Report of the Postmarket Transformation Leadership Team:

Strengthening FDA's Postmarket Program for Medical Devices

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Executive Summary

After a thorough review of its postmarket processes, CDRH recently published two documents – *"Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Framework"* and *"Ensuring the Safety of Marketed Medical Devices – Synopsis and Recommendations"*. These reports recommended improvements in the following four areas: intra-Center communication, postmarket data systems, risk communication efforts, and enforcement strategies.

The reports also recommended that a senior team of leaders evaluate the report's recommendations and propose an implementation strategy. The Postmarket Transformation Leadership Team (PTLT) was formed in response. The PTLT met several times from January to September, 2006 and identified issues that needed to be addressed. The Team also developed a list of prioritized recommendations for action to be taken by the Center in order to address these issues and achieve postmarket transformation.

Issues

The issues the PTLT identified included inadequacies in CDRH's internal communication network, shortcomings with the current system for receipt, processing and analysis of reports from the Medical Device Reporting system (MDR), underutilization of data and expertise outside of the Center to better evaluate postmarket issues, the inadequacy of the Center's current computer systems to efficiently track, search, and analyze data, confusion in the industry as to how and when to report adverse events, the lack of a comprehensive risk communication system for external stakeholders, need for increased coordination between CDRH and ORA especially given the shrinking resources available for field activities, and an inadequately coordinated system for using postmarket data to inform premarket decisions and assist in enforcement and compliance actions.

Recommendations

The PTLT made several recommendations to address these issues. These recommendations elaborated the four areas designated for improvement in the previous postmarket reports and are outlined below.

Create a Culture of Collaboration

The Center should add cross-cutting product-related groups over the current functionally-based organization to foster information sharing, collaboration and, ultimately, more effective public health promotion and protection. This cross-cutting matrix should be permanent, so that collaboration occurs not just in crisis situations, but also as a part of routine, day-to-day operations. In addition, Center managers should encourage cross-organizational collaboration through training and recruitment. Employee recognition should be based on successful collaboration, and communication with outside experts on postmarket issues should be formalized and expanded.

Develop World Class Data Systems

Data input, mining, analysis, and tracking systems should be strengthened, improved, or created as needed for postmarket issues. Unique device identifiers, electronic registration and listing, electronic medical device reporting (eMDR), and alternative summary reporting strategies would streamline the process of acquiring data. The MAUDE database, which houses the Center's MDR data, should be updated. MedSun, the Center's user facility reporting network, should play a larger role in the early identification of postmarket issues. CDRH staff should be cross-trained to evaluate adverse event reports, and outside experts should be asked to assist in the review process. Finally, a pilot project should be initiated to prospectively quantify the risks associated with different medical devices.

Enhance Risk/Benefit Communication Efforts

CDRH should be a trusted, publicly identifiable source for safety information about medical devices and radiation-emitting products. To that end, an analysis of the communication needs of CDRH stakeholders should be performed, and a process for the development and dissemination of risk-benefit information should be done in collaboration with clinical practitioners and professional communities.

Collaborate on Enforcement Strategies and Outcomes

Both the quantity and the quality of Center /ORA interactions should be transformed through increased collaboration among CDRH, the Office of Regulatory Affairs, and the Office of Chief Counsel. Postmarket data and information should be considered when prioritizing inspections, and part of the inspection preparation process should include a review of recent postmarket data. These data should also be integrated into

other CDRH programs. CDRH should develop ways to leverage the audit results obtained by accredited third-party auditing bodies. Enforcement data systems should be updated, and employees trained to use them. All available enforcement tools should be used, including civil money penalties.

Immediate Priority Actions

Immediate priority actions were identified by the PTLT. They are to:

- Create a matrix system of collaborative product groups to complement the largely functional organization of the Center
- Develop metrics and methods for tracking the handling of postmarket issues
- Pursue the development of unique identifiers (UDI) for medical devices
- Propose mandatory electronic MDR reporting
- Revise and update the MAUDE system, and expand the premarket data-warehousing project to include postmarket needs
- Increase the quality and quantity of Center/ORA/OCC interactions
- Develop and implement a risk-communication strategy
- Design a pilot project to test the usefulness of quantitative decision-making methods for medical device regulation across the total product life cycle
- Enhance utility of MedSun programs

The PTLT acknowledged that much work is required to realize each of these recommendations, and the Team proposed next steps for beginning the process.

Introduction

The Center for Devices and Radiological Health (CDRH) is committed to achieving a seamless approach to the regulation of medical devices.   In such an environment, the Center's premarket evaluation activities would be integrated with continued postmarket vigilance and enforcement, and appropriate and timely information would be fed back to all of its stakeholders. This regulatory approach, which encompasses the entire life cycle of a medical device, is described in the Center's "total product life cycle" (TPLC) model – a model that guides CRDH as it works to fulfill its public health mission to protect and promote public health.

Most observers tend to break the life cycle of medical devices into premarket and postmarket phases, based on the legislative framework for device regulation. While this approach has been very useful to date, it does not reflect CDRH's vision of TPLC in which premarket activities and postmarket activities are integrated into a smoothly functioning and efficient whole.

Recently, CDRH published two documents on the postmarket safety of medical devices. One describes CDRH's postmarket goals and the approaches the organization uses to monitor and address adverse events and risks associated with the use of devices that are currently on the market (see "*Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Framework"*). The second document provides a number of recommendations for improving the postmarket program (see "*Ensuring the Safety of Marketed Medical Devices – Synopsis and Recommendations"*). Both of these documents are available on the CDRH Website at http://www.fda.gov/cdrh/postmarket/mdpi.html.

One of the recommendations in the *Synopsis and Recommendations* is that a senior-level team, comprised of Center management and experienced outside consultants, be established to evaluate the recommendations in the report and propose an implementation strategy. This recommendation led to the formation of the CDRH Postmarket Transformation Leadership Team (PTLT).

Charge to the CDRH Postmarket Transformation Leadership Team (PTLT)

The PTLT was given the following charge in January, 2006, by the Director of CDRH:

> *A comprehensive TPLC approach to postmarket safety is necessary to identify and address problems with marketed products, integrate the information learned into Center activities, and feed back the lessons learned to the public, manufacturers, and health professionals. The Postmarket Transformation Leadership Team will evaluate the recommendations in the CDRH document, "Ensuring the Safety of Marketed Medical Devices – Synopsis and Recommendations," collect additional data as necessary, supplement the recommendations if needed, and propose a prioritized implementation plan for a transformed postmarket process to the Center Director.*

The name of the group was deliberately chosen to underscore the expectation that the recommendations that resulted were to be targeted toward nothing less than a *transformation* of the Center's postmarket program. Members of the PTLT are listed in Appendix A.

The PTLT used a series of meetings to focus on the structural, programmatic and procedural changes that would be necessary to transform the postmarket program. Presentations were made by each Center Office on what works and what does not work in that Office's handling of postmarket issues. Important insights into the impact of organizational change were presented by the Office of In-Vitro Diagnostic Device Evaluation and Safety (OIVD) and the Office of Science and Engineering Laboratories (OSEL). Meetings and phone discussions were also held with selected CDRH staff. In addition, the PTLT heard from the chair of one of the Center's most visible cross-cutting teams, the Defibrillator Working Group, and from the outside consultant who recently completed an analysis of internal communication in CDRH. During the same time period that the PTLT was meeting, a series of meetings to discuss postmarket issues was held with an industry working group.

The insights obtained in these meetings were used to review the four recommendations made for improving the postmarket program in *"Ensuring the Safety of Marketed Medical Devices – Synopsis and Recommendations"* and to further refine the suggestions for improvements the Center should undertake.

This document reports the findings of the PTLT and lists its recommendations for action. It provides specific direction to the Center about how to implement the four recommendations in the previous documents. This focus on improvement should not obscure the fact that there are many successful processes and activities that are used in the Center's postmarket program. We refer the reader to the above mentioned report, *Ensuring the Safety of Marketed Medical Devices: CDRH's Medical Device Postmarket Safety Framework,* for a more detailed discussion.

The present document, however, is about change. CDRH is proud of the reputation it has built in public health promotion and protection, and it is interested in continually improving its programs to further reduce risks associated with the use of medical devices and radiation-emitting products.

Statement of the Issues

CDRH's ability to address postmarket issues is complicated by a number of challenges. Information about problems with marketed medical devices comes to the Center via a number of different channels, is often incomplete, and may not always be reviewed immediately. Information may come into one part of the Center but not be routinely shared with another part. Hence, information may not be recognized as being as important when initially evaluated by the receiving Center component as it might have been if it had been compared with information received by another component. Integrating information across offices for signal detection is not done systematically. Center-wide discussions of lessons learned about postmarket problems are sporadically conducted with few changes made to the postmarket program. Information is not routinely fed back into the premarket review process to mitigate or, ideally, to prevent future problems. Integration of the actions of staff from across the Center, and from the Office of Regulatory Affairs headquarters and the field, is often hampered by office-centric viewpoints. In other words, a 'culture of collaboration' is not fully realized. All of these challenges are compounded by the shrinking proportion of resources that are made available to the Center for postmarket activities.

It perhaps goes without saying that CDRH's premarket review program cannot guarantee that all legally marketed devices will always function or be used perfectly in a postmarket setting all of the time. Premarket data sets provide a reasonable estimate of device performance, but may not be large enough to detect the occurrence of low frequency, or

rare, adverse events. In some conditions of postmarket use, device performance can render unanticipated outcomes. Different user skills and levels of knowledge compared to controlled study environments further complicate postmarket device performance. Efforts are made to forecast postmarket performance through sufficient premarket testing and analyses, but the dynamics of the postmarket environment create variables that are unpredictable or difficult to investigate with manufacturing inspections, bench testing or clinical evaluation.

Postmarket issues are complex *and involve every part of the Center*, as one would expect when trying to implement a TPLC approach. Major issues that impact the Center's postmarket program include, but are not limited to, the following:

a) CDRH is organized functionally, with premarket and postmarket responsibilities assigned to separate organizational units. There are few formal, cross-cutting communication channels along product, project, or scientific specialty lines. As a result, staff may find it difficult to identify counterparts in other offices who share an interest in or concern about a particular issue. This lack of easy connection to other staff inhibits handling issues in a TPLC fashion. Under the pressures of daily deadlines, managers may not consistently insist upon collaboration and staff may not routinely seek the necessary consultations to allow them to act on information outside their typical workflow. Hence, in spite of CDRH's shared mission across work groups, differences in culture, work priorities, and organizational structure often make knowledge sharing and management of postmarket issues difficult.

b) The Center relies on both in-house and external scientific, engineering and clinical expertise to ensure that its premarket decisions are based on the best available information, but the flow of information into the Center and use of expert consultation for postmarket issues is not similarly coordinated. For example, the Center has not established standard operating procedures for engaging experts already serving on advisory panels or recruiting additional experts from medical and professional societies to evaluate postmarket issues.

c) Center funding levels have not allowed routine connection to outside databases, registries, and other vigilance or surveillance systems. As a result, much of the data upon which the Center might base postmarket actions is limited to that received via the MDR system or from inspections.

d) Information from industry on postmarket device use and performance in PMA annual reports and MDR reports is not always complete, and not always reviewed in a timely way.

e) Center staff may not always have a clear understanding of what postmarket authorities can be utilized to address problems. For example, Section 522 Postmarket Surveillance authority is an available, but widely misunderstood and underutilized, tool.

f) In-house information related to specific medical devices across the product life-cycle is not easily accessed by staff. The Center lacks a modern data system that would allow Center-wide access to data derived from different sources. No unified archiving system exists that allows staff to easily search adverse event reports, device modifications, enforcement issues, or recent approvals and clearances.

g) Center data systems do not exist to regularly provide managers with quantitative information about the Center's handling of postmarket problems. This information is routinely available for the premarket review program. Without such information, it is difficult to identify areas for improvement or to establish performance targets or metrics.

h) The primary mechanism for receiving adverse event data is the Medical Device Reporting (MDR) system. MDR is a passive surveillance system and, as is often the case with passive surveillance systems, the data coming in are frequently incomplete. Reporting of adverse events is mandatory for manufacturers, but manufacturers complain that it is difficult to obtain information from device users when attempting to follow-up on reports, and confusion still remains about what is required to be reported. In addition, the regulation that established MDR requires manufacturers to report a device problem to CDRH within 30 days of becoming aware of the event. This period of time was believed to ensure timely Center awareness of the problem. In practice, this time period often does not allow the manufacturer time to investigate the cause of the problem. Hence, incomplete initial reports and trailing supplemental reports choke the system.

i) The data that are submitted via MDR rely upon a generation-old software platform (MAUDE) to organize, store and allow management of the data. This software, due to its age and limitations, does not allow MDR to serve its customers well. FDA staff and stakeholders report that MDR:

- does not provide timely and usable data to staff or other system users
- does not provide data in a user-friendly format
- is costly because data entry is cumbersome and manual
- has a large backlog of reports which hampers the ability to detect signals or identify problems

j) The potential of MedSun as a postmarket tool has not been fully integrated into CDRH's other pre- and postmarket activities. CDRH has enrolled 350 health care facilities in its Medical Device Surveillance Network (MedSun), a pilot sentinel reporting program which encourages user facilities to report adverse events. The Center has been successful in enrolling MedSun participants, receiving voluntary and mandatory reports, and providing safety information back to the MedSun hospitals. However, the program needs to make this safety information available to all health care facilities, not just facilities that are MedSun participants. MedSun is a valuable resource that could improve reporting and provide more targeted adverse event information.

k) The flow of information out of the Center to practitioners, patients and consumers is not optimum. Although the Center has much important information to impart to the public, it does not always take maximum advantage of its opportunities to communicate that information. This includes basic information for consumers about product availability, safety and use, as well as time-sensitive information about potential problems with marketed products. For example, the first time many health care practitioners learn about a recall may be in the newspaper.

l) The Center's recall information is a rich source of manufacturing data, manufacturer compliance information, and postmarket adverse event documentation. The Center would benefit by routinely sharing this information across the Center to enhance and expedite other pre- and postmarket activities.

m) Current implementation of the Quality System (QS) regulation may not have the desired effects on design and manufacturing quality unless manufacturers are committed to the purpose of the QS regulation, and FDA is rigorous in its inspections. The QS regulation was expanded to include design controls to address the problem of recalls due to faulty designs and usability issues, yet recalls related to these issues persist.

n) Information from adverse event reports and recalls is not routinely used in an organized way to direct diminishing field resources. While the Agency is committed to a risk-based inspection process, inspection assignments often are not based on adverse event data, and these data may not be considered prior to conducting inspections.

Recommended Actions

The handling of postmarket issues requires an approach that is well integrated with premarket review, that is informed by science and engineering, that provides necessary information for health care practitioners and patients, and that generates the necessary documentation for compliance actions when needed. Solutions must be found that promote smooth working relationships within the organization, that provide ready access to reliable data, and that foster a collaborative response to problems.

The discussion below, with resulting recommendations, is organized into the four areas that were highlighted in the recommendations in the CDRH document, "*Ensuring the Safety of Marketed Medical Devices – Synopsis and Recommendations*". The recommendations in the report were to:
- Create a "culture of collaboration" on postmarket safety within the Center
- Develop world class data sources and systems
- Enhance risk/benefit communication efforts
- Focus enforcement strategies on postmarket issues

I. Create a Culture of Collaboration

The Center's goal in creating a culture of collaboration is to operate CDRH as a coordinated whole, rather than a collection of pieces. Critical to the success of any organization is the understanding of, and commitment to, a common mission. Although most Center staff would invoke "public health" if asked to describe their mission, many identify more with the tasks of individual Offices than with the mission of the Center. As a result, the understanding of the Center's public health mission can be fragmented. To institutionalize a collaborative culture, CDRH should identify the characteristics of the culture it seeks, and it should ensure that staff understand the processes and have the skills (e.g., conflict resolution, team building, communication abilities) to realize transformation. Individual staff members must recognize their place in fulfilling the Center mission. Center leaders should model the value of collaboration in their language, behavior and in performance expectations.

Recommended Actions:

1. ***Create a cross-cutting organizational configuration to support the Center's TPLC regulatory approach by establishing a formal matrix system***
    A CDRH collaborative matrix model is detailed in Appendix B. Such a system would encourage:
    -   Vertical authority, accountability, and communication to manage operational systems
    -   Horizontal interaction and collaboration to ensure timely awareness and proactive discussion of priorities along product lines

2. ***Promote the Center's TPLC vision in order to foster a culture of collaboration***
    -   Articulate the Center's values and focus attention on cross-center collaboration at all levels
        o   Publicly state the organizational values that drive the CDRH culture of collaboration
        o   Describe the culture that is sought, using successful examples (such as the use of cross-center review teams), situations, behaviors, and success measures
    -   Model key collaborative behaviors that are expected
    -   Engage staff in discussing the Center's collaborative vision. Hold "All Hands" meetings on a routine basis specifically to discuss collaborative values and the CDRH vision
    -   Emphasize the need for collaborative skills as part of the Center's staff recruitment efforts

3. ***Create tools and processes that facilitate collaboration***
    -   Develop and adopt processes to ensure the comprehensive involvement of Center offices in the handling of postmarket issues. Use checklists and other instruments of accountability for staff to ensure that collaboration is occurring in appropriate situations
    -   Commit Center resources preferentially to collaborative efforts
    -   Support the use of cross-Center details for staff to foster understanding of Offices' roles and processes
    -   Develop standard measures for documenting and tracking postmarket issues to provide a means of measuring collaborative accomplishments

4. ***Provide incentives, training opportunities, and rationale to motivate staff to achieve a successful Center collaborative culture***

- Emphasize collaborative efforts when preparing and reviewing honor award nominations
- Re-evaluate the requirements for the "master reviewer" position to ensure that career progression depends upon a broad base of competence and collaboration
- Encourage staff to develop collaborative skills by including formal course work and on-the-job training elements in performance review plans
- Expand "core competency skills" to include collaborative skills
- Hold all managers accountable for staff performance on postmarket issues
- Require senior leaders/subject matter experts to participate in the design and delivery of training that model collaboration.
- Design orientation courses and continuing education opportunities to instruct staff in the TPLC model of doing business, and offer courses in the skills needed to be collaborative such as conflict resolution, team building, and communication strategies

5. ***Create a learning culture that emphasizes continuous improvement by developing Center-wide mechanisms to share lessons learned***

- Develop and use routine "process learning reviews" (i.e., "after action reviews") of complex postmarket issues, and encourage routine informal discussion and review for less complex issues
- Discuss both problematic and successful issues

II. Develop World Class Information Systems

The Center's goal is to develop the ability to collect data on postmarket device performance from both regulatory and non-regulatory sources and be able to efficiently analyze that data to detect signals of adverse device performance. Currently, the main source of information on postmarket device performance is derived from MDR reports. Data collected from manufacturers and users on device-related deaths, serious injuries, and malfunctions are collected in the Center's MAUDE (Manufacturers and User Facility Device Experience) database. Over a dozen years of history with this system has revealed that device-related adverse events are vastly under-reported and that the data that are reported are often incomplete and unreliable. In addition, the MAUDE database

does not provide a user-friendly data interface to access and analyze data. The challenge for the Center is to improve MDR, complement it with other data collection mechanisms, and to make the data more widely available across the Center.

A. Improve Data Systems

The following recommendations are made with the assumption that a system for uniquely identifying medical devices (UDI) will not be in place and available for a number of years. UDI would dramatically change information management at CDRH and would alter these recommendations (see also II.C and Appendix C).

Recommended Actions:

1. Develop management information data systems
- Develop management information data systems for postmarket issues similar to the ones that the Center has developed for premarket review. This will require identification of the items to be tracked, including metrics and timeframes, development of the systems, and use of the resulting data by Center managers
- Explore whether software used by other industries, such as the insurance industry uses for handling "cases," would be applicable for postmarket issues

2. Make postmarket data more widely available to Center staff and supplement search and reporting tools
- Revise and update the MAUDE system
- Meet with FDA's Center for Drug Evaluation and Research (CDER) to learn more about that Center's plans for a major overhaul of their adverse event reporting system (AERS II). Continue to closely monitor and identify potential opportunities to partner and/or leverage their investment as it applies to CDRH
- Build upon the data warehouse currently under development to make in-house data (adverse event reports, compliance information, etc.) easier to query by Center and ORA staff, particularly to determine historic trends and predict potential future trends
- "Push" relevant adverse event data and compliance information to reviewers and other staff so that they would not be required to navigate through an adverse event reporting/management system to find needed information

- Investigate the use of data and text mining techniques to identify the "needles in the haystack" by identifying patterns in the incoming data that equate to public health signals. These techniques are successfully used, e.g., by law enforcement to detect abnormalities in massive amounts of data that could indicate security fraud.

3. Ensure the use of eConsult, a Center system used by staff for requesting consults from other offices on premarket review issues, for postmarket issues

B. Enhance Data Quality
<u>Recommended Actions:</u>

1. Institute electronic reporting
- Implement electronic reporting for MDR, expand it to include MedSun and alternative summary reports, and integrate it into the Center's IT systems
- Make electronic reporting of adverse event data mandatory

2. Evaluate other alternative summary reporting strategies
- Determine whether additional alternatives to individual MDR reporting are warranted for other device types or different adverse event types. These alternatives might include changes to the 30-day reporting requirements or exemptions for some types of products.

3. Assess the MDR regulation
- Assess what beneficial changes, if any, could be made to the regulatory requirements for MDR by forming a CDRH/industry working group to assess current requirements, identify strengths and shortcomings, and develop a plan for improvement
- Revise and update guidance to MDR reporters to clarify uncertainty about what is "reportable" to the MDR system

4. Expand the potential of MedSun
- Expand the use of MedSun hospitals to obtain real-time information on postmarket problems
- Feed safety information obtained from MedSun participants back to all stakeholders in order to make information equally available to all health care

facilities and the public

- Target high-risk user facility areas by providing some clinical staff in MedSun participating facilities (in addition to the current risk managers and biomedical engineers) the ability to report device-related adverse events directly to CDRH

5. *Expand access to external sources of data*

- Reach out to clinical professional societies and hospital risk managers, who are often the gatekeepers for adverse event reporting from user facilities, in an organized, non-crisis-driven way
- Investigate the possibility of partnering with FDA's Center for Drug Evaluation and Research (CDER), which buys information from health maintenance organizations (HMOs) and other organizations
- Look for relevant outside databases and networks to determine what opportunities are available for partnering. First priority should be given to exploring cooperative efforts with other federal agencies, especially the Department of Veterans Affairs (VA), DoD, and the Centers for Medicare and Medicaid Services (CMS) to see if the data collected by these agencies would be helpful.
- Increase collaboration and participation in postmarket registries. Determine the resource requirements for access to databases and registries run by professional societies (e.g., the Scandinavian orthopedic registry and the Society of Thoracic Surgery database).
- Request denominator information from industry in PMA annual reports

C. *Improve Data Analysis*
Recommended Actions:

1. ***Pursue the development of unique device identifiers (UDI) in order to easily identify specific devices when postmarket questions are raised***
   This effort can be expected to take years to implement, but would dramatically improve information management at CDRH.
- Collaborate with industry and health care providers to develop a UDI system for medical devices
- Leverage the efforts of the Department of Defense (DoD), which is making UDI mandatory (geared primarily toward inventory control) in 2007. The Center should continue to engage DoD to ensure that public health concerns are

considered during the setting of specifications by DoD.

2. ***Investigate quantitative decision-making techniques to evaluate medical devices throughout the total product life-cycle***
   (This recommendation is detailed in Appendix E.)
   - Launch a pilot project within one of the new collaborative product groups (see Appendix B) to initiate a retrospective evaluation of previous models of devices to determine whether premarket review could be strengthened or changed when evaluated from the perspective of subsequent postmarket performance
   - Determine whether formal methods would be useful in assessing the seriousness of adverse event signals and the appropriateness of subsequent corrective actions

3. ***Augment routine MDR analysis with additional product area and technical experts***
   - Train staff across the Center to review MDR data to allow the MDR staff opportunities to gain more knowledge about specific device technologies, while staff across the Center would become more familiar with postmarket issues related to their products
   - Include an analysis of MDRs – with the capability of linking to the actual report – in the database of information about the product or product area as one of the deliverables from the new collaborative product groups
   - Explore the use of outside experts, such as panel members and other scientific and technical experts, for routine evaluation and analysis of MDRs

III. Enhance Risk-Benefit Communication Efforts

The Center's goal is to maximize its ability to communicate information in a clear and timely way to practitioners, patients and consumers. The Center has much important information to impart to the public, and it needs to take maximum advantage of its opportunities to communicate that information. A number of active Center projects have communication themes:

- The redesign of the CDRH Website to improve the way the Center provides information to its stakeholders
- A recently completed assessment of internal communications
- Focus group testing of current risk messages and communications vehicles

However, these projects are being conducted independently and without a coordinated strategic vision of what the Center wants to accomplish with respect to risk-benefit communications, with whom the Center could partner to accomplish that vision, or how the Center could use its position in the healthcare community to greatest advantage.

At least two types of messages must be accommodated in the Center's strategic vision. The first is the so-called "reference library information," i.e., communication to the public of non-emergency public health messages, such as the information CDRH has developed for its web site regarding laser eye surgery (LASIK), heart health, and the safety of cell phones. The development and review of this information is usually not time-constrained.

The second type of message is the communication of time-critical information (for example, a Class I recall). Health care professionals must be kept abreast of this kind of information as it develops, so they can answer questions and do proper treatment planning for their affected patients.

Doing each of these tasks well involves examining the way the Center interacts with health care practitioners and institutions, and determining how to create and use routine communication channels with these groups. Other issues will also need to be explored, including how the Center addresses potential problems when important data are incomplete, at what stage information is given out, and how information gets reviewed and updated after it has been released. Improving risk communication efforts will require collaborative interactions with stakeholders, and all of these actions should be done in line with FDA's communication strategy.

Recommended Actions:

1. Develop and implement a Risk Communication Strategy
- Develop processes for risk communication, including message development, documenting of who is involved, cataloguing potential communication vehicles, prioritizing efforts, sharing information with Center staff, and archiving for future use
- Assess communication tools and stakeholder needs to improve messages and distribution methods

2. Improve the quality, and expand the use of, the Center's communications tools
- Complete the redesign of the CDRH web site to improve the way the Center provides information to its stakeholders
- Work with health professionals to craft and distribute public health messages
    - Gain access to publications and newsletters used for communicating with members, since health care practitioners find out about device problems through these vehicles
    - Seek to author "FDA news" columns in professional society newsletters
- Work with the Commissioner's Office and FDA's Office of External Relations to develop a plan to market and brand CDRH's role in providing risk communication information to consumers and health care professionals
- Engage industry in the postmarket process through education and information sharing, including working with industry on specific issues affecting an entire sector (e.g., design or use instructions)

IV. Focus Enforcement Strategies

The Center's goal is to improve the prioritization, coordination, consistency, quality and timeliness of inspections, reporting and enforcement actions. This goal complements the FDA/ORA transformation effort currently underway. There are many challenges in this area, the most obvious of which involve the resource restrictions affecting the Agency's field enforcement program. Resources are diminishing, and relief in the form of increased appropriations or the introduction of user fees for inspections is not likely.

Field performance goals must be consistent with CDRH goals and strategies, time-sensitive compliance cases must be treated as critical by staff with other pressing responsibilities, appropriate metrics need to be developed to determine the success of actions, and enforcement information must be shared with and utilized by the premarket program. The Center's success in these areas will require prioritizing and targeting efforts, building improved data systems and leveraging the information obtained in audits conducted by other global Competent Authorities.

<u>*Recommended Actions:*</u>

1. Provide training through Staff College to educate ORA about CDRH operations and CDRH about ORA operations

- Establish a CDRH/ORA team to design, develop, and implement learning initiatives that foster knowledge transfer and result in more effective and efficient collaboration and delivery of mission related activities.

2. Enhance enforcement strategies though increased collaboration within CDRH and among CDRH, ORA and the Office of Chief Counsel (OCC)

- Establish routine and frequent communication on enforcement priorities and resource expenditure between the Associate Commissioner for Regulatory Affairs and the Center Director
- Establish routine and frequent communications among the ORA's Office of Enforcement and the directors of CDRH's postmarket offices (OC and OSB)
- Provide routine and frequent feedback to all Center offices
- Restructure the periodic meetings and communications with the Device Field Committee to concentrate on enhancing processes and on risk-based issues
- Improve case development training in a collaborative manner between ORA and the Center, with constructive feedback on cases between ORA and the Center
- Collaborate on firm-oriented and product-based enforcement strategies
- Focus efforts on minimizing the frequency of recalls (more detailed data analyses on hazards, mitigations, and trends, and targeted enforcement and training)
- Provide flexibility within the QSIT model in surveillance and directed inspections, when appropriate, as described in the revised compliance program

3*. Revise inspectional strategies.*

- Explore innovative ways to maintain inspectional coverage of the industry by adjustments to the device inspection program and more efficient use of inspection resources
- Focus a significant percentage of routine inspections on systematically identified firms or products based on analysis of existing or emerging problems
- Ensure appropriate follow-up inspections
- Increase Center expert participation in inspections, when the product(s) or issues are particularly novel, or when special expertise could be beneficial
- Develop a risk-based approach for device imports similar to radiation-emitting products

*4. **Leverage audit results obtained by other global Competent Authorities***
- Develop ways to obtain supplemental information on the quality systems status of those manufacturers that cannot be covered under FDA's yearly work plan but who are visited by other accredited third-party auditing bodies
- Continue to work through the Global Harmonization Task Force (GHTF) to harmonize international operating procedures so that one audit or inspection could be useful to regulatory authorities in all participating countries

*5. **Increase postmarket industry education***
- Disseminate enforcement information by describing the problems FDA is finding during inspections as is done in the Mammography Quality Standards Act (MQSA) program's web-based "industry scorecard"

*6. **Update data systems***
- Increase electronic handling of cases and improve the database systems that are needed to support this effort
- Improve training on Field and CDRH data systems
- Evaluate existing enforcement metrics, upgrade where needed and make sure that staff are familiar with them and use them to monitor and improve performance
- Integrate the Field operation in the work of the proposed cross-organizational collaborative product groups (see Section I recommendations and Appendix B)

*7. **Increase the use of MDR data to help direct inspectors***
- Facilitate the use of MDR data to help direct inspectors by eliminating the MDR backlog, evaluating adverse event reports by increased numbers of qualified staff, and using the information in the planning of inspections (See also Section II recommendations)

*8. **Use all available enforcement tools***
- Seek voluntary compliance as a first step in resolving violative actions
- Use regulatory meetings as an optional enforcement tool
- Use innovative methods, such as corporate-wide enforcement actions, to achieve compliance
- Use civil money penalties as a routine consequence for companies that don't submit required postmarket studies

Prioritization of Recommended Actions

The goal of this report is to transform the way the Center handles postmarket information to enable the Center to achieve its TPLC vision for regulating products. Given this goal, it is not surprising that the recommendations are far-reaching and will require new processes, new leadership styles and management tools, and a general recommitment to the Center's mission and how it can best be achieved.

The Center currently has many other important demands upon its time and resources, including the ongoing negotiation of MDUFMA 2. There are important recommendations resulting from the recently completed survey on internal communication that must be addressed if the Center is to be successful in implementing the postmarket changes we are recommending here. For those reasons, we recommend that the Center begin with the actions below to ensure an immediate Center-wide focus on postmarket transformation. Next, the Center should develop an implementation schedule for the other improvements proposed above. The implementation schedule should pay special attention to the longer term actions needed to establish a proactive approach to postmarket safety.

Recommended Actions

1. Create CDRH cross-cutting "collaborative product groups" to provide the Center with a TPLC look at regulated products on a routine basis (Recommendation I.1)

2. Develop methods and metrics for tracking and assessing progress in the Center's performance in handling postmarket issues (Recommendation II.A.1)

3. Aggressively pursue the development of unique identifiers (UDI) for medical devices, in collaboration with industry and health care providers, in order to easily identify specific devices when postmarket questions are raised (Recommendation II.C.1)

4. Optimize the Center's passive surveillance systems by making electronic reporting of adverse event data mandatory (" eMDR") (Recommendation II.B.1)

5. Make MDR and other postmarket data broadly available to staff by revising and updating the MAUDE system, and expanding the premarket data warehousing effort to include postmarket applications (Recommendation II.A.2)

6. Transform the quantity and quality of Center/ORA interactions through increased collaboration within CDRH and among CDRH, ORA and OCC (Recommendation IV.2)

7. Develop and implement a risk-communication strategy to maximize CDRH's ability to communicate information in a clear and timely way to practitioners, patients and consumers (Recommendation III.1)

8. Design a pilot project to test whether quantitative decision-making methods can be useful in regulating medical devices across the total product life cycle (Recommendation II.C.; see also Appendix E)

9. Increase active surveillance by enhancing MedSun programs that reach out to participants and get answers to pressing public health questions (Recommendation II.B.4)

Next Steps

This report suggests *what* should be done. *How* the recommendations get implemented will require a great deal of collaborative effort on the part of all Center staff. Many of the recommendations will need to be staged. Success will ultimately depend on the extent to which Center managers are able to tap into the creativity and knowledge of staff in determining implementation steps.

A suggested implementation path:
- Begin with a general Center presentation of the recommendations to staff
- Follow with a series of discussion sessions at the Office and Division levels to ensure that everyone understands why this effort is happening, why it is important, and to obtain staff suggestions on implementation

- Develop a comprehensive schedule, analogous to the way the Center handled the implementation of FDAMA and MDUFMA, which lays out the priorities and long-term time-frames within which these recommendations will be implemented
- Assure that the implementation of these recommendations is coordinated with the implementation of recommendations from the internal communications report
- Establish implementation teams and product groups with clear charges, timelines, and expectations
- Hold routine report-back meetings with Senior Staff
- Bolster these meetings with regular Center All-Hands meetings to give comprehensive feedback to staff, and to celebrate progress

Appendices

Appendix A – Members-Postmarket Transformation Leadership Team

The Postmarket Transformation Leadership Team included:

Senior Management of the Center for Devices and Radiological Health:
    Daniel G. Schultz, M.D., Director of the Center for Devices and Radiological Health
    Lillian Gill, D.P.A., Senior Associate Director, CDRH
    Timothy A. Ulatowski, Director, Office of Compliance, CDRH
    Lynne L. Rice, Director, Office of Communication, Education, and Radiation Programs, CDRH
    Miriam Provost, Deputy Director, Office of Device Evaluation, CDRH
    Steven I. Gutman, M.D., Director, Office of In-Vitro Diagnostics Devices, CDRH
    Susan N. Gardner, Ph.D., Office of Surveillance and Biometrics, CDRH
    Larry G. Kessler, Sc D., Director, Office of Science and Engineering Laboratories, CDRH
    Ruth E. McKee, Director, Office of Management Operations, CDRH.
External consultants:
    Elizabeth D. (Jacobson) Krell, Ph.D., a private consultant
    Jeffrey A. Brinker, M.D., Professor of Medicine, The Johns Hopkins Hospital
    Steven M. Niedelman, FDA Associate Commissioner for Regulatory Operations, (until retirement).
Susan Meadows, Office of Communication, Education and Radiation Programs, CDRH served as Executive Secretary, and special editorial assistance was provided by Stephen M. Sykes, Deputy Director, Office of Surveillance and Biometrics, CDRH.

Other participants:
    Linda S. Kahan, Deputy Director, CDRH
    Anne Kirchner, FDA Office of Regulatory Affairs
    Donna-Bea Tillman, Director, Office of Device Evaluation, CDRH
    Robert Ciperson, Office of Surveillance and Biometrics, CDRH
    Diane Mitchell, M.D., on detail from the Office of Device Evaluation to the Office of Surveillance and Biometrics, CDRH
    James Woods, Deputy Director, Patient Safety and Product Quality, Office of In-Vitro Diagnostics, CDRH
    John L. McCrohan Jr., Deputy Director, Office of Communication, Education, and Radiation Programs, CDRH
Other attendees:
    Don St. Pierre, Deputy Director, New Product Evaluation, Office of In-Vitro Diagnostics, CDRH
    Larry D. Spears, Deputy Director for Regulatory Affairs, Office of Compliance
    Kimber C. Richter, M.D., Deputy Director for Medical Affairs, Office of Compliance

Appendix B – CDRH Collaborative Product Groups

CDRH is currently organized around vertical operational or "business" functions. These functions, housed in five of the seven Center's Offices, are device evaluation, education and outreach, compliance and enforcement, surveillance and laboratory science. Three other essential Center operations are housed vertically, but function horizontally. The Office of Management Operations provides services across all Offices horizontally. The Office of In-Vitro Diagnostics is a multi-functional organization with responsibilities covering both pre-market review and postmarket surveillance of in-vitro diagnostic medical devices. Staff College, the corporate human resource development component of the Center, is housed in the Office of Communication, Education, and Radiation Programs (OCER), one of the vertical business Offices.

There are currently a number of vehicles designed to provide cross-cutting communication, for example, PMA Review Teams, Post Market Issue Action Teams, Working Groups, and MDUFMA Teams, but these are primarily reactive and problem focused. The authority of each team, reporting relationships, charges to the teams, disposition of team recommendations, and termination of the teams are variable and issue- and team-dependent.

CDRH staff bring two important types of expertise to the work they do. They have extensive knowledge and experience in the operations and management of regulatory systems. They also have great depth of understanding and experience with the effective design and performance of complex medical devices. Both strengths are essential for the Center's mission of promoting and protecting the public health. The Center should have an organizational structure that capitalizes on both types of expertise. For this reason, Section II of this report recommends that the Center create a cross-cutting organizational matrix to support the Center's TPLC regulatory approach   A formal matrix system, which adds an organizational component along product lines, would encourage:
- Vertical authority, accountability, and communication to manage operational systems
- Horizontal interaction and collaboration to ensure timely awareness and proactive discussion of priorities along product lines

The development of a matrix system of formal "CDRH collaborative product groups" would complement the existing offices which house the Center's regulatory systems. The

offices would continue to maintain the authority to provide management, resource allocation, prioritization, and program decisions. The core businesses of device evaluation, surveillance, compliance and enforcement, outreach and education and laboratory science, would continue as the vertical operational hierarchies of the matrix. A cross-cutting matrix could provide consistent rich and timely communication and problem solving *across* these vertical components. Horizontal CDRH collaborative product groups would be developed that would bring together representatives from the core business offices who have responsibility and expertise in a specific product area. The intent is to communicate and collaborate across boundaries to increase organizational learning and capability.

These new CDRH collaborative product groups would bring together, on a regularly scheduled basis, experts in the manufacture, use, operation, and regulation of products to collaboratively manage and discuss the quality and impact of their products on the public health. These groups would be an authoritative and continuous forum for communication among reviewers, technical and scientific experts, compliance and regulatory experts, inspectors, and risk communicators about products from inception to obsolescence. Within the product groups, the staff would be aware of the common product problems and work together in pursuit of common solutions. The product groups could be learning groups, committed to developing better device evaluation and analysis tools that could improve the way each office conducts business.

Each collaborative product group would have a group leader. The leaders could come from any office within the Center and would be expected to have special training in, or be recognized for, their leadership skills. They also would be knowledgeable about medical device products, and demonstrate a keen interest in improving the quality of device pre- and postmarket evaluation and analysis work across the Center. Leadership opportunities will be publicized throughout the Center and will be selected in accordance with standard personnel practices.

The CDRH collaborative product groups would provide an interactive forum for device experts to discuss their product area and:
- Determine the greatest risks posed by the products in their product area and how those risks can be mitigated
- Assess recalls, public health notifications, and other postmarket actions that have been taken on the products and whether any general conclusions can be drawn

from them
- Analyze MDR and any other adverse effects information
- Determine what type and how many premarket applications are in house and what, if any, postmarket information there is to inform the reviews
- Predict problems lurking ahead
- Predict what new technologies are on the horizon and what the Center needs to do to get ready for them
- Assess the state of collaboration between the Center and outside stakeholders, including medical specialty groups and consumer groups
- Assess the adequacy of the Center's communications to the public about public health problems or issues with the products

The CDRH collaborative product groups would be charged with keeping Center management aware of the issues they identify that are critical to their product area's safety and effectiveness.

The groups would be intimately aware of current needs for their device areas. The product group leaders would be knowledgeable about staff participation within this framework. Therefore, input from the leaders will be required by Senior Staff and Center management in considering:

- Additional needs requests
- Hiring requests
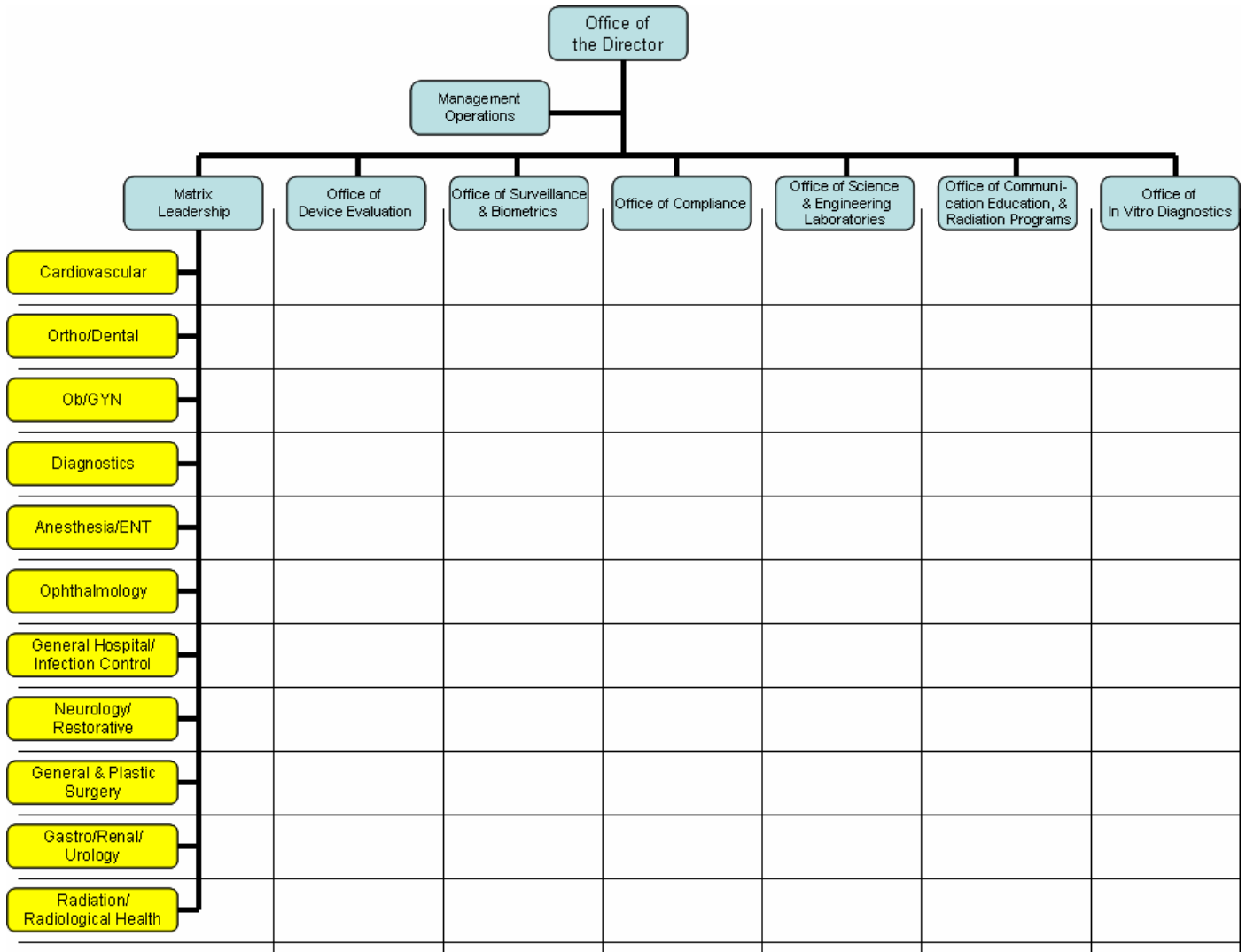- Group award nominations
- Performance evaluations

The Center would recognize the work of the product groups by reinforcing the emphasis on collaboration and integrating their work into the Center's regulatory decision-making process. Leadership and oversight would be provided by a new matrix leadership function in the Office of the Center Director that will oversee and facilitate the implementation of the product groups, provide mentoring for leaders, and work with group leaders and office directors to find solutions for organizational issues that occur in implementing a matrix organization.

This recommended action requires extensive planning by Center staff and managers working in cross-center teams prior to implementation. Their work would include

identifying the criteria for organizing work into the newly formed product groups and selecting who will participate as product group members, and criteria for identifying group leaders.

The implementation teams(s) would also provide initial guidance on how to proceed with integrating the CDRH collaborative product groups into existing work processes and on ways to take advantage of the seating arrangements in the new offices at White Oak to increase opportunities for collaboration.

Matrix Model for CDRH Collaborative Product Groups

	Matrix Leadership	Office of Device Evaluation	Office of Surveillance & Biometrics	Office of Compliance	Office of Science & Engineering Laboratories	Office of Communi- cation Education, & Radiation Programs	Office of In Vitro Diagnostics
Cardiovascular							
Ortho/Dental							
Ob/GYN							
Diagnostics							
Anesthesia/ENT							
Ophthalmology							
General Hospital/ Infection Control							
Neurology/ Restorative							
General & Plastic Surgery							
Gastro/Renal/ Urology							
Radiation/ Radiological Health							

Office of the Director

Management Operations

Appendix C – FDA Information Management Initiatives

There are a number of strategic and tactical initiatives in FDA and the Center that stand to have a major impact on information management in CDRH, including postmarket systems. These include a unique device identification (UDI) system, development of an IT Strategic Plan and the formation of an Agency-wide Bioinformatics Board (BiB) with subcommittees for major FDA business areas, including postmarket issues.

Unique Device Identification System If successfully implemented, a UDI system, more than any other single initiative, has the potential to dramatically change information management in CDRH. Without a UDI system, establishing the relationship between adverse event reports, listed/marketed products and devices submitted for review is an inexact science depending on such things as product codes, product names and company names, and much of this work depends on manual effort. UDI would not only allow for the ability to easily establish these relationships, but it could do so with significant reductions in manual efforts.

IT Strategic Plan The Center's IT Strategic Plan will prioritize the investments made in information technology in line with the strategic goals of the Center, Agency and Department, in such a way that solutions are designed and built to meet the target architectures of these same organizations. For CDRH, that places particular emphasis on supporting the concepts of regulating using the total product life cycle approach and knowledge management.

FDA Bioinformatics Board The BiB has established a postmarket Business Review Board (BRB) that is presently guiding and overseeing efforts to develop an Agency-wide electronic reporting system for adverse events. The specifics of this system have yet to be determined, but will likely have implications for both eMDR and MAUDE.

Appendix D – Background Information on Postmarket Data Collection

The Center routinely obtains postmarket data from the MDR system, MedSun, supplemental summary reports, inspection and recall reports, annual reports, and post approval studies. At times the Center is able to obtain additional surveillance information from external data sources such as medical device registries, administrative and other external data bases. Each data collection tool has its own characteristics, and strengths and weaknesses. Ideally, these tools would complement each other and fit together to improve the accuracy and timeliness of risk identification. The data are collected to inform the Center about device performance through its lifecycle use in the clinical community or by the public. Timely consideration and analysis of the data remains problematic and hampers comprehensive evaluation of postmarket device performance.

MDR and Alternate Summary Reports Over 90% of the reports in the MDR system are mandatory reports submitted by industry, about 5% are voluntary reports from health care professionals and about 5% are user facility reports. This system is the Center's primary source of adverse event data, however, it has a number of problems. The reports are often incomplete and lack context in which to evaluate the event, the 30 days reporting requirement encourages the submission of reports prior to the analyses being completed and then the submission of supplemental reports, and the volume of reports continues to grow. (It should be noted that the total number of individual reports for some devices has been significantly decreased by the Center's adoption of alternative summary reporting. This program captures well-characterized and well-known device events in a quarterly submission by the manufacturer. These data are reviewed by looking for month-to-month trends or changing averages.) Finally, industry complains that reporting requirements are unclear.

The current MDR contract costs continue to rise. The MDR system is paper-based, reports are time-consuming to handle, and this inefficiency contributes to the current backlog. The backlog hampers access to timely information about device problems, and is an obstacle to efficient and timely responses to postmarket issues. It further prevents the field force from obtaining information about adverse events that could be useful in guiding the conduct of inspections. An electronic MDR reporting process (eMDR) has been developed and is currently in the pilot phase. This electronic system should result in efficiencies in processing, cost savings and the reduction of the MDR backlog problems.

MedSun The MedSun program was developed as a pilot program to test whether adverse event reporting by user facilities could be improved by receiving higher quality reports from a selected group of well-trained, motivated users. In addition, the system was designed to encourage reporting of "close calls" so that preventative action can be taken before patients are injured. This program has been favorably received by participating user facilities with over 80% of MedSun participants reporting that being part of the program has improved safety in their facilities.

External Data Sources External data sources can provide valuable information to the Center. Two external data sources that merit special attention are *registries*, which have become increasingly popular as a tool for postmarket surveillance, and the intelligence to be gleaned from the members of *clinical professional societies*.

A well-designed registry can be used to gather real world experience in medical device use and assess whether premarket clinical trial data can be generalized. CDRH could utilize registry information to improve and enhance the analysis of MDR data. Registries also offer opportunities for collaboration among potential users of the data, reducing duplicative efforts for data collection. This is critical because of the cost of establishing and maintaining registries. The Center can leverage its efforts by looking for opportunities to collaborate on existing sources of registry information, when appropriate, to provide further analyses of signals detected by other CDRH systems.

Although clinicians can provide excellent intelligence about the clinical significance of adverse event information from postmarket sources such as MDRs and recalls, the Center has no "routine" permanent liaisons with clinical professional societies. Existing connections have usually resulted from specific problems or other issues. For example, a very productive working relationship developed between CDRH's Defibrillator Working Group and the Heart Rhythm Society after last summer's concerns about defibrillators.

Appendix E – Improving the Postmarket System for Medical Devices: Utilizing Quantitative Decision Making Methods

This pilot project involves the use of formal, quantitative decision-making methodology to evaluate medical devices throughout the total product life cycle, by known, suspected, and unknown risks of products as well as known, suspected, and unknown benefits. For each risk and benefit, the approach requires estimating the population of patients (or users) that would be affected, the duration of use, the probability of the risk or benefit, and the health outcome associated with the risk or benefit.

These estimates would then be communicated within both the premarket and postmarket system in the Center in a commonly available format. Decision-making could take the form of a formal combining of the risk and benefit values via a commonly used scale, such as quality adjusted life years (QALYs). Alternatively, decision-making could happen much the way it does now, after examination of the evidence but without the use of a quantitative tool.

However, what is new is the transparency of the estimates involved, the assumptions necessary to achieve those estimates, and the description of the decision tied to these estimates. If the distribution of the probabilities and the risk/benefit estimates is then made available, there is a natural framework for the systematic incorporation of postmarket information.

This is typically referred to as Bayesian updating of estimates, although a pure Bayesian approach is not necessary. However, this is a natural mathematical structure for decision-making.

The project would be piloted in one of the new collaborative product groups and would entail the following steps:
- Invest in a short course designed by experts in decision-analysis tailored for medical device decision-making
- Train appropriate staff within the product groups
- Construct a template for using these methods at all stages of TPLC – pre-IDE/IDE (if applicable), review of premarket applications, postmarket data collection and analysis, compliance/enforcement
- Select previously reviewed products (number and type will depend on staffing,

workload, and candidates available). Pull together data and information about the product that were available at the time of review. Re-review product using a decision-analysis approach: namely, explicitly list risks and benefits, attempt to quantify where possible, then add value information to the possible outcomes

o Search out all available postmarket/compliance information relevant to the product. Use the decision-analysis framework to incorporate this information into what we know about the product and evaluate what this tells us about the product. Conduct a formal postmarket study via a mechanism such as Section 522

o Evaluate the performance of our decision-analysis methods and refine as needed (this is the feedback mechanism we will need continuously, especially early in this process)

o Assess whether quantitative decision-making methods are feasible and useful for medical device regulation across the total product life-cycle.