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Safe Medical Devices for Children

Committee on Postmarket Surveillance of Pediatric Medical Devices
Board on Health Sciences Policy

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Summary

Advances in biomedical science and engineering—combined with achievements in public health—have brought significant benefits to millions of children and their families. Vaccines and drugs are often cited, but medical devices too have helped reduce the burden of illness and injury and improve the quality of life for countless children. For example, mechanical ventilators, in combination with medications and additional therapies, rescue thousands of fragile newborns each year and allow many children who rely on respiratory support to live at home with their families, attend school, and participate in community life. Children who once would have died from congenital heart conditions today survive with the aid of implanted devices such as pacemakers, mechanical heart valves, and devices that close holes in the heart. In addition, a multitude of simple devices such as catheters and other kinds of tubing are essential for modern medical care.

As depicted in Box S.1, some medical devices are intended solely or primarily for use with children. Often, however, devices used with children have been initially developed for, tested with, and most frequently employed to treat adults, who constitute a much larger market for medical services than children.

BOX S.1

Design or Adaptation of Medical Devices for Children

Devices unique to children

- Infant incubators
- Bililights (for treating neonatal jaundice)
- Newborn hearing screener

Devices developed primarily for children but also used with adults

- Atrial septal defect occluder
- Cerebrospinal fluid shunt

Same core device, different accessories for pediatric use

- Pulse oximeter with different sensor attachment for infants
- Automated external defibrillator with paddles that deliver electrical shocks based on pediatric-specific algorithms

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Variations in device use or technique to accommodate developmental differences

- Adjustment in radiation dose and frequency for computed tomography
- Shift in implantation site for pacemakers used with young children
- Use in pediatric cardiac procedures of adult bile duct stents

Variation in device size for use with small patients

- Bronchoscopes
- Heart valves
- Testicular prostheses

Sometimes it is obvious that a device developed for adults is not—in that form—suitable for some children, for example, when an implanted device is too large for infants. Other times, problems with pediatric use—such as more intense inflammatory reactions to implant materials than seen with adults—are not self-evident and are also not detected during initial clinical studies. Instead, problems are only identified after a device is marketed and then used for longer periods and with larger and more varied populations, including children.

As illustrated in Box S.2, benefits and harms with pediatric use of medical devices may be identified in several ways: (1) *a priori* based on expert understanding of children's developmental characteristics and detailed knowledge and modeling of the operating characteristics of a particular device; (2) during the clinical testing of a device with children to demonstrate safety and effectiveness; and (3) as experience with a device accumulates following its entry into the market. At each stage, the key questions are whether the expected benefits of a device, on balance, outweigh expected harms and whether the benefit-harm profile is more favorable than that of available alternatives.

BOX S.2

Identifying Concerns or Adaptations with Pediatric Use of Medical Devices (with Examples)

A priori identification

- Pacemaker implant: choice of implant site to better protect device
- Deep brain stimulator: avoidance of use when patient brain growth is less than 90 percent complete
- Orthopedic fixation device: avoidance of device that will interfere with bone growth

Identification through premarket clinical testing

- Deep brain stimulator: modification of implant placement when 2 stimulators are used with small child
- Titanium rib: modification of device and implantation strategy to reduce migration or bone overgrowth

Identification after marketing

- Cochlear implant: association of meningitis with certain devices
- Home apnea monitors: lack of effectiveness in detecting apnea consistently and preventing sudden infant death syndrome

STATEMENT OF TASK

This report responds to a provision in the Medical Device User Fee and Modernization Act of 2002 (P.L. 107-250) that called for the Institute of Medicine (IOM) to assess whether “the system under the Federal Food, Drug, and Cosmetic Act for

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the postmarket surveillance of medical devices provides adequate safeguards regarding the use of devices in pediatric populations.” The IOM was to examine specifically: (1) the Food and Drug Administration’s (FDA) monitoring and use of adverse reaction reports, registries, clinical studies, and other postmarket surveillance activities; (2) the adequacy of FDA’s monitoring of commitments for further clinical studies made by manufacturers at the time of approval of specific devices; (3) the adequacy of postmarket surveillance studies to evaluate how children’s active lifestyles may affect failure rates and longevity for implanted devices; and (4) the length of postmarket surveillance studies of implanted devices, including whether studies continue long enough to evaluate the impact of children’s growth and development given the expected length of time that a child will have an implant. The committee was not asked to evaluate FDA’s premarket review of medical devices or to assess barriers to the development of medical devices to meet children’s special needs.

Postmarket surveillance of medical devices used with children is a little-investigated topic. This is partly because the market for most medical products is concentrated among adults, especially older adults. Moreover, discussions of medical product regulation and patient safety focus more on pharmaceuticals than on medical devices and more on the assessment of products prior to marketing than on the subsequent surveillance of product performance.

During the course of this study, several themes emerged. They include:

- *Children and their families benefit from safe, effective medical devices.* Timely access to such devices prevents premature deaths and significantly improves quality of life.
- *Systematic attention to children’s needs and characteristics is important in medical device design, use, and evaluation.* Children differ from adults in important ways.
- *An effective regulatory program for evaluating and monitoring the safety of medical devices in general is a necessary foundation for efforts to safeguard children in particular.* This basic foundation then requires the addition of pediatric expertise and resources.
- *The regulation of medical devices reasonably differs from the regulation of drugs.* Medical devices are more variable than drugs in their mode of operation, range of function, dependence on user skills, and potential for harm.
- *A careful assessment of medical device regulations weighs potential positive and negative outcomes, including whether the potential negative effects of a regulation are acceptable.* Like medical treatments, regulations can do harm as well as good.
- *The shift of medical device use from institutions to homes, schools, and the community complicates postmarket surveillance.* Patients, families, and others have taken on roles in device operation, maintenance, and troubleshooting that were formerly performed by health care professionals, but postmarket surveillance has not yet adapted to this reality.
- *Medical device safety is a shared responsibility.* Clinicians, health care providers, engineers, manufacturers, research funding agencies, consumer organizations, patients and families, and others in addition to regulators have critical roles to play.

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FDA REGULATION, MEDICAL DEVICES, AND CHILDREN

Medical devices constitute an extremely varied category of medical products—some as simple and low risk as an infant cap, others as complex and high risk as a cardiac pacemaker. Unlike drugs, which work chemically, devices such as pacemakers, artificial joints, ultrasound machines, and mechanical ventilators have quite different and variable modes of operation. The statutes governing the regulation of medical devices by FDA reflect this variability, particularly in provisions specifying the agency's premarket responsibilities, that is, what it does before a device can be legally marketed.¹

In simplified overview, low-risk devices need not be reviewed by FDA before marketing. Innovative, high-risk devices are subject to an *approval* process that evaluates clinical and other studies of safety and effectiveness. Intermediate-risk devices go through a *clearance* process that involves a more limited review of evidence of safety and equivalence to certain previously marketed devices; clinical evidence of safety and effectiveness is not usually required. Additional regulations, particularly those intended to assure quality and safety in manufacturing, apply to all devices.

After devices enter the market, FDA's postmarket surveillance includes requirements or opportunities for manufacturers, health care facilities, and others to report serious problems—adverse events—that are caused or potentially caused by any kind of medical device or errors in its use. For certain devices, the agency can also require postmarket studies to evaluate device performance or safety as devices are used for longer periods, in different settings, and with more varied patients than during their initial testing. FDA's public health notifications, monitoring of device recalls, and inspections of device manufacturing sites are additional postmarket tools to assure the safety of medical devices.

Virtually the entire regulatory framework for the regulation of medical devices is general; that is, it applies to devices whether their primary or exclusive use is with adults or children. One exception is that when devices are tested with children in studies that will be submitted to FDA, the studies are covered by regulations for the protection of human research subjects that provide additional protections for children. Also, FDA may take special notice of children, for example, by limiting the approved use of a device to patients over a specific age.

FDA PERFORMANCE IN BRIEF

The basic goal of FDA's program of postmarket surveillance for medical devices is to protect patients from harm by identifying and evaluating safety problems and assuring appropriate corrective responses, such as a recall or a precautionary notice to physicians. As undertaken by FDA, postmarket surveillance should be seen as objective, trustworthy, and effective in limiting patient exposure to unsafe devices (or to devices unsafely used). It should seek to minimize avoidable constraints on beneficial innovation while also serving as a resource and stimulus for product improvement.

¹ In referring to *premarket* and *postmarket* rather than *premarketing* and *postmarketing* activities, this report follows the legislative language that provided for this study and FDA's usual terminology.

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With respect to the questions posed for the IOM, this report notes some shortfalls in FDA performance. These shortfalls, by and large, are not specific to children, so responses must be general. Although evaluating FDA resources for postmarket device surveillance was beyond the scope of this study, the committee notes that Congress has authorized but not appropriated additional funds for this purpose.

The discussion below highlights selected recommendations (which are numbered by report chapter). All recommendations are listed at the end of the summary.

Monitoring of Postmarket Study Commitments

The most obvious deficits in FDA's performance are the agency's lack of effective procedures for monitoring the status of required postmarket studies and the lack of public information regarding such studies. One consequence for this report was that neither the agency nor the committee could reliably identify required postmarket studies that included questions related to children's growth and development or active lifestyles.

The agency recently announced plans to shift responsibility for study monitoring within the Center for Devices and Radiological Health (CDRH) to the postmarket surveillance unit. It has not released details, including what information will be made public.

Recommendation 5.1: Congress should require FDA to establish a system for monitoring and publicly reporting the status of postmarket study commitments involving medical devices. The system should also cover voluntary studies negotiated between FDA and manufacturers as part of the device approval or clearance process. The public database should, among other features, allow easy determination of the status of postmarket studies that involve questions about device use with children.

Public Access to Information about Postmarket Studies

Monitoring of postmarket study commitments is important but so is greater openness about study methods and findings. Given the limited research on medical devices used with children, FDA should, at a minimum, provide for more open access to information about required pediatric studies. The details (e.g., how to screen studies for soundness before making results public) will require careful consideration so that the agency does not publicize findings from studies that are badly designed, poorly executed, or inappropriately analyzed. Continuing discussions about the design of a public clinical trials registry may yield useful guidance.

Recommendation 5.2: FDA's system for monitoring and reporting postmarket study commitments should include information about the disposition of study findings, for example, a change in the labeling of a device. It should also provide for the responsible and understandable

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reporting of the source, methods, and findings of monitored postmarket studies.

Adequacy of Required Postmarket Studies

Without a systematic database of postmarket device studies, FDA could not identify for the committee those studies that involved children or investigated growth and development, activity levels, or other pediatric questions. Furthermore, because statutes on trade secrets and confidentiality require FDA to hold study protocols and much other information confidential, even if the committee knew of a relevant pediatric study, it might not have been able to learn enough about the study to assess it.

FDA's authority to order postmarket studies is limited. It cannot require studies as a condition of clearing devices for which the more extensive premarket approval process is not required. In addition, for devices that have already been approved or cleared, the agency cannot require studies to last more than 3 years. For children, some important developmental consequences may not be evident within that period.

Recommendation 6.5: Congress should amend Section 522 of the Federal Food, Drug, and Cosmetic Act to

- permit FDA to order postmarket studies as a condition of clearance for the categories of devices for which Section 522 Postmarket Surveillance studies are now allowed and
- allow FDA to tailor the duration of Section 522 studies of devices likely to have significant pediatric use so that studies can take into account children's growth and development and, if appropriate, exceed the current 3-year limit on study length.

The committee recognizes that most postmarket research does not result from FDA requirements but is undertaken voluntarily by industry, academic, and other researchers. The committee also recognizes that a requirement for a postmarket pediatric study might, in some cases, prompt a device manufacturer to label a device as not indicated for use with children rather than incur the costs of a study. Thus, FDA should promote additional strategies for building new knowledge that extend beyond required manufacturer studies.

Recommendation 6.6: FDA should collaborate with the National Institutes of Health, the Agency for Healthcare Research and Quality, and other research funding agencies and interested parties to define a research agenda and priorities for the evaluation of the short- and long-term safety and effectiveness of medical devices used with growing and developing children.

The expanding use of electronic patient information systems presents opportunities to strengthen studies of device outcomes and also improve surveillance for adverse events. Capitalizing on these opportunities will require further work to develop

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feasible coding standards that allow more precise identification of specific types and models of devices than is possible now.

Recommendation 6.2: As part of government and private health informatics initiatives, such as those supporting the electronic medical record, FDA should promote the development and adoption of common device coding and other standards and approaches for capturing and linking use and outcomes data for medical devices. FDA should also work with agencies such as the Agency for Healthcare Research and Quality and university- and industry-based methodologists to strengthen methods and tools for epidemiologic research on medical device safety.

Adverse Event Reporting

Judgments about the adequacy of FDA's program of adverse event reporting must take into account the generally recognized problems with such reporting. Underreporting and incomplete or inaccurate reporting are not confined to this program.

In important respects, substantial progress in detecting, reporting, understanding, and preventing adverse device events will depend less on FDA regulations than on the collective results of institutional and collaborative efforts by health care institutions, professional societies, state and federal public health agencies, and others. FDA is, however, uniquely situated to promote attention to events related to medical devices.

Recommendation 4.1: FDA should collaborate with industry, health care professionals and organizations, and parent and patient advocates to

- focus more attention on adverse device events, including events involving children;
- promote linkages between adverse event reporting systems, various FDA databases, and other safety programs;
- update product labeling, patient information, and other communications to promptly reflect safety-related findings from analyses of adverse event reports; and
- issue yearly reports on results from adverse event analyses, including findings involving children.

The evaluation plan for the MedSun program (the agency's pilot Medical Product Surveillance Network, which involves more intensive and active interaction with a sample of 300 medical facilities, including more than 20 children's hospitals) should, among other elements, include comparisons of adverse event reports from MedSun and the mandatory user facility reporting system. It should assess the extent to which either program produced important reports that were missed or delayed by the other (Recommendation 4.3).

With MedSun, the agency has an opportunity to use the participating children's hospitals as connecting points to strengthen device-related surveillance at other hospitals serving children. Adverse event reporting is particularly important for medical devices in

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pediatric use because pediatric events are often unusual and sometimes extreme, and involve problems in a patient population that frequently has not been studied before marketing.

Recommendation 4.7: Children's hospitals and other user facilities should establish a focal point of responsibility for medical device safety. Tasks include reviewing and monitoring the adequacy of institutional programs in areas such as tracking of safety alerts and recalls, responding to safety alerts and recalls, training in adverse event evaluation and reporting, and factoring safety data or evaluations into device purchase decisions.

Independent Oversight

In February 2005, the Department of Health and Human Services (DHHS) announced the creation of an independent drug safety oversight board within FDA (but outside the Center for Drug Evaluation and Research) to oversee the management of high-profile drug safety issues. The board would also provide "emerging information" to clinicians and patients about the risks and benefits of medicines. That is, discussion of potential safety problems would not wait until FDA reached firm enough conclusions to prompt a safety alert or other action. The board would include experts from FDA and elsewhere in DHHS and other government departments.

Notwithstanding certain differences between drugs and devices, the criteria for responsibly making emerging drug safety information public and overseeing high profile issues should—if soundly designed and implemented—apply, at least in broad outline, to the evaluation of similar information from postmarket studies of medical devices. Whether the independent board approach is advisable is another matter. In particular, whether an independent board could obtain sufficient independent technical and clinical expertise would need careful assessment.

Organizational Attention to Pediatric Issues

In addition to calling for this study, Congress has directed attention to pediatric device safety in other ways, for example, by directing FDA to prepare reports on premarket assessment of pediatric medical devices, barriers to pediatric device development, and pediatric expertise for device safety advisory panels. Also as directed by Congress, FDA created an Office of Pediatric Therapeutics to coordinate and facilitate FDA activities that affect children and the practice of pediatrics, but its activities focus almost entirely on drugs.

Recommendation 7.1: FDA should establish a central point of responsibility for pediatric issues within the Center for Devices and Radiological Health to evaluate the adequacy of the Center's use of pediatric expertise and its attention to pediatric issues in all aspects of its work.

*SUMMARY***TENSIONS IN PUBLIC POLICY AND DEVICE INNOVATION**

FDA is charged with simultaneously safeguarding public safety and encouraging timely access by patients to beneficial new products. Recent controversies have focused attention on tensions between these two broad roles. Tension may also exist between the public's desire for government to protect them from an array of threats to their health and safety and their willingness to pay for such protection.

Another area of tension centers around trade secret and confidentiality provisions related to studies of FDA-regulated products. In this case, the objective of encouraging product innovation by allowing innovators to hold certain information secret can sometimes conflict with the objective of providing clinicians and patients with full information to guide decisions. Special regulatory protections for children involved in research may also impede certain kinds of research.

SHARED RESPONSIBILITIES FOR MEDICAL DEVICE SAFETY

Medical device safety is a shared responsibility that necessarily involves manufacturers, researchers, clinicians, engineers, health care facilities, regulators, and patients and families. The sharing of responsibilities extends throughout the medical device product cycle—from innovation and development through testing, marketing, clinical use, safety monitoring, and eventual refinement or replacement.

This spectrum of shared responsibility for device safety itself operates within a broader system of shared responsibilities for overall patient safety and health care quality. In the past two decades, institutional and collaborative initiatives to improve the quality of health care and protect patients from harm have grown to involve a wide range of public and private parties. This diversity of involvement reflects not only the broad concern about health care quality and patient safety but also the range of parties whose participation is essential to improve health outcomes.

Patient safety initiatives often emphasize drug safety. The focus on medications reflects analyses of medical errors in which medication mishaps figure prominently, although some of these mishaps also involve flaws in device design or use. Like most patient safety initiatives, initiatives that focus on children tend not to feature medical devices.

Still, even programs that focus on adults, drug safety, or other topics may encourage practices, procedures, and ways of thinking that can—indirectly or directly—help create an environment that promotes the safe use and design of medical devices for children. For example, increased expertise in root cause analysis of medical errors and assessment of human factors can be broadly applied. Beyond appreciating such spillover effects, those concerned about device safety can consider how quality of care and safety initiatives might be expanded or adjusted to include medical devices.

Recommendation 7.2: All those engaged in improving the quality of health care and protecting patients from harm should evaluate and sharpen

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as appropriate their attention to medical device safety, including safety issues that particularly affect children.

Complete List of Recommendations

Adverse Event Reporting

Recommendation 4.1: FDA should collaborate with industry, health care professionals and organizations, and parents and patient advocates to

- focus more attention on adverse device events, including events involving children;
- promote linkages between adverse event reporting systems, various FDA databases, and other safety programs;
- update product labeling, patient information, and other communications to promptly reflect safety-related findings from analyses of adverse event reports; and
- issue yearly reports on results from adverse event analyses, including findings involving children.

Recommendation 4.2: FDA should continue educational and communication programs to promote recognition and useful reporting of serious adverse device events and device problems by hospitals and other user facilities. Such encouragement should continue whether or not requirements for mandatory reporting by user facilities are eventually eliminated with the effective implementation of the MedSun program. Reporting by user facilities of events possibly related to devices should continue to include deaths, serious injuries, and device malfunctions.

Recommendation 4.3: FDA's plan for evaluating MedSun's performance as a replacement for and improvement on mandatory user facility reporting should include, among other elements,

- assessment of ongoing program and participant facility success in educating facility personnel about identifying, evaluating, and reporting adverse device events and improving the quality, timeliness, and usefulness of event reports;
- determination of the extent to which the sample of MedSun participating hospitals—including children's hospitals—represents the relevant range of facility characteristics and experiences, including representation of both academic medical centers and community hospitals and sufficient representation of facilities with device-oriented specialties and procedures;
- comparison with the mandatory user facility reporting system, including the extent to which either program produced reports for FDA or manufacturers of emerging hazards, important close calls, or other significant events (including those involving children) that were missed or delayed by the other; and
- evaluation of the active surveillance components of the program in reducing harm to patients, promoting constructive communication between facilities and FDA, and improving timely knowledge of the nature and extent of selected device problems, including errors in the use and design of devices.

Recommendation 4.4: Within the pilot MedSun program, FDA and participating children's hospitals should serve as a resource for the broader involvement of children's hospitals in patient safety programs to identify, evaluate, respond to, or prevent problems with the use and design of medical devices. In addition, FDA should promote efforts to link or otherwise employ event reporting, device recall, safety notification, and other databases within and outside FDA to better assess and report on device safety issues involving children.

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Recommendation 4.5: When FDA mandates or agrees to device labeling that requires professionals to be trained in the safe and appropriate use of a medical device, the training should include information on the identification of adverse events, voluntary adverse event reporting under MEDWATCH, and user facility and manufacturer medical device reporting (MDR) requirements.

Recommendation 4.6: Medical, surgical, and other organizations or societies that include health professionals who care for children should

- establish working groups to evaluate problems as well as benefits in the pediatric use of devices of particular importance to their practice;
- collaborate with existing public and private patient safety initiatives to add or expand attention to safe and appropriate use of medical devices with children;
- establish standards for professional education and competency in the use of these devices; and
- include as professional competencies the identification and appropriate reporting of device problems and the successful communication with patients and families about how to prevent, recognize, and respond to device problems.

Recommendation 4.7: Children's hospitals and other user facilities should establish a focal point of responsibility for medical device safety. Tasks include reviewing and monitoring the adequacy of institutional programs in areas such as tracking of safety alerts and recalls, responding to safety alerts and recalls, training in adverse event evaluation and reporting, and factoring safety data or evaluations into device purchase decisions.

Recommendation 4.8: FDA should continue to improve and expand its medical device safety resources for patients and families and its focus on devices used in the home and community by

- working with patient, family, and consumer organizations, providers, and industry to make it easier for patients or their families to report device problems to manufacturers or FDA and to learn about resources to support the safe use of medical devices;
- making online reporting and information resources more accessible by using language and directions appropriate for lay users; and
- enlisting hospitals, home care agencies and vendors, and other professional and provider groups to promote patient and family understanding of how to use devices safely, when and how to seek help, and when and how to report problems.

Monitoring Study Commitments

Recommendation 5.1: Congress should require FDA to establish a system for monitoring and publicly reporting the status of postmarket study commitments involving medical devices. The system should also cover voluntary studies negotiated between FDA and manufacturers as part of the device approval or clearance process. The public database should, among other features, allow easy determination of the status of postmarket studies that involve questions about device use with children.

Recommendation 5.2: FDA's system for monitoring and reporting postmarket study commitments should include information about the disposition of study findings, for example, a change in the labeling of a device. It should also provide for the responsible and understandable reporting of the source, methods, and findings of monitored postmarket studies.

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Strengthening Postmarket Studies

Recommendation 6.1: FDA should develop additional guidance for its own staff as well as for manufacturers and investigators on the identification and evaluation of pediatric questions or concerns at all stages in the design and evaluation of medical devices used with children.

Recommendation 6.2: As part of government and private health informatics initiatives, such as those supporting the electronic medical record, FDA should promote the development and adoption of common device coding and other standards and approaches for capturing and linking use and outcomes data for medical devices. FDA should also work with agencies such as the Agency for Healthcare Research and Quality and university- and industry-based methodologists to strengthen methods and tools for epidemiologic research on medical device safety.

Recommendation 6.3: As a resource for itself and others, FDA should create or collaborate with others to create a registry of relevant registries, that is, a database with information about registries that are either device specific or that have the potential to provide information useful in evaluating device safety and effectiveness.

Recommendation 6.4: As part of a public commitment to postmarket surveillance of device safety, the Center for Devices and Radiological Health should have its own extramural research program to support studies using external data sources.

Recommendation 6.5: Congress should amend Section 522 of the Federal Food, Drug, and Cosmetic Act to

- permit FDA to order postmarket studies as a condition of clearance for the categories of devices for which Section 522 Postmarket Surveillance studies are now allowed and
- allow FDA to tailor the duration of Section 522 studies of devices likely to have significant pediatric use so that studies can take into account children's growth and development and, if appropriate, exceed the current 3-year limit on study length.

Recommendation 6.6: FDA should collaborate with the National Institutes of Health, the Agency for Healthcare Research and Quality, and other research funding agencies and interested parties to define a research agenda and priorities for the evaluation of the short- and long-term safety and effectiveness of medical devices used with growing and developing children.

Responsibilities for Medical Device Safety

Recommendation 7.1: FDA should establish a central point of responsibility for pediatric issues within the Center for Devices and Radiological Health to evaluate the adequacy of the Center's use of pediatric expertise and its attention to pediatric issues in all aspects of its work.

Recommendation 7.2: All those engaged in improving the quality of health care and protecting patients from harm should evaluate and sharpen as appropriate their attention to medical device safety, including safety issues that particularly affect children.