Medical Product Safety Network (MedSun) Collaborates with Medical Product Users to Create Specialty Subnetworks

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Abstract

The U.S. Food and Drug Administration (FDA) is now in its fifth year of identifying medical device-associated risks through the Medical Product Safety Network (commonly known as MedSun). MedSun has expanded nationally to 350 facilities. These are primarily hospitals, but outpatient clinics, nursing homes, and home health agencies are also represented. The basic reporting team for each participating site comprises primarily risk managers and clinical patient safety officers. MedSun participants receive device-related feedback from the FDA relevant to their reported issues. In particular, the exchange of device-related safety information and reports on adverse events with the clinical community provides the FDA Center for Devices and Radiological Health (CDRH) MedSun program with enhanced understanding of medical device-related problems. In order to reach more deeply into the participating hospitals to obtain incident information from the actual clinical users of the medical devices, MedSun is now implementing targeted surveillance efforts that are directed toward "high-risk" areas of the hospitals. This effort has resulted in the development of subnetworks within MedSun to give attention to the types of products of interest to the FDA. Currently, four subnetworks have either been launched or are under development for data collection that began in 2007. The goal is to build relationships between MedSun/FDA and frontline medical device users so the FDA can work with clinicians to learn about, understand, and solve problems related to the use of medical devices. The FDA is evaluating the impact of developing these reporting relationships on the overall effectiveness of MedSun data collection. The subnetworks also offer the FDA an opportunity to obtain more "real-time" information from subnetwork participants through focus group discussions, teleconferences, and educational offerings.

Introduction

The Medical Product Safety Network, commonly known as the MedSun Program, is a United States Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) program that works with a sample of hospitals, nursing homes, and other health care facilities (350 sites nationwide) to:

- Rapidly identify and understand problems related to the use of medical devices.
- Provide a "laboratory" for research into understanding problems with these medical products as they are used in the clinical environment.
- Provide actionable feedback to the clinical community.

The key element of MedSun is its relationship with a relatively small, specifically trained, and motivated group of reporters from each MedSun site. These MedSun reporters typically include a risk manager and a biomedical or clinical engineer from each site, but many sites also include quality managers, material managers, patient safety managers, and clinicians on their MedSun teams. They send reports about problems with the use of medical devices through the secure online system into the FDA database. The FDA provides feedback to the MedSun reporters so they can improve patient safety related to the use of medical devices at their sites.

MedSun has used a "train-the-trainer" model, which employs numerous educational tools for MedSun reporters to use with health care professionals throughout the hospital. These tools promote staff recognition of device-related events and encourage notification through the hospital's in-house reporting system, which the designated reporter then passes on, when appropriate, to MedSun. MedSun sites also help the FDA understand device issues by responding to surveys, participating in focus groups, and providing clinical experts to participate in individual telephone interviews on an as-needed basis.

The specifics of the early years of MedSun, and the concepts used to build the beginning phases of this highly collaborative, interactive, and successful reporting program, were presented in the Agency for Healthcare Research and Quality (AHRQ) 2005 publication *Advances in Patient Safety: From Research to Implementation.*[1]

This update provides a brief overview of the program to date and then a lengthy discussion of the newest phase of MedSun, its subnetworks, which target specific clinical specialty areas to obtain information directly from end users of devices and human tissue and cell products.

Update on Current MedSun Program

The FDA has been working with a contractor, Social & Scientific Systems, Inc. (SSS), in Silver Spring, MD, to design and implement MedSun since 1996. Data collection began in February 2002 with 25 sites on the east coast. The cohort reached 350 sites across the continental United States in 2005. As of July 31, 2007, data collection had yielded the types and number of outcome reports shown in Table 1.

MedSun encourages the reporting of medical product problems before a patient is injured or dies because of the use of that medical product. This permits the FDA, the clinical community, and device manufacturers to become aware of and solve problems before patients are injured. The very large percentage of reported problems falling into the "potential for harm" category speaks to the responsiveness of the MedSun sites to this important patient safety agenda.

The most recent MedSun Annual Report, issued in March 2007, demonstrated that MedSun reports have been extremely useful in improving patient safety nationwide.[2] Here are a few facts concerning actions stemming from the FDA and manufacturer receipt of MedSun adverse event reports:

Table 1. Patient safety data reported to MedSun through July 31, 2007

Reported outcome	N[a]
Death	184
Serious injury/illness	828
Minor injury	1,132
Potential harm to patients	5,312
Potential harm to health care provider	371
"Other" (e.g., out-of-box failures, reports of poorly designed devices, complaints about manufacturers)	1,371
Total outcomes	**9,198**

a Total number of reports = 8,767; some reports showed more than one outcome.

- Ten device recalls and 39 other manufacturer actions (e.g., letters issued to customers, improving labeling, changing suppliers to obtain parts, and current and future design improvements) came out of review of information provided in MedSun reports.
- Eight CDRH investigatory teams were formed to investigate and solve complex issues, which required a multidisciplinary approach.
- A variety of followup efforts were implemented to learn more about certain medical device issues, including focus groups and surveys of professionals from the MedSun sites.
- Safety tips (five in total) were written. Sometimes the best approach in helping to solve a problem is to develop educational articles for members of the clinical community about safer ways to interact with the devices they use.

Expanding MedSun to Include Subnetworks

The MedSun program is highly successful in generating signals about problems with medical devices. Due to the success of this model, the FDA explored avenues for increasing the number and quality of reports from "high-risk" areas of the MedSun sites. Numerous areas in hospitals utilize devices that are considered "high-risk" or serve highly vulnerable populations. Given that the FDA does not have unlimited resources to investigate and address adverse events with medical devices, the question for the FDA became, "How and where in the hospital should MedSun focus its attention to increase the number and quality of reports?"

The answer to "how" was to create subnetworks within some selected existing MedSun facilities to include, as additional reporters, health professionals who work in areas where high-risk devices are used or where patients may be especially vulnerable. It was anticipated that this approach would increase the likelihood that the FDA would learn about device problems that occur in these selected areas. Also, access to frontline users of devices in these "high-risk" areas would enable the FDA to quickly canvass several users to see if they were having problems similar to those reported by others in the subnetwork. This strategy increased MedSun's enhanced surveillance to the level of obtaining information in "real-time" when needed.

Selecting the Subnetworks

The idea of "subnetworks" was the easy part. The hard part was selecting the "where" because of the many areas in the reporting facilities where "high-risk" devices are in use. Narrowing the subnetworks to a few areas was important due to the resource-intensive effort necessary to recruit and orient health care professionals in the subnetworks; develop useful feedback to the subnetworks, which the reporters could use to improve patient safety; develop ongoing educational opportunities to keep the reporters engaged in each subnetwork; and to process, analyze, and take action on the large increase in reported issues that was expected.

It was critical to target subnetworks that would provide CDRH with timely information about rare events that is often difficult to obtain from the broader MedSun program, from registries, from the literature, or from other sources. Therefore, the MedSun team announced to CDRH that it wanted to create these subnetworks and asked for input.

In 2004, Steven Gutman, MD, the Director of the Office of In-Vitro Diagnostic Evaluation and Research (OIVD) in CDRH, asked the MedSun team to provide his office with a connection to clinical laboratories within hospitals so that OIVD could have more in-depth and timely reports directly from the laboratories about problems with in vitro diagnostic products and point-of-care devices, such as glucose meters. Thus, LabNet was conceived and created. The lessons learned from LabNet have provided the basis for design of the subnetworks that came afterwards: the Tissue/Cell subnetwork (implemented for our sister FDA Center – the Center for Biologics Research and Development), HeartNet, and KidNet.

In 2005, while LabNet was being launched, FDA's Center for Biologics Evaluation and Research (CBER) contacted the CDRH MedSun team to explore the inclusion of human cells, tissues, and cellular and tissue-based products (HCT/Ps) as products that certain hospitals would be trained to report about through MedSun. CDRH staff were very interested in collaborating with a sister Center within the FDA to help ensure the safety of additional types of medical products. FDA staff from CDRH and CBER began developing the Tissue and Cell Pilot Project to obtain information from MedSun sites about adverse events and events representing potential for harm associated with various types of tissues, cells and related products.

The concept for HeartNet took hold in 2005 when Thomas Gross, MD, MPH, the Director of the Division of Postmarket Surveillance within CDRH, asked the MedSun team to develop a subnetwork that would collect unanticipated/unexpected problems with devices used in electrophysiology (EP) laboratories [e.g., cardiac pacemakers and implantable cardioverter defibrillators (ICDs), ablation catheters]. ICDs had been the focus of highly publicized recalls in 2005 and 2006, and CDRH receives thousands of reports about these types of devices, so it is well informed about the routine types of problems seen with them. However, rare or unusual problems often go unreported.

Therefore, Dr. Gross asked that electrophysiologists be recruited from within MedSun hospitals who would be highly motivated to report device-related adverse events that, based on their clinical experience, were something they believed to be unanticipated or unexpected. Additionally, he requested that these volunteers be willing to respond quickly to the FDA's queries about whether they too might have experienced a particular problem about which the FDA needed more information. This would provide the ability to quickly amplify a particular

problem, so that the FDA could ascertain whether a problem might be widespread. This strategy has quickly been incorporated into the other subnetworks as well.

The importance of developing a subnetwork focusing on pediatrics was clear from the early concept development of the subnetworks. Numerous special issues surround medical device use in children. One example is the lack of clinical data on how the pediatric population responds to treatment with many of the medical devices used in the pediatric setting. Clinical trials might have included adults, but once a device is cleared for marketing, it might also be used on children because of the lack of a pediatric version of the product. Since children might react in unexpected ways to devices, it seemed critical for the pediatric clinical community to be aware of the types of problems that could occur.

In 2007, MedSun began planning and developing KidNet. This subnetwork focuses on collecting data from neonatal intensive care units (NICUs) and pediatric intensive care units (PICUs). Participation in this subnetwork is not limited to MedSun pediatric specialty hospitals but extends to all MedSun hospitals with large NICUs and PICUs. This broader inclusion of hospital types provides for larger numbers of reported events. KidNet data collection began in June 2007.

LabNet

CDRH estimates that 80 percent of all professionals' medical decisions are determined from laboratory results, with 15 to 50 billion health care dollars spent on laboratory tests each year. Laboratory tests and their results play a prominent role in the diagnosis of patients' conditions and constitute a foundation of modern medical practice. The primary goal of OIVD is to ensure the safety and effectiveness of in vitro diagnostic (IVD) devices. An important instrument in the FDA's "toolbox" to ensure the safety and effectiveness of IVD devices is the active surveillance of "signals" and of any adverse events associated with their use.

OIVD relies heavily for adverse event data on IVD devices on LISTSERVs™, literature reviews, manufacturer reports, trade complaints, consumer complaints, government reports, and manufacturers' recalls. In early 2006, OIVD wanted to enhance its surveillance efforts to include a more active type of monitoring using the MedSun program. LabNet was then developed as the first MedSun subnetwork in collaboration with OIVD.

LabNet has two principal objectives. The first is to promote health care providers' awareness about IVD devices and their role in patient safety. Thus, staff working in hospital laboratory areas and "sharp-end" clinicians in patient care settings are targeted as candidates for education and training geared toward promoting this awareness. LabNet's training efforts encompass a broad scope of clinicians: hospital laboratory directors and managers, medical technologists, and bench technologists, as well as clinicians in various patient care areas.

LabNet's second objective is to emphasize the importance of adverse event reporting to OIVD about both adverse events and situations indicating the potential for harm related to these devices. LabNet is designed to collect information about devices, whether problems (e.g., with point-of-care devices like glucose meters) have been observed in hospital laboratories or in clinical patient care areas.

LabNet was created after a small MedSun pilot effort in 2004 and 2005 indicated that OIVD could obtain very important reports about problems with diagnostic devices from laboratories. Although the number of reports received was small, the vast majority of the reports provided important information that was the first signal OIVD received about these issues.

The pilot provided lessons that were incorporated into the current design of LabNet. For example, OIVD became aware that laboratories expected direct and timely feedback from the FDA in exchange for their reporting efforts, they required reminders to report, and they needed a system of adverse event reporting that was simple and fairly quick (e.g., using forms that could be completed in less than 15 minutes). Obstacles to reporting adverse events to the FDA were identified as well. For instance, the culture in many hospital laboratories fosters reporting only to manufacturers and not necessarily directly or indirectly to the FDA. Bench and medical technologists, who were in the best position to witness errors, were often unaware of the importance of reporting adverse events (actual and potential) to the FDA. The pilot's participants commented that staff were confused about exactly what products/situations merited reports.

These lessons suggested that LabNet would require an education program at its onset. Such a program would focus on identifying IVD devices and the problems that can occur with them, stressing the importance of reporting to the FDA adverse events and the potential for harm, and highlighting the benefits for public health. Additionally, a successful data collection effort would require useful feedback to the participants and frequent followup efforts on OIVD's behalf.

During the planning effort for LabNet, OIVD staff indicated the kinds of situations that were of interest to them as regulators. These included (but were not limited to) incorrect diagnosis as a result of inaccurate laboratory results, inappropriate labeling, unclear instructions in labeling/ packaging, repeated quality control failures, defective sample collection devices, and calibration failures.

In July 2006, OIVD "kicked off" the LabNet network with an informational audioconference for all MedSun participants, including an invitation for MedSun hospitals to participate in the subnetwork. More than 60 individuals called, with 30 sites then committing to LabNet participation. Since OIVD's Director was very interested in learning about the effectiveness of product labeling being made available to laboratories either online or via electronic format, during that same month, drawing upon those interested in the subnetwork, LabNet hosted a telephone focus group discussion concerning electronic labeling.

Within a few months, educational Web-cast orientation sessions were provided for MedSun representatives and laboratory staff members interested in participating in the network. The LabNet orientation provided participants with useful information on the reporting of adverse events involving IVD devices. Examples of laboratory devices were provided, along with a listing of the problems that could occur with such products and report examples.

To date, 50 network participants representing 25 MedSun facilities are involved in the pilot program. OIVD was also interested in increasing IVD device signaling from areas outside the MedSun communities. In 2007, they brought in the National Institutes of Health, which had not previously been participating in MedSun, as a LabNet site.

Roundtable discussions with a major health care system's laboratory managers began in March 2007. Discussion topics have included IVD device reports submitted by the health care system and the FDA's followup, exploration into the health care system's experiences with problems reported into OIVD (thus permitting "amplification" of the signal for OIVD), and an educational session on erroneous troponin results.

Feedback to the FDA about laboratory device reporting from such forums verified a culture of reporting IVD device problems primarily to the manufacturer. The managers did acknowledge that they understood that reporting only to the manufacturers leaves the FDA in the dark. As a common occurrence, many IVD device problems were taken care of by the manufacturers, and reporting to the FDA had usually been reserved for those few instances in which problems were not resolved in this way. All communications with manufacturers are logged in a log book for tracking purposes. With the health care system's permission, LabNet is piloting the use of a MedSun representative to review the log books to determine whether incidents of interest to OIVD can be found there.

All LabNet reports are reviewed by the LabNet team, followup and potential patient safety efforts are discussed, and actionable items are determined by the team. Patient safety actionable items might include placing reports in the MedSun newsletter to share with the general public, creating a safety tip, creating an internal working group to further explore problems, and involving CDRH's pre-market approval or compliance specialists (who work with manufacturers to improve products' safety and effectiveness).

Personal contact with LabNet participants has been critical to the program's success. Through one-on-one discussions with LabNet participants, OIVD has learned about issues pertaining to the lab values for special patient populations and important human factors regarding specific lab products. The MedSun annual conferences have also served as important opportunities for OIVD staff to build relationships with LabNet participants.

Preliminary efforts to measure the program's success demonstrate that for the 6-month period prior to LabNet's introduction, MedSun received eight reports involving in vitro products; for the following 6-month period, 16 reports were received. Although these are small numbers, this represents a 100 percent increase for IVD device reporting since the informational kickoff. During the first year of LabNet, 33 IVD device reports were submitted. The descriptive LabNet reports received by the FDA in this short period have been very useful.

OIVD finds LabNet a valuable resource because of the quality of the signals it generates. The training of staff at sites and the free exchange of information between sites and OIVD have contributed to the fact that LabNet is a particularly important source of post-market information. In addition, OIVD has benefited from two unique features of LabNet. The first is the ability to create, in a streamlined manner, focus groups to address old or emerging problems identified by this network or originating on the outside. The second feature is the ability, as noted above, to make personal connections between OIVD and working laboratory managers and workers. An initial series of information queries to representative members of the LabNet network has clarified OIVD thinking in the arena of patient safety monitoring from the perspective of laboratory services. Candid discussions with high-, moderate-, and low-volume laboratories have reinforced the view that, in general, the current regulatory framework for IVD devices is working

well; manufacturers are able to make and label quality products for routine laboratory use; and with few exceptions, manufacturers are also quite sensitive to needs, questions, and requests raised by the laboratories they supply.

Human Tissue and Cell Subnetwork

Just as CDRH regulates medical devices, CBER regulates human cells, tissues, and cellular- and tissue-based products, including (but not limited to) the following:

- Eye tissue (cornea).
- Sclera.
- Bone.
- Musculoskeletal soft tissue (tendons, fascia lata).
- Skin.
- Heart valves.
- Blood vessels.
- Dura mater.
- Reproductive cells (semen, oocytes, embryos).
- Hematopoietic stem cells (peripheral, cord).

Nonhuman cells and tissues (usually porcine or bovine), which are used in medical care, and human cells or tissues, which have been incorporated into nontissue products (e.g., mesh backings), are generally regulated by CDRH. Collaboration with regard to data collection was seen as mutually beneficial to both FDA Centers. The focus of the FDA Tissue and Cell Subnetwork is on detecting, understanding, and sharing information about adverse events and situations indicating potential for harm from these products.

The timing of this collaboration was especially important for CBER because in May 2005, the FDA implemented regulations that require HCT/P manufacturers to report serious adverse reactions to the FDA, if the reactions are related to their products and involve communicable disease. This regulation was followed by the issuance of a Joint Commission standard for hospitals, effective July 2005, which required hospitals to report to the suppliers of these products any adverse events for human cells, tissues, and related products.[3] Under this Joint Commission standard, hospital staff report to the HCT/P establishment. The manufacturer, in turn, reports to the FDA for events required by FDA regulation (i.e., serious events involving communicable disease).

CBER staff wanted to learn more from health care facilities about problems with cells, tissues, and related products, in addition to the problem of infections. A MedSun subnetwork was seen as one way of facilitating that line of communication.

The subnetwork began recruitment in late 2005, at which time the FDA established a goal of enrolling at least 50 MedSun sites. By 2007, 58 sites had agreed to join and had personnel trained to report. An average of 38 sites have been enrolled in the program at any one time over the project's duration, and 99 personnel affiliated with MedSun sites have received training on

reporting HCT/P events through the MedSun Tissue and Cell Subnetwork. Many of these personnel are infection control practitioners, tissue managers, operating room staff with tissue- and cell-related knowledge and responsibilities, or clinical staff from hospital tissue or blood banks. Once they have completed the Web-cast orientation program, they report directly to MedSun through the secure online reporting system or through their risk managers.

Although the number of cell/tissue-related reports from this group has not been large (approximately 40 reports so far), the reports have augmented reporting to CBER for HCT/Ps. The 40 MedSun reports represent one-third of all voluntary (i.e., non-manufacturer-based) reports submitted to CBER during the project's operation and 12.1 percent of all HCT/P reports to CBER during that timeframe. By leveraging the infrastructure of the existing MedSun program, developing the Tissue and Cell Subnetwork has been a cost-effective way to augment the overall number of HCT/P reports submitted to the FDA.

The Tissue and Cell Subnetwork is the first enhanced surveillance program for HCT/P-related adverse events. CBER and CDRH staff are encouraged by the number and quality of the reports they have received and by the link the project provides to the clinical community. Infection-related MedSun reports are routinely investigated by CBER's Tissue Safety Team to detect any product-related disease transmissions. In one case, for example, a MedSun site reported a serious infection in an Achilles tendon. This event was eventually related to a recall by the tissue manufacturer of other tissues from the same donor, as the firm had discovered that another recipient of this donor's tissue had become infected with the same organism. The MedSun report expedited the Tissue Safety Team's investigation of this case.

The Subnetwork also serves as a conduit for participating sites to ask questions and receive feedback from CBER staff on FDA regulations, adverse reaction reporting, and other HCT/P-related concerns.

By not restricting reports to communicable disease-related events, the project broadens the scope of HCT/P reports normally submitted to the FDA. Sites are asked to submit any type of HCT/P related safety information, including noninfectious adverse events and problems with potential for harm, such as damaged products or labeling concerns. These events do not individually initiate FDA regulatory actions (although they might stimulate a response from the manufacturer). However, these reports are qualitatively different from the infectious adverse reactions normally submitted to CBER, and they provide insight for the Tissue Safety Team on the transplantation community's experience with HCT/Ps.

Because the HCT/P manufacturer also receives the report, the project also helps MedSun sites meet the Joint Commission requirement to report to the tissue establishment.

In June 2006, MedSun held an audioconference about this Subnetwork, during which CDRH and CBER learned from participating hospital representatives that the information presented through this Subnetwork was helpful to them, especially for complying with the new Joint Commission requirement for reporting on infections. Participating representatives also indicated that they liked being able to report about cells and tissues and related products using the MedSun system, as they do for medical devices.

MedSun staff provide feedback about the reports they receive and about activities related to this Subnetwork through the MedSun newsletter. In addition, weekly FDA recall information concerning biologics is provided to those MedSun participants who have opted to receive that service. The June 2006 audioconference also provided an opportunity for CBER staff to conduct educational outreach, presenting on the FDA's new regulations concerning adverse reaction reporting for HCT/Ps (21 CFR 1271).

A MedSun representative wrote an article for the MedSun newsletter in 2006 about how the Tissue and Cell Subnetwork has raised awareness about changes to certain procedures needed to remove recalled products from hospital shelves. As with the other subnetworks, educational programs will be developed for relevant staff to learn about the importance of their reports on cells and tissues and related products.

HeartNet and KidNet

HeartNet targets the collection of early warning data on newly emerging or unexpected device-related adverse event problems with diagnostic and therapeutic cardiac ablation, mapping, pacing, and defibrillation device-related adverse events occurring in the electrophysiology (EP) laboratory setting that are:

- Unexpected.
- Not commonly known.
- Not listed in the current labeling of the device.
- Commonly known, but more severe or specific than noted in the labeling.
- Commonly known, but occurring as part of an unanticipated cluster.

KidNet's focus is on identifying and reporting all medical device-related adverse events that occur in PICUs and NICUs and involve death or serious injury, or events that represent a "near miss," "close call," or "potential for harm" if the event is not caught in time in patients, family members, or health care providers. KidNet is particularly interested in problems with medical devices that fail or do not perform optimally in the pediatric patient population because of sizing or fit. Like other subnetworks, HeartNet and KidNet emphasize educating the "hands-on" device user to recognize and report medical device-related adverse events.

Building on the lessons learned with LabNet, the development of the HeartNet and KidNet subnetworks incorporated visits to various types of MedSun sites with EP laboratories or, for KidNet purposes, with ICUs for children and/or for newborns. These visits were undertaken to obtain information on organizational culture, with a special emphasis on reporting barriers that were unique to these clinical areas. Common barriers to reporting include:

- A lack of awareness by clinicians of the need to identify and report device-related problems.
- A perception of reporting being burdensome, since staff are already required to fill out many forms. Reporting needs to be fast, user-friendly, and easily accessible.
- A lack of feedback from the FDA. Such feedback should be easily accessible, convenient in light of staffing and patient care responsibilities, and limited to safety issues of clinical relevance.

To address these concerns, the HeartNet and KidNet Subnetworks collect and share information in three ways:

- Through user-friendly, easily accessible online reporting of adverse events or potential-for-harm events.
- Through discussion groups with CDRH and subnetwork colleagues to share information about medical device safety issues and lessons learned via audioconference, online, and through Web-cast formats.
- Through CDRH posting of "reports of interest" to the HeartNet and KidNet Subnetwork communities, in order to solicit collaborative, interactive feedback on Subnetwork participant experiences with similar device-related adverse events.

Most important, clinicians have the opportunity to learn how to recognize and report medical device-related adverse events within their clinical specialty areas by participating in free educational offerings via audioconference and Web-cast formats with continuing education credit awarded upon successful completion.

KidNet data collection began June 1, 2007, and HeartNet began data collection in the fall of 2007. As of August 2007, a dozen reports had been received from six KidNet participating hospitals on adverse events involving patient injury and device problems associated with intravenous pumps, infusion ports, tubing, catheters, orthopedic screws, and surgical instruments.

Conclusion

CDRH has found MedSun to be very helpful in its efforts to learn about medical device adverse events and situations indicating the potential for harm. However, there is a need for targeting certain kinds of products under the MedSun umbrella by reaching out to specialists in pediatric/neonatal intensive care, hospital laboratories, EP laboratories, and, for both CDRH and CBER, to those who are knowledgeable about tissues, cells, and related products in order to learn about product problems unique to these medical specialty areas.

For this reason, the MedSun subnetworks are being developed with an emphasis on recognizing and reporting adverse events by the health care professionals who use medical products in the clinical setting. Although much work remains, the results of these efforts are expected to increase the number and quality of reports the FDA receives concerning high-priority medical product adverse events and situations indicating potential for harm and to improve the feedback the FDA provides to the clinical community. These efforts should generate communication and collaborative partnerships between clinicians, the FDA, and medical product manufacturers to help ensure the safety and effectiveness of the types of medical products used in the subnetworks. The combined effects of the general MedSun program with the new MedSun subnetworks enhance the FDA's ability to promote and protect the public health.

Those who may be interested in having their hospital or other health care facility join the MedSun Network should call 1-800-859-9821 or e-mail medsun@s-3.com for more information about this matter.

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