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## BAYLOR COLLEGE OF MEDICINE

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August 18, 2004

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane Room 1061  
Rockville MD 20852

Gentlemen:

This letter is in response to the request for comments regarding the barriers to the availability of medical devices for children. My comments specifically pertain to devices for pediatric and congenital heart patients.

I am a Professor of Pediatrics at Baylor College of Medicine and director emeritus of the cardiac catheterization laboratories at Texas Children's Hospital, Houston, Texas where I have been in practice for 35 years. My comments/suggestions are on the basis of 40+ years of experience in the field of pediatric/congenital heart disease and in particular, in the area of cardiac catheterization and catheter interventions (since its inception). I had the privilege of collaborating in the investigations of all of the early devices used in pediatric/congenital heart patients except the Rashkind balloon and am still active in the use and development of pediatric and congenital heart devices and techniques.

### **1. The unmet medical device needs specifically in the pediatric and congenital heart patients:**

The barriers to obtaining devices for the pediatric and congenital heart patients are ongoing and represent significant delays in obtaining available devices as well as barriers to developing new and/or improving existing devices. My concept of the barriers are listed below with examples under items I – X. There is some redundancy, since the “barriers” often overlap.

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**2. Barriers to the development/availability of new devices for pediatric/congenital heart use:**

I. Pediatric congenital heart disease is a relatively rare disease with *all patients* accounting for less than 0.5 % of live births and all *lesions*, which might require devices being less than half of those. Of that number there are several hundred *different defects in patients in a huge range of age and size*, each of which requires a different device. As a consequence, there are extremely small numbers of any particular lesion and/or the requirement for any particular intracardiac device. This results in:

- a. Inadequate total numbers of any particular lesion to provide a “control” and/or achieve “statistical significance” in a “study.” Unlike adult cardiac disease where thousands of similar lesions can be gathered (from one center!) in a short period of time, “significant numbers” of “identical” congenital patients either are not available at all and/or require collaborative studies of 10 – 20 institutions over several (many) years.
- b. Because of the small numbers, the pediatric patients do not represent a reasonable and/or sensible “commercial investment” for the expensive development of a “small volume” device.
- c. This lack of interest in the pediatric population by industry is aggravated by the threats and real risks of financial penalties from both regulatory and legal sources for perceived deviations and not perfect results.

II. Most devices, which are used in the pediatric/congenital cardiac population are used “off label” as “hand-me-downs” of devices approved for humans, but only for *adult* humans--although many of the devices and/or the procedures are recognized as the “standard of care” by all knowledgeable professionals caring for these patients. Examples:

- a. Coils used for PDA occlusions.
- b. The balloons used for the dilation of stenotic valves and vessels in pediatric/congenital lesions
- c. Intravascular stents in pulmonary arteries, systemic veins, central systemic arteries

III. Most devices in pediatric/congenital cardiac patients are used to avoid the significant physical and mental trauma of “comparable” surgery. When a new device is developed, it usually is suggested (or even required) that the surgical procedure be the “control” in “clinical trials” of new procedures and/or devices. No knowledgeable and/or moral person can require that a child and/or older patient, who happen to be “randomized” to the “short straw,” be subjected to the additional trauma and risks of the surgical procedure, which has been established previously and usually over decades with no “controlled trials” of the surgery itself. Examples:

- a. All ASD and PDA occlusion devices.
- b. Balloon valvuloplasties of pulmonary and aortic valve.

IV. Regulatory agencies appear to be afraid to commit to full approvals for “pediatric devices” which results in considerable regulatory foot-dragging to avoid a true commitment:

- a. Rashkind PDA device-never allowed to be commercialized even a year after IDE panel approval.
- b. Muscular VSD occlusion devices-Humanitarian use approval only although several generations of devices have been demonstrated to be equally effective as surgery over almost two decades-total numbers of patients over this time still too few to become statistically significant.
- c. Coils for PDA occlusion have been used successfully “off label” for over a decade in the US and now are considered the standard of care by the medical community, but they officially still “don’t exist” for PDA occlusion in the US - “Ostrich technique” at avoiding a decision.
- d. Intravascular stents in branch pulmonary stenosis and systemic veins. Used in these lesions “off label” for over a decade. The results are exceptional, far better than can be achieved by *any* surgery and accepted by the profession as the standard of care, but still not “approved” for this use.

V. Regulatory agencies unwilling to consider and/or accept data from over-seas without the total repetition of studies in the US although, thanks to restrictions in the US, the rest of the world now leads the US in the use of pediatric/congenital (and most other) devices in spite of most of the new devices and procedures being conceived and developed in the US. For example:

- a. ASD occlusion devices
- d. VSD occlusion devices
- e. Detachable/controllable coils for PDA occlusion
- e. New intravascular stents in unique and different sizes and configuration for the unique congenital lesions.
- f. Covered stents in larger sizes for central vessels in congenital lesions.

VI. Rather than a support and advisory role to US medical device industries, there appears to be an adversarial attitude and distrust of US industry by the regulatory agencies with the threats of extreme fines and/or the destruction of a company for perceived “deviations.” For example, discussing the use of an “adult device” in a pediatric/congenital patient, much less a modification of such a device with a pediatric cardiologist is construed as illegal “marketing” of a “non-approved” product. This does not produce an atmosphere, which is at all conducive for industry even to talk to the pediatric/congenital physicians much less to provide any support. As a consequence, the large manufacturers of medical devices avoid even talking to pediatric cardiologist, much less supporting educational meetings and/or seriously discussing new products! Examples:

- a. Development of new balloons specifically for pediatrics- Cordis and Boston Scientific in particular.
- b. Pre mounting large stents for specifically intravascular use in congenital lesions

VII. As a consequence of their fear of reprisals from the FDA, industry has become unwilling and/or afraid to produce any changes in existing devices specifically for pediatric/congenital heart patients in the US--even though the changes in the devices have been demonstrated to be safer and more effective in use outside of the US and/or in compassionate use cases. Examples:

- a. Dilation balloons for congenital cardiac defects-Pediatrics have been stuck with hand-me-downs from the "adult" labs for the last two decades with industry still unwilling and/or afraid to make changes specifically for pediatrics.
- b. STARFlex ASD occlusion device, which is a simple centering modification of older CardioSEAL device, which makes device easier to implant and seat better--available in Europe.
- c. A simpler, safer attach/release and delivery system for CardioSEAL/STARFlex devices--in use in Europe.
- d. Larger diameter, stronger (six legged) CardioSEAL/STARFlex device which would be applicable for larger ASDs and VSDs. These devices were tried in Europe and probably are better than any available device for post myocardial infarction VSDs and as such hopefully and eventually will become available as "hand-me-downs".
- e. 6 & 8 mm cutting balloons for use in congenital vascular stenosis-in routine use in Europe.
- f. Covered stents for both emergency bail-out and for rare and imaginative uses in extremely rare congenital lesions-also commonly used in Europe.

VIII. Pediatric/congenital heart disease represents a very small *commercial* market, which, combined with the fear of regulatory reprisals, results in little or no support from the major medical manufacturers for research and/or new product development for *pediatric/congenital* devices per se. The larger medical device manufacturers are far more responsive to their stockholders than to individual patient care. Examples:

- a. J & J and P-308 stents: Data from a 5 year clinical trial of more than 200 patients was not in "commercial goals" of company and PMA was never submitted.
- b. Cordis-J & J: Larger pre mounted stents, which allow a much safer delivery and use in central vessels--have been produced and used in animals, but no need for them in the large "adult market" so not produced for pediatrics.
- c. Boston Scientific: Larger cutting balloons for Pediatric use. These are available and used in pediatric centers outside of the U S and centers in the US are willing and anxious to study but no funding for a study of 2-3 patients per center per year -"only" a market of few hundred children per year!

IX. Many pediatric/congenital heart lesions represent very diverse anatomy in a very small population along with a wide distribution in the size and age of the patients, which, in turn, makes it impossible to achieve "statistical significance" in clinical "trials".

- a. Systemic and pulmonary vascular stenosis in congenital heart disease requiring dilation with stent implants.

- b. Abnormal intravascular communications (systemic to pulmonary fistulae, coronary arteriovenous fistulae, pulmonary arteriovenous fistulae).
- c. Complex "Fontan" or cavopulmonary circuits in single ventricle patients.

X. Achieving adequate numbers in a pediatric cardiac trial, when attempted, takes so long that the devices frequently are improved by the manufacturers during the trial. Even though the improvements make the device/procedure easier and safer, they cannot be incorporated into the "trial" without starting the "trial" all over and/or without incurring severe penalties for the sponsor/manufacturer. Example:

- a. The initial, rather crude "Owens" balloon was approved for "pulmonary valve dilation" on the basis of data from the large VACA registry. By the time it received "approval" that particular balloon was no longer available and had been superseded by balloons, which were much smaller and had better profiles. These and newer balloons still are not "officially approved" for pediatric/congenital use.
- b. Improved delivery system for CardioSEAL/STARFlex Devices, which make delivery safer and more secure are in routine use in Europe.
- c. The use of newer, improved versions of Amplatzer PDA device and/or minor changes to improve the ease of delivery and safety of the existing devices, which are available in Europe are prevented in the US by the requirement of a new trial.
- d. Nit-Occlud PDA occluders from PFM are an improvement over the existing Duct-Occlud, but require an entirely new trial.

### **3. Suggestion to facilitate availability and approval of devices for pediatric and congenital heart patients:**

I. The apparent distrust of the FDA toward physicians as well as industry in the medical field must be overcome in order for these, often life saving techniques/devices to become available for pediatric patient care. Most pediatric/congenital cardiologists who are involved with the development of techniques and/or devices are salaried and in academic institutions. Many of the congenital heart patients are under and/or non-insured, yet all comers are accepted to pediatric hospitals. Many of the long and complex cardiac procedures actually cost the hospital money and utilize the physician's time far beyond any monetary compensation. Without support from both regulatory agencies and industry, the pediatric/congenital patients increasingly will be denied optimal care.

There are several organizations of pediatric cardiologists and more specifically pediatric interventionists who could and would be willing to provide *true expertise* in the field, without commercial or financial bias. These include the Congenital Heart Committee of the Society of Catheterizations and Interventions, The Pediatric Committee of the American College of Cardiology and the Cardiology Section of the American Academy of Pediatrics.

II. There are extremely rare and bizarre lesions in human congenital heart disease. There is no possibility of creating a comparable animal model or a controlled "trial" even if they could be "funded." As a consequence, "trials" of promising new technologies in the rare, more exotic

lesions must be performed on human patients during compassionate use. These trials should be very *closely supervised* by a “peer” review group of *knowledgeable physicians* who are *expert in the particular field*. When successful even in a small group of patients, such trials should lead to “official” approval for use by recognized cardiac centers. Examples:

- a. The Rashkind balloon atrial septostomy, which has saved the lives of thousands of infants over its three and one half decades of use, would *never* have received approval--in the *present regulatory environment*, but on the basis of a single center small trial was approved in 1966.
- b. Branch pulmonary artery stenosis of multiple etiologies, each of which is different, cannot be lumped into a single meaningful trial—yet with off label use of stents in this lesion is the current standard of care for these lesions, but is non “officially approved” for this use.
- c. Completion of “Fontan” circuits following “single ventricle” repairs-potentially avoiding two cardiac surgical procedures within the first 2-3 years of the patients life! These are relatively rare patients, each of which is different and, in turn, cannot be prospectively studied any more than the “semi-annual: variations, which are now made in their surgical repairs can be studied by the surgeons.
- d. Percutaneous pulmonary valve replacement for pulmonary valve regurgitation following “total repairs” of tetralogy of Fallot, pulmonary atresia with ventricular septal defect and truncus arteriosus. This procedure/device now is available and fortunately has continued to have improvements in the equipment/technique, which hopefully *never* will be completed but should not require “restarting” trials each time an improvement is introduced.

III. Investigate, through a panel of *knowledgeable practitioners* in the field of pediatric/congenital interventional procedures, changes, which are made in devices/procedures during the course of studies and approve improvements in the devices without restarting study. These investigations and approvals would have to be in a timely manner—weeks to a few months; not years!

IV. Encourage US industries who are interested in the pediatric/congenital field without the threat of reprisals for supporting innovative ideas. Provide guidance for expedited studies/approval.

Sincerely,



Charles E. Mullins, M.D.

Professor of Pediatrics

Baylor College of Medicine

Medical Director Emeritus, Cardiac Catheterization Laboratories

Texas Children's Hospital

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the Social Security Act, and as amended, hereafter.

This delegation supersedes all previous delegations of authority to administer the Abstinence Education Program under Title V, section 510 of the Social Security Act. Except as provided above, the existing delegations of authority to officials within the Health Resources and Services Administration concerning Title V of the Social Security Act are unaffected.

This delegation shall be exercised under the Department's existing delegation and policy on regulations, and under financial and administrative requirements applicable to all Administration for Children and Families authorities.

I have ratified any actions taken by the Assistant Secretary for Children and Families, or any other Administration for Children and Families officials, which, in effect, involved the exercise of this authority prior to the effective date of this delegation.

This delegation is effective immediately.

Dated: June 9, 2004.

Tommy G. Thompson,  
Secretary.

[FR Doc. 04-13895 Filed 6-18-04; 8:45 am]

BILLING CODE 4184-01-M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): BECAUSE Kids Count (Building and Enhancing Community Alliances United for Safety and Empowerment), Program Announcement Number 04142

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following meeting:

**Name:** Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): BECAUSE Kids Count (Building and Enhancing Community Alliances United for Safety and Empowerment), Program Announcement Number 04142.

**Times and Dates:** 4 p.m.-5:30 p.m., July 15, 2004 (Open), 9 a.m.-4:30 p.m., July 16, 2004 (Closed).

**Place:** Sheraton Buckhead, 3405 Lenox Road, NE, Atlanta, GA 30326, Telephone 404.261.9250.

**Status:** Portions of the meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of

the Director, Management Analysis and Services Office, CDC, pursuant to Pub. L. 92-463.

**Matters To Be Discussed:** The meeting will include the review, discussion, and evaluation of applications received in response to Program Announcement Number 04142.

**For Further Information Contact:** La Tanya Butler, Deputy Branch Chief, Program Implementation Branch, DVP/NCIPC, 4770 Buford Highway, NE, MS-K60, Atlanta, GA 30310, Telephone 770.488.4653.

The Director, Management Analysis and Services Office has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: June 15, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 04-13913 Filed 6-18-04; 8:45 am]

BILLING CODE 4163-18-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0254]

#### Possible Barriers to the Availability of Medical Devices Intended to Treat or Diagnose Diseases and Conditions that Affect Children; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), is requesting comments concerning the possible barriers to the availability of medical devices intended to treat or diagnose diseases and conditions that affect children. This action is being taken to assist the agency in preparing a report to Congress required by the Medical Devices Technical Corrections Act of 2004 (MDTCA).

**DATES:** Submit written or electronic comments by August 20, 2004.

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Joanne Less, Center for Devices and Radiological Health, Food and Drug

Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-1190.

**SUPPLEMENTARY INFORMATION:** The President signed MDTCA (Public Law 108-214) into law on April 1, 2004. Section 3 of the MDTCA was added to address potential difficulties in bringing pediatric devices to market. Over the last few months, several professional organizations representing pediatric interests expressed concern about the availability of safe and effective devices intended for this population.

Representatives from CDRH and the Office of Pediatric Therapeutics met with these organizations to explore the issue. The agency has also received anecdotal reports suggesting there is an unmet need in the pediatric population, but additional information is needed to assess the accuracy of these reports.

By October 1, 2004, the new law requires FDA to submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report addressing the "barriers to the availability of devices intended for treatment or diagnosis of diseases and conditions that affect children." The law also states that the report must include "any recommendations of the Secretary of Health and Human Services for changes to existing statutory authority, regulations, or agency policy or practice to encourage the invention and development of such devices."

Through this notice, FDA is soliciting comments that will help the agency draft its report to Congress under section 3 of MDTCA. In particular, FDA seeks input in response to the following questions:

1. What are the unmet medical device needs in the pediatric population (neonates, infants, children, and adolescents)? Are they focused in certain medical specialties and/or pediatric subpopulations?

2. What are the possible barriers to the development of new pediatric devices? Are there regulatory hurdles? Clinical hindrances? Economic issues? Legal issues?

3. What could FDA do to facilitate the development of devices intended for the pediatric population? Are there changes to the law, regulation, or premarket process that would encourage clinical investigators, sponsors, and manufacturers to pursue clinical trials and/or marketing of pediatric devices?

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic

comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 7, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 04-13872 Filed 6-18-04; 8:45 am]

BILLING CODE 4160-01-S

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Reimbursement Rates for Calendar Year 2004**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** Notice is given that the Director of Indian Health Service (IHS), under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a) and 249(b)) and the Indian Health Care Improvement Act (25 U.S.C. 1601), has approved the following rates for inpatient and outpatient medical care provided by IHS facilities for Calendar Year 2004 for Medicare and Medicaid Beneficiaries and Beneficiaries of other Federal Agencies. The Medicare Part A inpatient rates are excluded from the table below as they are paid based on the prospective payment system. Since the inpatient rates set forth below do not include all physician services and practitioner services, additional payment may be available to the extent that those services meet applicable requirements. Legislation, effective July 1, 2001, allows IHS facilities to file Medicare claims with the carrier for payment for physician services.

**Inpatient Hospital per Diem Rate (Excludes Physician Services) Calendar Year 2004**

Lower 48 States .....	\$1,512
Alaska .....	\$1,837

**Outpatient per Visit Rate (Excluding Medicare) Calendar Year 2004**

Lower 48 States.....	
Alaska .....	\$402

**Outpatient per Visit Rate (Medicare) Calendar Year 2004**

Lower 48 States.....	
Alaska .....	\$367

**Medicare Part B Inpatient Ancillary per Diem Rate Calendar Year 2004**

Lower 48 States .....	\$307
Alaska .....	\$638

**Outpatient Surgery Rate (Medicare)**

Established Medicare rates for freestanding Ambulatory Surgery Centers.

**Effective Date for Calendar Year 2004 Rates**

Consistent with previous annual rate revisions, the Calendar Year 2004 rates will be effective for services provided on/or after January 1, 2004, to the extent consistent with payment authorities including the applicable Medicaid State plan.

Dated: February 3, 2004.

Charles W. Grim,

Assistant Surgeon General, Director, Indian Health Service.

**Editorial Note:** This document was received by the Office of the Federal Register on June 15, 2004.

[FR Doc. 04-13892 Filed 6-18-04; 8:45 am]

BILLING CODE 4160-16-P

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; Comment Request; Multi-Ethnic Study of Atherosclerosis (Mesa) Event Surveillance**

**SUMMARY:** In compliance with the requirement of Section 3506(c)(2)(A) of

the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Heart, Lung, and Blood Institute (NHLBI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**Proposed Collection:** Title: Multi-Ethnic Study of Atherosclerosis (MESA) Event Surveillance. Type of Information Request: Renewal (OMB No. 0925-0493). Need and Use of Information Collection: The study, MESA, will identify and quantify factors associated with the presence and progression of subclinical cardiovascular disease (CVD)—that is, atherosclerosis and other forms of CVD that have not produced signs and symptoms. The findings will provide important information on subclinical CVD in individuals of different ethnic backgrounds and provide information for studies on new interventions to prevent CVD. The aspects of the study that concern direct participant evaluation received a clinical exemption from OMB clearance (CE-99-11-08) in April 2000. OMB clearance is being sought for the contact of physicians and participant proxies to obtain information about clinical CVD events that participants experience during the follow-up period. Frequency of response: Once per CVD event. Affected public: Individuals. Types of Respondents: Physicians and selected proxies of individuals recruited for MESA. The annual reporting burden is as follows: Estimated Number of Respondents: 555; Estimated Number of Responses per respondent: 1.0; and Estimated Total Annual Burden Hours Requested: 42.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Physicians .....	279	1.0	0.20	19
Participant proxies .....	276	1.0	0.25	23
<b>Total .....</b>	<b>555</b>	<b>1.0</b>	<b>0.225</b>	<b>42</b>