health program, which now has only 10 percent of the Center's resources, cannot adequately do its job under the law. The situation is worsening through personnel loss, and also because changes in product technology and an increase in overseas manufacturers will require more of our attention.

We're committed to revitalizing the radiological health program, although in the absence of significant new funding we can't undertake major changes. Relying on ingenuity and leveraging with others, we're exploring several possibilities, including further work with the States, training manufacturers to perform certain inspections themselves, "triaging" manufacturer reports, and making use of retired Center radiation experts.

Re-use of single-use devices

The reprocessing of single-use devices by hospitals and third parties continues to be an important issue from the standpoint of both public health and medical economics. Our goal in this area is to assure patient safety with minimum impact on health care costs. Toward this end, we issued formal guidance on our plan to enforce premarket submission requirements for third party processors and hospitals the same way we do for original equipment manufacturers. The first phase of our enforcement program will take effect in February 2001 (see http://www.fda.gov/cdrh/reuse/index.shtml).

Strategic planning

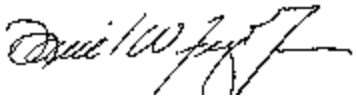
This past year we worked hard to develop a strategy for the future-- a statement of the broad principles and goals to which we will commit ourselves over the next several years. As a first step, we re-affirmed our ***mission***: to promote and protect the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products. Then we developed a ***vision***: ensuring the health of the public throughout a product's life cycle. And finally we proposed four ***strategic goals*** to fulfill the vision: (1) to apply the total product life cycle model across the

Center's activities; (2) to serve as a magnet for excellence in attracting and retaining a diverse workforce who want to help us fulfill our public health mission; (3) to manage knowledge in support of the total product life cycle model; and (4) to develop meaningful metrics to assess our continuing impact on public health and our communication with stakeholders.

A more detailed description of the Center's strategic plan can be found at www.fda.gov/cdrh/ocd/strategic.html. I invite you to look it over and send me your comments. We're now embarking on the first stage of implementation, and I welcome any suggestions you might have.

This has been a stimulating year, in which we addressed long-standing Center issues and confronted new challenges. For me, one of the most satisfying aspects of Fiscal Year 2000 was having the opportunity to meet with so many of you to discuss issues of common concern. I look forward to more of these exchanges.

Sincerely yours,



David W. Feigal, M.D., M.P.H.
Director, Center for Devices and
Radiological Health

I. Bringing New Products to Market

New Leadership . . .

In July 2000, the Center filled a key position when it welcomed Bernard E. Statland, M.D., Ph.D., as the new Director, Office of Device Evaluation (ODE). Dr. Statland is a board certified clinical pathologist and brings a wealth of experience to the Center's premarket program. He leads an experienced management team that includes ODE Deputy Directors Philip Phillips, Kimber Richter, M.D., and—most recently—Daniel Schultz, M.D. Dr. Schultz directed ODE's Division of Reproductive, Abdominal and Radiological Devices before his September 2000 selection as an ODE Deputy Director.

. . . and Continued Success

Our premarket review processes remained highly productive and timely during this period of management transition. We maintained—and, in some areas, even improved upon—last year's near-record performance, allowing safe and effective devices to reach the market rapidly. For the fourth consecutive year, no premarket submissions were overdue at the year's end.

- Premarket Notification (510(k))
  Most medical devices receive premarket review through the 510(k) process. In fiscal year 2000, we reviewed 4,397 510(k) submissions, slightly less than the 4,593 reviews completed last year. Our average review time (77 days) was the shortest in more than a decade. The average total elapsed time to clearance (which includes time while FDA review was "on hold" awaiting more information) remained stable at 102 days.

- Premarket Approval
  Premarket approval applications (PMAs) represent the highest level of regulatory scrutiny applied to medical devices. We approved 43 PMAs this year, compared to 39 approvals last year (not including HDE applications, discussed below). Average total elapsed time to PMA approval was 11.9 months, an improvement from last year's average of 12.5 months, and a 54 percent reduction from the "peak" time of 25.9 months in fiscal year 1996. In addition, we approved 474 PMA supplements, the most in any year since 1991. The average total elapsed time for approval of PMA supplements was 4.0 months—comparable to last year's average of 3.9 months, the most rapid since the early days of the PMA program.

- Humanitarian Device Exemption (HDE)
  HDE applications are similar in form and content to PMAs, but are exempt from the effectiveness requirements of PMAs. We approved 6 HDE applications this year, the same number as in Fiscal Year 1999. The average total elapsed time to approval increased from 163 days to 216 days, but our average review time (i.e., excluding time "on hold") was 112 days, similar to last year's average of 113 days.

- Investigational Device Exemption (IDE)
  IDEs are the mechanism through which FDA assures that human subjects are protected in medical device clinical trials. We reviewed 320 original IDE submissions in Fiscal Year 2000, the second highest number of reviews completed in any year since the IDE program began. We also reviewed 4,335 IDE supplements this year, more than any prior year. Our average review time for original IDE submissions (28 days) was similar to last year's average (27 days). Seventy-six percent of original IDEs were approved for clinical trials in their first 30-day cycle—a greater percentage than in any prior year. Our average review time for IDE supplements remained at last year's level (20 days), which was the best in the history of the program.

Significant Advances in Patient Care

Underlying the program statistics are the products that we review. This year, we granted marketing approval or clearance to numerous medical breakthrough devices that will provide significant improvements in patient care. These devices reflect the increasing sophistication and complexity of medical technology. Examples include:

- A robotic arm that enables a surgeon to perform laparoscopic gall bladder and reflux disease surgery while seated at a console with a computer and video monitor;

- A digital mammography system for breast cancer screening in women. This new technology offers several potential advantages over film/screen mammography, including electronic storage and transfer, manipulation of image area, and large dynamic range;

- A new type of fetal monitor that measures oxygen saturation in the baby's blood as a sign of fetal health during labor and delivery;

- A surgically implanted device intended to help adults with moderate to severe nerve hearing loss, as an alternative to traditional hearing aids;

- A new type of artificial embolization device used to occlude blood flow to facilitate surgical treatment of cerebral arteriovenous malformations (AVM);

- A cardiac catheter with technology that allows more rapid and accurate mapping of the inside of the heart to improve the technique of cardiac ablation for treating arrhythmia;

- Diagnostic tests for detecting chronic alcohol abuse, to help triage patients with alcoholism and to monitor compliance with treatment programs;

- A laser device for treatment of hyperopia, hyperopic astigmatism, and mixed astigmatism; and

- A new type of surgical sealant used to seal air leaks in lungs following lung cancer surgery.

Improved Communication

Recent approvals, such as those listed above, are being communicated to the public through a new web page (http://www.fda.gov/cdrh/mda/index.html). This initiative recognizes the public's rapidly growing use of the internet to obtain important health-related information. The new web page contains timely, consumer-oriented information about recently approved devices.

Greater Efficiency and Effectiveness

We continued efforts to increase the efficiency of premarket reviews and to focus our review resources on devices that present the most risk. For example:

- In March 2000, we published a final rule down classifying 28 well-understood, pre-1976 device types from Class III (premarket approval) into Class II (special controls). Had we not initiated this action, these devices—such as denture repair kits—eventually would have required premarket approval even though other, less costly controls are sufficient.

- In April and July 2000, we published final rules for four pre-1976 Class III devices, so that they now require premarket approval.

- In August 2000, we down-reclassified, from Class III to Class II, extracorporeal shock wave lithotripters used for fragmentation of kidney and ureteral stones. This action is noteworthy not only because it exemplifies our efforts to reduce regulatory burdens—consistent with the least burdensome provisions of the FDA Modernization Act of 1997 (FDAMA)—but also because it represents our first use of FDAMA's 6-year data provision (Section 216). The 6-year data provision allows reclassifications and certain other actions to be based on data contained in PMAs that have been approved for at least 6 years. PMA data provided part of the basis for this action. (This use of the 6-year provision also led to the issuance of FDA guidance on how the provision will be used in the future--see additional information on the implementation of FDAMA elsewhere in this Annual Report).

New Challenges

Even as we strive to keep pace with a diverse and dynamic industry and to make improvements to our review processes, new challenges arise. One such challenge stems from the Clinical Laboratory Improvements Amendments of 1988 (CLIA). In January 2000, the responsibility for categorization of commercially marketed products under CLIA was transferred from the Centers for Disease Control and Prevention to FDA. This allows manufacturers to submit premarket applications for products and CLIA requests for complexity categorization of those products to one agency. This year, we issued draft guidance on the administrative procedures for CLIA categorization (see http://www.fda.gov/cdrh/ode/guidance/1143.pdf) and took other steps to address this new responsibility. We also addressed premarket issues associated with preparations for Y2K, re-use of single use devices, global harmonization, and other challenges.

II. Regulatory Science and Standards

Some of the Guidance Documents Issued For Industry

- In August 1999, we issued a draft guidance document entitled, "Electro-optical Sensors for the In Vivo Detection of Cervical Cancer and its Precursors: Submission Guidance for an IDE/PMA, Draft Guidance." This document includes the requirements for a clinical protocol based on reported medical indications. Also addressed are requirements to provide a complete description of the optical radiation aspects of the device, the calibration procedures planned and the hazard analyses of the optical radiation emissions. These requirements help both the agency and the sponsors in determining whether a device is either "Significant risk" or "Non-significant risk".

- In October 1999, we issued a guidance document entitled, "Information Disclosure by Manufacturers to Assemblers for Diagnostic X-ray Systems" to clarify the requirement to provide assembly, installation, adjustment, and testing instructions, whether printed or software (see http://www.fda.gov/cdrh/comp/2619.html).

- In March 2000, we issued a guidance document entitled, "Use of Standards in Substantial Equivalence Determinations" (see http://www.fda.gov/cdrh/ode/guidance/1131.pdf) clarifying how information on conformity with standards may be used to support 510(k) substantial equivalence determinations. This guidance document, along with other initiatives such as our June 2000 expansion of the 510(k) third-party review program (see http://www.fda.gov/cdrh/thirdparty), were aimed at stimulating greater industry use of streamlined submission/review procedures. The results are encouraging—our combined receipts of *abbreviated* and *special* 510(k)s, plus *third party-reviewed* 510(k)s, rose from 513 in fiscal year 1999 to 778 this year, a 52-percent increase. These streamlined submissions now comprise nearly one-fifth of all 510(k) receipts. Similarly, in the PMA process, *real time* PMA supplements account for more than one-fourth of all PMA supplements received.

- In August 2000, we issued a guidance document entitled, "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals." This guidance document finalizes FDA's policy on how it intends to regulate entities that reprocess devices intended for single-use for reuse in humans. This document sets forth FDA's priorities for enforcing premarket submission requirements, based on the device's Code of Federal Regulations classification. Beginning on February 14, 2001, the agency will enforce premarket submission requirements for all class III single-use devices that are re-used. Beginning on August 14, 2001, and February 14, 2002, respectively, premarket submissions will be required for all non-exempt class II devices and non-exempt class I single-use devices that are re-used. . In addition to the premarket requirements, entities engaged in reprocessing of single-use devices also must comply with requirements pertaining to registration and Listing; Medical Device Reporting; Medical Device Tracking; Medical Device Corrections and Removals; Quality System Regulation; and Labeling. The findings of the laboratory studies on issues associated with the reuse of single use devices added substantially to the science base for these regulatory decisions on reuse of single use devices.

- In August 2000, we issued a guidance document entitled, "Labeling for Electronic Anti-Theft Systems" (see http://www.fda.gov/cdrh/comp/guidance/1170.html). Electronic implantable medical devices may be affected by the radiated emissions of electronic anti-theft systems. The 1998 and 1999 meetings of the Technical Electronic Product Safety Standards Committee (TEPRSSC) recommended that various groups, including anti-theft system manufacturers, the medical community, and the retail industry work together to develop solutions to this issue. Although the risk of interference is low (a relatively low number of incidents of interference and primarily moderate or mild incidents), we recommend posting labeling or signage on or near anti-theft systems so that implant wearers can take appropriate precautions when entering or leaving areas containing these systems. The precautions, recommending that implant wearers "don't linger, don't lean" near these systems, resulted from research conducted by the medical community in collaboration with anti-theft system manufacturers. The Office of Surveillance and Biometrics notified physicians of the necessary precautions in a 1998 informational letter.

- In September 2000, we issued a guidance document entitled,"Wireless Medical Telemetry Risks and Recommendations" (see http://www.fda.gov/cdrh/comp/guidance/1173.html). The guidance was drafted as part of a our Electromagnetic Compatability (EMC) Working Group action plan to endorse a recently adopted U.S. Federal Communications Commission (FCC) rule to create the Wireless Medical Telemetry Service (WMTS). The WMTS provides a spectrum for primary use by medical telemetry to reduce the risk of interference to telemetry equipment from other radiofrequency (RF) transmitters. The guidance primarily recommends that all wireless medical telemetry manufacturers conduct a risk analysis to determine whether their equipment is at risk of interference, and to take action to reduce the risk to their equipment as appropriate. The guidance also encourages manufacturers of wireless medical telemetry equipment to use the new WMTS to minimize the risk of interference from other in-band RF transmitters.

Some Performance Standards for Industry

- In May 2000, we finished implementing our first medical device performance standard entitled, "Electrode Lead Wires and Patient Cables". The standard responds to reports of patient deaths caused when the cables were accidentally plugged into110 volt wall circuits. The standard requires electrically protected connectors for electrode lead wires and patient cables to prevent unintended electrical shock or electrocution. It now applies to all medical devices that use patient connected electrodes – both new devices and devices already in use in healthcare facilities.

- We are drafting proposed amendments to our performance standard for laser products promulgated under Chapter 5, Subchapter C of the Federal Food, Drug and Cosmetic Act. The proposed amendments are intended to reduce the gap in requirements between our Center standard and that of the International Electrotechnical Commission (IEC) and the European Community (CENELEC).

- We proposed and received approval from the American National Standards Institute's Accredited Committee N43 to develop a new standard for use of x-rays for non-medical screening of people to detect contraband and weapons. This new technology uses a small fraction of the radiation dose common in medical diagnostic procedures, but has a potential of

exposing large populations to ionizing radiation. Our staff is currently working on measurement protocols for this standard (see http://www.fda.gov/cdrh/ost/reports/fy99/OSTfy99.html).

- We served a leading role in the development of the International Organization for Standardization (ISO) performance standard for the quality and safety of ophthalmic diagnostic instruments. Standard ISO 15004 includes proposals for new emission limits, for classification of ophthalmic instruments, and performance requirements for the devices. Manufacturers will be able to certify conformance with this standard when they apply for approval of a new product.

- We participated in the review and further development of the draft ISO standards TC WG 4-14155-2, "Clinical Investigation of Medical Devices for Human Subjects, Part 1: General Requirements" and "Part 2: Clinical Investigation Plans", which cover specific requirements for the conduct and documentation of device clinical investigations. The draft ISO standards were reviewed as part of our Center's heightened awareness of the need for universal guiding principles regarding the proper conduct of medical device clinical trials and the protection of human research subjects.

- We prepared, submitted and the American Society for Testing and Materials (ASTM) approved the test method, "Standard Practice for Testing for Alternative Pathway Complement Activation in Serum by Solid Materials." This standard is applicable to safety testing for blood-contacting medical devices.

- Similarly we participated in the review and further development of the revisions of ISO TC 194 standards 10993-10 on irritation and sensitization in parallel with 10993-12 on sample preparation for universal guiding principles for preclinical evaluation of device materials. The resulting consistency between these two documents will now serve to help maintain consistency in terminology and methodology as the other 10993 documents meet their time frame for revision/renewal or in the development of new standards.

- We remain very active in the development of ASTM standards for performance or preclinical assessment of medical devices as part of ASTM F04 committees. Among these activities are new standards on biocompatibility dealing with local response to absorbable materials, complement activation, and scientific investigations leading to the revision of the F756 standard on hemolysis.

- Continued participation from laboratory studies and as members of the task group has led to development of standards for quantitating proteins and protein allergens on latex products as part of ASTM D11.40.

- We provided major technical expertise in the development and revision of the American Association for Medical Instrumentation (AAMI) standards on sterilization.

III. Regulatory Compliance

- Our Center and FDA's Winchester Engineering and Analytical Center (WEAC), together with the Consumer Electronics Association (CEA), are planning to sponsor a course to train manfacturers' personnel on the Federal requirements for television products under Chapter V of the Federal Food, Drug and Cosmetic Act. FDA and CEA have developed video tapes for the course which emphasize compliance with the performance standard for television receivers in section 1020.10 of Title 21 of the Code of Federal Regulations (21 CFR 1020.10) and procedures for testing products for compliance.

- The promotion and advertising of devices over the internet has expanded dramatically within the last year. In an effort to assure that the information provided on the internet is truthful and otherwise in conformance with the Food Drug and Cosmetic Act (FD&C Act), we have devoted significant resources to monitoring the internet. In 2000, we issued 22 warning letters to firms advertising on the internet. No additional follow-up regulatory action has been necessary, thus far.

Stimulator

A United States District Court judge ordered Universal Management Services, Inc. of Akron, Ohio, the maker and distributor of a gas grill igniter marketed for pain relief, to begin refunding approximately $82.00 to each purchaser of the fraudulent medical device. Letters have been mailed to over 500,000 consumers who bought the device called the Stimulator. This is the first case brought under the Federal Food, Drug, and Cosmetic Act in which a company has been ordered to pay restitution to consumers.

Abbott Laboratories

Abbott Laboratories, a major manufacturer of in vitro diagnostic devices, entered into a consent decree of permanent injunction with the Department of Justice on November 4, 1999, paying $100 million and ceasing shipment of several of its devices manufactured at the firm's northern Illinois plants. Several other devices manufactured by the firm continue to be available due to the medical necessity of these products. FDA requested the permanent injunction after Abbott failed to comply with Good Manufacturing Practice (GMP) and Quality System requirements and to fulfill past commitments to correct existing deficiencies. The $100 million payment sets a precedent as the largest amount of money ever paid by an FDA-regulated company for a violation of the Federal Food, Drug, and Cosmetic Act.

Lifescan

Lifescan admitted in a plea agreement that it failed to describe defects in their device to the Food and Drug Administration when it was trying to gain clearance to sell their SureStep Blood Glucose Monitoring System. Lifescan pleaded guilty to criminal charges and agreed to pay $60 million in fines for selling defective blood glucose monitoring devices to diabetics and submitting false information about the problems to FDA. The Settlement Agreement, dated December 15, 2000, requires the company to submit to CDRH a monthly report of complaints and analyses for seven specific categories of complaints about SureStep or SureStep Pro Blood Glucose Monitoring Systems.

Metrex Research Corp.
As part of an Office of Compliance project to evaluate chemical sterilants and high level disinfectants, an inspection and sample request for Metrex Research Corporation's ProCide NS Reusable Activated Dialdehyde Sterilizing and Disinfecting Solution resulted in a Warning Letter for deviations from the Quality System Regulation. FDA's lab testing revealed failure to achieve sterilization or high level disinfection, resulting in a Class I recall. Testing by the firm's independent laboratory revealed product failure of the tuberculocidal test. Metrex has stopped manufacturing and distributing ProCide products pending validation of their manufacturing processes, and improvement of their product efficacy and stability.

Laser Vision Centers, Inc. (LVCI)
LVCI agreed to pay a total of $1.5 million in Civil Money Penalties for their involvement in the illegal distribution of "Bermuda Cards" that enabled VISX excimer lasers to be used for capabilities beyond those approved by FDA. After an extensive discovery process, LVCI decided not to go to court, and agreed to pay the fine.

IV. Assuring Safe Products in the Marketplace

Post Market Surveillance: Medical Device Adverse Event Reporting

- Adverse Event Reports
  During Fiscal Year 2000, we received almost 50,000 individual medical device adverse event reports from manufacturers, user facilities, and importers. Additionally, 3,000 voluntary reports came in from health care professionals and the public. Our staff analyzes these reports to determine if the use of particular product is resulting in unexpected problems or risks, and to identify trends that can improve risk management and reduce user error. Additionally, manufacturers reported over 42,000 incidents via the new Alternative Summary Reporting program.

- Alternative Summary Reporting (ASR)
  We continue to enhance the ASR program. This program allows device manufacturers to submit abbreviated reports on certain adverse events in a summarized, line-item fashion. Thirty-eight device manufacturers, representing 48 different classified products, are currently participating, and they started to submit their new abbreviated reports in January 2000. To date, the reports cover a period of October 1, 1999, to October 1, 2000, and are being entered into a new database designed especially for the ASR program.

  A guidance document describing the ASR program and providing instructions for completing and submitting reports was recently published on the FDA website under Medical Device Reporting.

- Medical Products Surveillance Network (MedSuN)
  The FDA Modernization Act of 1997 **(**FDAMA) directed FDA to change the current MDR regulation pertaining to user facilities from a required universal reporting system to a system

comprised of a subset of user facilities. FDA has titled this new effort MedSuN, and under a Phase 1 pilot conducted testing to discern current barriers to reporting and incentives that may help overcome those barriers in the new system.

In preparation for Phase 2 of the MedSuN pilot, which will evaluate various aspects of this new reporting program, an internet based adverse event reporting system is being developed by the University of Maryland's Office of Academic Computer Services. The University's Survey Research Center is conducting research to ensure that the system is user friendly for both the future participating clinical facilities and FDA. A contract modification has been awarded to begin the process of planning and implementing the Phase 2 pilot, including the recruitment and training of 25 hospitals to participate in the initial phase of the program.

- International Postmarket Vigilance Reporting
  FDA and others participating in the Global Harmonization Task Force Study Group 2 (SG2) (Medical Device Vigilance and Postmarket Surveillance) developed a process for the global exchange of vigilance reports between National Competent Authorities (NCAs). The language in the US/EU Mutual Recognition Agreement (MRA) or SG2 documents provided the initial basis for the development of FDA's vigilance reporting criteria and procedures. Most of the postmarket vigilance reports exchanged thus far involve recalled devices with a potential for adverse events in countries where the product is distributed. The pilot portion of the program was recently concluded. The program is now fully operational with expansion to other NCAs planned.

- MDR Network
  We are working with an industry group to evaluate the feasibility of using the Failure Mode Effects Analysis (FMEA) as a basis for MDR Summary Reporting instead of reporting each malfunction separately. At present, our industry partners are comparing the costs of submitting individual medical device malfunction reports versus using summary reporting based on FMEA.

Post Market Collaborative Efforts

"Leveraging" is the creation of relationships and/or formal agreements with others outside the FDA that will ultimately enhance FDA's ability to meet its public health mission. The Office of Surveillance and Biometrics, in collaboration with the Office of Systems and Management, has continued to increase leveraging activities to support the use of partnerships and alliances. The Center coordinates with other FDA centers to learn about leveraging successes and share lessons learned. We have been particularly well placed to provide leadership to the Agency since we began our leveraging efforts two years ago when we conducted a seminar and workshop on what we called, "Outside Leveraging." Our experience since then, including documenting these activities (see http://www.fda.gov/cdrh/leveraging) has put us in an unusually strong position to work with our colleagues both within the government, industry and the public health community. Some examples include:

- FDA/NIH Clinical Center Interagency Agreement
  A five year agreement to conduct studies of thermal ablation, combining the clinical strengths of the National Institutes of Health (NIH) Clinical Center and the computational, engineering and animal research capabilities of our Center. Both the FDA and the NIH are concerned about safety and effectiveness issues that arise from the application of radiofrequency energy (RF) or other extreme thermal techniques for the treatment of soft tissue tumors and other disease

states.. This cooperative research project will investigate the physics of ablative technologies, including their methods of application and potential new applications, and should result in clinical refinements in the application of the techniques as well as new imaging-guided techniques.

- NASA/FDA Cooperative Agreement
  Early cataract detection has advanced under a cooperative agreement coupling dynamic light scattering (DLS) technology from NASA-Lewis with a unique animal model maintained by FDA. Animal studies have shown that the optical technique can detect changes in the lenses of diabetic animals long before the cataracts are apparent via standard clinical examination. This has provided a means for NASA to assess the capabilities of their optical instrumentation. Our scientists have benefited by being able to expand their investigations of the progression of the disease in this model. The project has also enabled us to investigate the capabilities of DLS and other optical technologies that will ultimately find their way into new medical devices.

- ONR/AFOSR/FDA Cooperative Agreement
  Funding from the Office of Naval Research (ONR) and the Air Force Office of Scientific Research (AFOSR) has been used to conduct investigations of optical fibers used for delivery of laser and optical radiation for diagnostic and therapeutic purposes. In the last decade, optical techniques for the diagnosis and treatment of diseases have rapidly evolved into an area of intense medical interest. This program has made possible the evaluation of new sources of laser light, new optical sensors, and new fiber and wave guide delivery systems. This research is helping to develop the knowledge needed by the Agency as applications for new devices utilizing these techniques are received.

- Cell Phone Standards
  We are leading the development of a draft voluntary international standard for evaluating the radiofrequency (RF) radiation dose to users of hand-held wireless handsets. These handsets include cellular and personal communications service (PCS) telephones. The Institute of Electrical and Electronics Engineers (IEEE) Standards Coordinating Committee 34, Subcommittee 2, chaired by one of our engineers, is completing a detailed technical document that recommends experimental protocols for the measurement of the Specific Absorption Rate (SAR) in a realistic model of the human head. It also specifies SAR measurement techniques, instruments, calibration techniques, measurement uncertainties, and the establishment of validation methods. The intended users of this Recommended Practice will include wireless handset manufacturers that are required to certify to the U.S Federal Communications Commission (FCC) and other foreign government agencies that their products meet maximum allowable SAR radiation dose criteria. We are also developing a measurement and quality assurance test laboratory for instruments that measure the SAR delivered to human head models by cellular phones and other wireless handsets.

Reuse of Single-Use Devices Issue -see **Regulatory Science and Standards**

- Systematic Technology Assessment of Medical Products (STAMP)
  Through the STAMP program, CDRH shares its knowledge of marketed medical devices with clinicians, consumers, and industry. A committee is selected for each device chosen for review through the STAMP program. The members of the committee, specially selected for their expertise in the particular device area, identify the issues related to the device, the public health

impact of the device, and the best vehicle for disseminating relevant information regarding the use of the device. Three STAMPs were conducted this year: Liposuction; Electronic Fetal Monitors; and LASIK. The Liposuction STAMP resulted in the publication of an article in FDA Consumer. Changes to the labeling for Electronic Fetal Monitors are currently under review. A website is now available for the LASIK STAMP (see www.fda.gov/cdrh/LASIK).

- Safety Notifications

  Notifications, in the form of Safety Alerts, Public Health Advisories and Public Health Notifications, are the primary means for CDRH to communicate to medical device users important information regarding postmarket safety issues.

  In 2000, we issued notifications on the risks of electromagnetic interference with medical telemetry systems, injuries from microwave thermotherapy for benign prostatic hyperplasia, the potential for injuries from circumcision clamps, and the recall of Clinipad sterile products used in prepackaged procedure kits and trays. To view these notifications see http://www.fda.gov/cdrh/safety.html.

  Hospital Bed Safety

  We led a multidisciplinary group representing the federal government, national health care organizations, manufacturers of hospital beds, patient advocate groups and medical researchers to address the safety issues of hospital beds and the vulnerable patients in all patient care settings--nursing homes, hospitals and at home. The group has been working in partnership to improve the safety of hospital beds for patients at risk for entrapment. The FDA developed a web site (see http://www.fda.gov/cdrh/beds/) to report on the work of the Hospital Bed Safety Work Group, increase awareness of the entrapment issue and educate the public on the problems associated with hospital beds and bed rails. In addition, the participating organizations produced a brochure, *A Guide to Bed Safety*, to educate caregivers, patients and families in the risk and benefits of bed rails. The brochure and other items are available on the FDA web site for bed safety.

- Global Medical Device Nomenclature (GMDN)

  The first phase of the three-year project to create an international device nomenclature is complete. The GMDN was created from six existing nomenclatures (including FDA's). The resultant nomenclature contains approximately 11,000 terms, most of which are preferred terms, but also includes synonyms to preferred terms as well as templates (higher order "root" terms). In addition, definitions are provided for all preferred terms and template terms. We helped to create GMDN, participating in the steering committee, the expert advisory team (set naming rules and conventions and oversaw process), and the device expert task groups (experts in particular categories of devices). Early in 2001, the GMDN (considered a technical report) will be presented to appropriate European and ISO standards representatives to begin the process for formal comment and vote. In the interim, FDA will review the GMDN for its suitability to meet FDA nomenclature requirements.

Post Market Epidemiology

- Our epidemiologists conduct applied epidemiological research using a variety of methods and databases and provide consultative services to ODE and others on issues requiring epidemiological expertise, from systematic reviews of the literature, to risk assessments, to the

design and conduct of observational studies. Major epidemiological research during the past year, resulting in publications in scientific journals and presentations at national professional meetings include: a study of factors associated with mammography screening in disadvantaged women; a study that assessed adverse events associated with breast implants; and a study which showed how medical device tracking can be useful in facilitating public health interventions when safety problems are discovered with implanted medical devices.

V. FDAMA Implementation

Implementation

We are now in our third year of implementing the FDA Modernization Act of 1997 (FDAMA). During the first two years of FDAMA, we issued a large number of guidance documents and final rules to implement its various provisions (http://www.fda.gov/cdrh/modact/modern.html). With this year's efforts, we have continued to revise and update previous documents, where appropriate, and we have focused on more complex and far-reaching issues.

- Six-year Data Provision
  We issued a guidance document to resolve conflicting interpretations of Section 216 of FDAMA (http://www.fda.gov/cdrh/ode/guidance/1135.html). This section governs the circumstances under which the agency can use data in one PMA to establish the safety or effectiveness of any device other than the one for which the data were submitted (this includes more than PMA approval, e.g., down classification).

- Accredited Persons Review Program
  We are working with the medical device industry to increase the use of third party review of low to moderate-risk devices (http://www.fda.gov/cdrh/thirdparty). During the first 17 months of the FDAMA Accredited Persons program, third parties reviewed only 54 510(k)s. In June 2000, we updated the list of devices eligible for third party review, immediately adding 57 devices for a total of 211. At the same time, we proposed procedures for an expansion pilot program that would add another 460 devices--overall, more than a 300 percent increase. Currently, we are considering comments received on the proposed procedures and will issue final guidance on implementation of the expansion pilot program in early 2001. In addition, we have prepared a Report to Congress that recommends deferral of a decision on removing the statutory exclusion of devices with clinical data from the program.

- Medical Devices Dispute Resolution Panel
  Les Weinstein was appointed as our Center's first Ombudsman and permanent members were recruited for the Medical Devices Dispute Resolution Panel. Mr. Weinstein, who reports directly to the Center director, investigates complaints from outside FDA, and facilitates the resolution of disputes between CDRH and the industry it regulates (see http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html). The Dispute Resolution Panel had its inaugural meeting in October. Final guidance is being prepared that will provide detailed information on bringing disputes before the panel.

- Least Burdensome Path to Market Devices
  Our goal is to get the right information to support submissions – not more, not less. We formed a CDRH-wide working group on least burdensome issues, created a dedicated webpage to consolidate information (http://www.fda.gov/cdrh/modact/leastburdensome.html), used our first CDRH-wide webcast to engage staff on this important topic, and have conducted training for staff and Advisory Panel Members. We've also changed many of our internal tracking documents and correspondence with companies to highlight least burdensome efforts. Working collaboratively with an Industry Task Force, we prepared a "Concepts and Principles" document. Efforts are continuing, both internally and with the Industry Task Force, to implement the least burdensome provisions in all of our activities.

VI. Radiological Health

Revitalization and Reengineering

In November 1999, we established a senior management Radiological Health Council to revitalize its radiological health program. In addition to overseeing reengineering efforts, the technical advisory committee agenda, and liaison with government agencies, the Council instituted activities to improve the radiological health web pages, coordination with the FDA field staff, assessment of our staffing and expertise resources and development of an internal training plan. Through contracts, the Council is investigating the possibility of a consortium for a training institute and locating internal materials to populate the web pages and include in training courses.

Several reengineering teams addressed the need to improve our radiological health processes. The Food and Drug Law Institute conducted a workshop in January 2000 where stakeholders concluded that our primary roles are leadership, expertise, information clearinghouse, guidance and training. They suggested that we conduct outreach, allow partners to help develop policy and philosophy, shift from conformance assessment activities to training, advertise the Top Ten priorities, and post all releasable information on the internet. At a November 15-16, 2000, open public meeting, stakeholders confirmed the proposed prioritization approach with minor modifications and suggested improvements in information exchange, product testing, standards and guidance development, and manufacturer reports and electronic submissions. Details are on the web at http://www.fda.gov/cdrh/reenging/radhlth/index.html.

Emerging Technology and Re-emerging issues

We are developing a prioritization process to address the products and issues of greatest concern. Technology is growing rapidly and our staff is trying to monitor the safety of exposures from many new radiation-emitting products. Examples include: computed tomography (CT), green laser pointers, high powered light-emitting diodes (LEDs) and fiber-optic lasers, infrared and microwave local-area-networks, ophthalmic surgery illuminators, and laser, microwave, and ultrasound weapons and security equipment. In addition, we are concerned about how digital medical diagnostic imaging is affecting radiation exposures, particularly when image display systems provide no indication of x-ray overexposures. We are actively working on emerging issues involving mobile phones, security scanners, and electronic article surveillance equipment.

The re-emergence of radiation safety issues is posing challenges to our staff. Examples include: high doses from fluoroscopy, whole-body medical diagnostic x-ray procedures, inefficient x-ray image display systems, and the potential for x-ray emissions from globally-manufactured television receivers and monitors.

Partnerships and Leveraging

- Training on X-Ray Testing of Televisions
  In a new and unique endeavor, we entered a co-sponsorship agreement with the Consumer Electronics Association (CEA) and FDA's Winchester Engineering and Analytical Center (WEAC) to develop and sponsor a course to train manufacturers in the Federal requirements for television products. FDA and CEA developed videotapes for the course, which emphasize x-ray testing procedures and compliance with the performance standard for television receivers. The first offering of the course is expected in May 2001.

- Diagnostic X-Ray Compliance Tests
  In an effort to salvage an existing program when contract money was unavailable, FDA negotiated partnerships with states to continue diagnostic x-ray compliance testing. In exchange for CDRH providing test instrumentation, calibrations, and training in test methodologies, 30 states agreed to continue testing equipment meeting our Center's criteria at or near the same level as in the contracts. We revised the qualification exam, conducted training, and issued certificates upon completion of both didactic and survey modules. Together, FDA and the States tested 1500 systems, 15 percent of which had one or more noncompliances with the performance standard.

- Suggested State Regulations
  We continued to assist the Conference of Radiation Control Program Directors (CRCPD) with revisions to the diagnostic x-ray suggested state regulations and with laser and microwave issues.

Other partnerships are evident in the research and studies listed below.

Radiation Emission, Exposure, and Risk Evaluations

- Medical X-Ray Exposures
  The CRCPD and FDA conduct the Nationwide Evaluation of X-ray Trends (NEXT). This collaborative Federal-State survey program is the sole mechanism in the United States for acquiring and updating nationally representative baseline data on medical x-ray exposures, image quality, and related clinical practice. During the surveys, information is collected on radiographic technique factors, patient x-ray exposure, x-ray beam quality, image quality, film processing quality, and darkroom fog. The survey results for a given year represent a statistically valid "snapshot" of x-ray exposure and related factors for that type of examination in the U.S. In FY 2000, computed tomography (CT) surveys are underway incorporating major improvements in survey methodology (electronic submissions, etc.).

- Mobile Telephone Measurements
  We are leading the development of an international standard for evaluating the radiofrequency (RF) radiation dose to users of hand-held wireless handsets, including cellular and personal

communications service (PCS) telephones (see "Leveraging" section under "Postmarket Programs.").

- Mobile Telephone Bioeffects Research
  In an effort to spur research on the possible health effects of RF emissions from wireless phones, we established a Cooperative Research and Development Agreement (CRADA). The focus of the research is on two study topics: epidemiology and mechanistic studies related to toxicity. We are seeking input from government, industry, and scientific and technical experts. Details are available on the web (see http://www.fda.gov/cdrh/ocd/wlessphonecrada.pdf).

- Suntanning Cancer Risk
  FDA established an inter-Center Photosciences Network to collaborate on ways to improve safety from exposures to ultraviolet (UV) radiation. Our Center established a research facility and, with a multi-disciplinary team from the National Cancer Institute, Washington Hospital Center, Philips Research Laboratories and FDA's Center for Food Safety and Applied Nutrition, investigated biomarkers for testing and standardizing human skin response to UV. In addition, we are conducting research on cell death mechanisms from ultraviolet-A exposure and have calculated an average annual solar UV dose based on data from the Environmental Protection Agency. This information is necessary to assess the relative increased risk of skin cancer resulting from use of ultraviolet-emitting electronic products (see http://www.fda.gov/cdrh/ost/reports/fy99/OSTfy99.html).

See the **Regulatory Science and Standards** section for the following:
- Information Disclosure to Diagnostic X-Ray Assemblers;
- Electronic Anti-Theft Systems;
- Amendments to Fluoroscopy and Laser Standards; and
- X-Ray Personnel Screening (People Scanners).

Surveillance and Compliance for Radiological Products

We reviewed approximately 63 percent of the nearly 6000 product reports and annual reports submitted by manufacturers documenting compliance with standards and radiation quality control and testing programs. Based on these reports, laboratory tests, field tests, and inspections, we issued over 60 noncompliance letters and disapprovals of radiation testing programs and assisted the field staff with over 30 import detentions.

VII. Mammography Quality and Radiation Programs

Mammography Quality

- General

  The goal of the Mammography Quality Standards Act (MQSA) is to enhance the detection of breast disease through high quality mammography services. Under the law, mammography facilities must be certified by the FDA and accredited by a non-profit body; this includes meeting Federally established quality standards and undergoing annual inspections. For detailed information on the items below, visit FDA's Mammography Program (see http://www.fda.gov/cdrh/mammography). The site includes a search engine that enables users to search by subject matter.

- Inspections

  To assure mammography quality, mammography facilities undergo annual inspections by FDA credentialed inspectors. Nearly 10,000 inspections take place each year. Fiscal Year 2000 was the first full year of inspections under the MQSA Final Regulations. More than half of the facilities [53%] had no adverse findings during their inspections this year. About 10% of facilities had nothing worse than minor (Level 3) findings, while 33% had moderate (Level 2) findings as their most significant result. Finally, about 4% had serious (Level 1) findings during their inspection. The Level 1 and Level 2 percentages were higher and the Level 3 and "no findings" percentages were lower than in the previous year. The increase in significant findings is related to the newly effective final regulations and was expected as mammography facilities accommodate to the new, and stricter, requirements. The percentage of facilities with significant inspection findings decreased as Fiscal Year 2000 went on and we view this as a positive sign. We are confident that mammography facilities will improve their performance as they become more familiar with the requirements of the final regulations.

- Digital Mammography

  FDA approved the first Full Field Digital Mammography (FFDM) system for commercial use in January 2000. The new technology promises to enhance mammography by reducing the need for some women to have additional exposures, while allowing interpreting physicians to quickly and easily manipulate the images. While the accreditation bodies are developing a process for accrediting FFDM units, at this time digital units are exempt from MQSA accreditation requirements. For a facility to lawfully use the FFDM system, it must submit a successful application with required information to FDA, including personnel and equipment requirements.

- States as Certifiers (SAC) Demonstration Project

  This project successfully transferred certain key MQSA responsibilities to the States of Illinois and Iowa. The program authorizes qualified States to certify mammography facilities within their jurisdiction, conduct inspections, and enforce the MQSA quality standards, under FDA oversight. The proposed rule to fully implement the program nationally was published in March 2000, comments were evaluated, and final regulations are expected in 2001.

MQSA Policy Guidance Help System (PGHS)

- In Fiscal Year 2000, all MQSA regulatory guidance materials and documents were compiled into one system -- PGHS. Mammography facilities and other interested parties now have access to a comprehensive online resource accessible via MQSA's web page on the internet. Previously, this information was only available in ten separate documents with no way to search through all of the information at once. PGHS users can search for answers to specific questions through an indexed list of topics and key words. For example, by selecting a particular subject, such as "revocation of accreditation" or "accreditation and certification," the user will see the regulatory citation, any relevant guidance documents, and any other appropriate information and references.

***The Nationwide Evaluation of X-ray Trends (NEXT)* –** see **Radiological Health**

***The Technical Electronic Products Radiation Safety Standards Committee (TEPRSCC)* –**see **Regulatory Science and Standards**

VIII. International Activities

Global Harmonization Task Force (GHTF)

The GHTF was formed in 1992. Participants include regulatory body and industry representatives from the founding members: the United States, Canada, the European Union, Japan, and Australia. Other countries are welcome to participate in GHTF activities. The mission of GHTF is to encourage convergence of medical device regulatory practices worldwide while ensuring the safety, effectiveness and quality of medical devices; promote technological innovation; and facilitate international trade. To achieve these goals, GHTF develops guidance documents on basic regulatory practices and makes them available through its web site (see http://www.ghtf.org). The United States, through the FDA/CDRH, is a major partner in GHTF and throughout 2000 actively participated in the work of its four study groups as well as the 8th Conference of the Global Harmonization Task Force held September 18-22, 2000 in Ottawa, Canada. FDA is committed to full participation in the advancement of the GHTF's mission and initiatives.

U.S./EC Mutual Recognition Agreement (MRA)

The Medical Device Annex of the United States (U.S.) / European Community (EC) Mutual Recognition Agreement (MRA) went into effect for the FDA in December 1998, initiating the beginning of a three year confidence building period during which training and evaluation activities are to take place. The Medical Device Annex of the U.S./EC MRA provides for three types of regulatory activities: (1) the exchange of quality systems evaluation/inspection reports for all medical devices; (2) product evaluation reviews for selected low to medium-risk devices; and (3) establishing a program for exchanging information on serious health hazards posed by medical devices. In this second year of the three-year transitional period, the FDA has completed training of four auditors from four European Union (EU) Conformity Assessment Bodies (CABs), received and evaluated dossiers from eight U.S. CABs, and transmitted those dossiers to the Commission for

the European Community (CEC). In addition, the FDA has published version 7 of the MRA draft implementation procedures for comment on the MRA web site (see http://www.fda.gov/cdrh/mra/index.html).

Joint Premarket Review Activities

In conjunction with our involvement in the GHTF, a partnering program with Canadian health authorities has been established to test common approaches to conducting premarket evaluation for selected types of devices as the possible basis for mutually recognized and joint premarket evaluations. On September 27 – 29, 2000, CDRH representatives met with scientific and regulatory officials in Ottawa, Canada to discuss the scientific partnering initiative between CDRH and Health Canada. The purpose of the meeting was to discuss expansion of the partnering process to include implantable cardiac devices. The success of the partnering program over the past three years shows promise as a model that may eventually reduce the resources being spent on global premarket evaluations of devices and avoid delays in market introduction of new devices.

IX. Preparations for Y2K

Final Y2K Preparations and Y2K-Readiness within the Center

- Desktop Computers, Network Infrastructure and Facilities
  The CDRH computer and network infrastructure was validated as Y2K-compliant in March 1999. However, our computer support staff tested and installed software upgrades and Y2K patches on desktop computers, servers and network equipment throughout the Fall and up until the last weeks in December, in order to keep current with last minute software vendor releases correcting Y2K-bugs. We finalized Day One testing plans and coordinated efforts with other FDA components and the FDA Network Control Center.

- Day One Testing
  Our computer support staff gathered on the evening of December 31, 1999, and by noon on January 1, 2000, completed the testing of servers, electronic mail system, network infrastructure, desktop computers, and database applications. Staff was especially vigilant for virus and hacker attacks, none of which were encountered. The Y2K rollover was uneventful and we were able to report a successful Y2K transition to the FDA Y2K Command Center. During the first few weeks of 2000, a few minor Y2K problems were encountered in several application report programs. All were corrected immediately and no problems have been encountered since January 2000.

- Leap Day
  Because of additional date issues arising with the leap year in 2000, staff prepared and conducted additional computer system testing on February 28 and February 29. There were no leap day problems discovered.

Response to Y2K outside the Center

- Web-based Biomedical Equipment Clearinghouse
  Data regarding the Y2K status of biomedical products was made available to the healthcare community through the FDA-operated Federal Y2K Biomedical Equipment Clearinghouse at http://www.fda.gov/cdrh/yr2000/year2000.html and remains available. Data from over 4,200 manufacturers was provided via this mechanism.

- Assessment of Manufacturers' Y2K Readiness
  We completed and reported on a survey of the manufacturers of essential medical and surgical supplies whose availability is critical to patient care. The voluntary survey of 3,070 manufacturers demonstrated that the medical devices industry had taken appropriate steps to assure the uninterrupted supply of necessary supplies. The full report on the survey is available at http://www.fda.gov/cdrh/yr2000/cdrh/readiness/y2kreadrpt.pdf. Following January 1, 2000, no significant shortages of medical supplies were encountered.

- Assessment of Computer-Controlled, Potentially High Risk Devices
  We completed focused, on-site assessments of a sample of manufacturers (US and foreign) of computer-controlled potentially high risk devices to assess the adequacy of their actions to assure device safety and to implement needed corrective actions. Results of this survey indicated that the medical device industry had made appropriate evaluations and preparations (see http://www.fda.gov/cdrh/yr2000/cdrh/phrds/phrds.html).

- Outreach to Healthcare Facilities
  We communicated with healthcare facilities to urge that they assess the Y2K status of the devices they use, to provide information on the resources available to assist with Y2K preparations, and to explain how to report Y2K-related medical device problems or malfunctions to the FDA and to urge such reporting in conjunction with the "roll-over" to January 1, 2000. We also provided an internet-based, rapid reporting mechanism for use by healthcare facilities to report Y2K-related problems with medical devices to FDA.

- Preparation for Rapid Response to Y2K Problems
  We developed plans and procedures for rapidly dealing with any Y2K-related medical device problems during transition to January 1, 2000 and February 29, 2000. We also staffed FDA's Emergency Operating Center and the Federal Y2K Information Coordination Center with medical device expertise during transition periods to provide immediate response and investigation of any reported problems. Our staff followed up on a number of reports of Y2K device problems from the press and other sources with the result that no significant incidents affecting patient care or safety in the US were identified.