designs. Second, we must consider the extent to which the vessel hull design registration process contained in chapter 13 of title 17 has been utilized by those eligible to claim protection. Third, we must consider the extent to which the creation of new designs of vessel hulls have been encouraged by the VHDPA. Fourth, we must examine the effect, if any, that the VHDPA has had on the price of protected vessel hulls.

Finally, we are directed to consider any other factors deemed relevant to accomplishing the purpose of this study. One item for consideration under this category is what, if any, amendments need to be made to the VHDPA to improve its function and/or effectiveness.

Request for Written Comments

In order to accomplish our assigned task, the cooperation and participation of marine manufacturers, designers and those affected by the VHDPA is essential. Consequently, we request interested parties to submit written comments and information/data relevant to the study factors described above. Although we are desirous of information related to all factors, we are particularly interested in receiving information as to how the VHDPA has stimulated the creation of new vessel hull designs, and what effect, if any, protection for designs has had on the price of watercraft. Interested parties submitting data or information that they consider confidential should appropriately mark such documents so that they are not included in the public record of this proceeding.

Public Hearing

To further the goal of obtaining relevant information and drafting the report, a public hearing will be held at the Copyright Office (see above for the specific address) on Thursday, March 27, 2003, at 10 a.m. The public hearing is intended to allow participants to present relevant information and answer questions from staff preparing the report. Those wishing to attend should notify the Copyright Office by fax or e-mail no later than March 20, 2003.

Dated: February 10, 2003.

David O. Carson,

General Counsel, Copyright Office.

Jonathan W. Dudas,

Deputy Under Secretary of Commerce for Intellectual Property and Deputy Director of the United States Patent and Trademark Office.

[FR Doc. 03–3749 Filed 2–12–03; 8:45 am]

BILLING CODE 1410–30–P

CONSUMER PRODUCT SAFETY COMMISSION

Sunshine Act Meeting

TIME AND DATE: Friday, February 21, 2003, 10 a.m.

LOCATION: Room 420, Bethesda Towers, 4330 East West Highway, Bethesda, Maryland.

STATUS: Open to the Public.

MATTER TO BE CONSIDERED:

Product Registration Cards (Petition CP 01–1)

The staff will brief the Commission on Petition CP 01–1 submitted by the Consumer Federation of America (CFA) requesting that the Commission issue a rule requiring product registration cards with every product intended for children.

Certain members of the public have been invited to give oral presentations based on their written comments previously submitted to the Commission.

For a recorded message containing the latest agenda information, call (301) 504–7948.

CONTACT PERSON FOR ADDITIONAL INFORMATION: Todd A. Stevenson, Office of the Secretary, 4330 East West Highway, Bethesda, MD 20207 (301) 504–7923.

Dated: February 11, 2003.

Todd A. Stevenson,

Secretary

[FR Doc. 03–3748 Filed 2–11–03; 2:16 pm]

BILLING CODE 6355–01–M

DEPARTMENT OF DEFENSE

Office of the Secretary

TRICARE: In-Utero Surgical Repair of Myelomeningocele Randomized Clinical Trial

AGENCY: Office of the Secretary, DoD.

ACTION: Notice.

SUMMARY: This notice is to advise interested parties of a demonstration project in which the Department of Defense (DoD) will participate in a clinical trial for prenatal and postnatal myelomeningocele repair approved by the National Institute of Child Health and Human Development (NICHD). The study is being done to find out whether it is better to close a spina bifida defect before the baby is born or shortly after birth. Participation in this clinical trial will improve access to prenatal and postnatal surgical intervention for the repair of myelomeningocele for active duty members, former members, and their dependents when their condition meets protocol eligibility criteria. DoD financing of this procedure will assist in meeting clinical trial goals and arrival at conclusions regarding the safety and efficacy of intrauterine repair of fetal myelomeningocele. It is anticipated that new enrollments into the clinical trial will end in April 2004, with those enrolled having periodic examinations during a three-year follow-up period. This demonstration project is being conducted under the authority of 10 U.S.C. 1092.

EFFECTIVE DATES: March 17, 2003.

FOR FURTHER INFORMATION CONTACT: Gail L. Jones, Health Care Policy Analyst, Medical Benefits and Reimbursement Systems, TRICARE Management Activity (TMA), 16401 East Centretech Parkway, Aurora, CO 80011–9066, telephone (303) 676–3401.

SUPPLEMENTARY INFORMATION:

A. Background

Myelomeningocele is the most severe form of spina bifida. In a fetus with myelomeningocele, there is evidence that neurologic function deteriorates during gestation. While myelomeningocele is not necessarily life threatening, it is the most common debilitating birth defect. Those who survive are likely to experience significant life-long disabilities. Approximately 2,000 fetuses annually are affected with some kind of open neural tube defect in the United States, half of which are open spina bifida. The surgical repair of myelomeningocele in utero is the technique that may provide early intervention in preserving the neurologic integrity of these children. To date, clinical results of fetal surgery for myelomeningocele are based on comparisons with past controls and addresses efficacy rather than safety. A randomized clinical trial for myelomeningocele is necessary to determine whether fetal repair of myelomeningocele, with its attendant maternal and neonatal morbidity, is warranted.

The Department of Defense (DoD) provides and maintains readiness to provide medical services and support to the Armed Forces during military operations, and to provide health services and support to members of the uniformed forces, their family members, and to others entitled to DoD medical care. The services offered to TRICARE beneficiaries other than active duty members must be medically necessary, appropriate, and proven care and are governed by 10 U.S.C. 1079(a)(13).

Active duty service members are authorized civilian medical care under 10 U.S.C. 1074(c), and may be referred for unproven therapy when controlled in a formal clinical research trial. The trial must be operating under the structure of an institutional review board process, which conforms to the requirements of DoD Directive 3216.2, Protection of Human Subjects and Adherence of Ethical Standards in DoD Supported Research, the requirements of 32 CFR part 219, Protection of Human Subjects, as well as Service specific human experimentation regulations.

DoD has the authority to waive the statutory limitation for all other DoD beneficiaries that health care services must be medically necessary, appropriate, and proven care, as long as these services are provided within the context of an interagency agreement with the National Institutes of Health (NIH) for beneficiary participation in NIH-sponsored or approved clinical trials. The Secretary of Defense must also determine that such waiver will promote access by covered beneficiaries to promising new treatments and contribute to the development of such treatments.

B. Caseload, Costs

Each year approximately 60,000 TRICARE births occur at the Military Treatment Facilities (MTFs). Approximately 40,000 TRICARE births occur in civilian hospitals. According to the Center of Disease Control, in 2001 there were 20.09 cases of spina bifida per 100,000 births. Based on various studies, we estimate that 95 percent of these reported cases are related to myelomeningocele. We then interpret that approximately 19 cases would occur annually in TRICARE. We expect six to sixteen TRICARE members each year would have a fetus with a prenatal diagnosis of spina bifida that would be eligible for the NICHD clinical trial and would agree to participate.

Treatment protocol costs are estimated between $300,000 and $1.3 million over Fiscal Years 2003 through 2006 for TRICARE participation in the NICHD clinical trial of myelomeningocele fetal repair.

C. Operation of the Demonstration

The National Institute of Child Health and Human Development (NICHD) will fund an unblinded randomized controlled clinical trial conducted by three participating centers. The NICHD will provide administrative support, all NICHD enrollments, and study monitoring activities. DoD will provide a Project Officer who will coordinate DoD activities.

The DoD will develop initiatives to educate military healthcare providers and civilian TRICARE network providers about this initiative and the processes that are available for referral and pre-authorization of individuals with affected fetuses. DoD will require pre-authorization for any clinical services necessary or resultant from participation in an NICHD sponsored clinical trail before reimbursement by TRICARE. A pre-authorization for enrollment in the trial will suffice to cover each incidental expense or claim related to participation in the clinical trial extending through the duration of the clinical trial. The pre-authorization process will include verification with the NICHD that the patient has been enrolled in the study.

The TRICARE contractor(s) would not be involved in clinical issues or in directing patients to a particular institution.

D. Requirements for Participation

Active duty members, former members, and their dependents eligible for TRICARE who meet the clinical trial protocol would be eligible to participate in the demonstration. NICHD anticipates a total of two hundred patients whose fetuses have been diagnosed with myelomeningocele at 16 to 25 weeks' gestation who are over the age of 18 years would be enrolled and referred to the Data and Study Coordinating Center (DSCC) at George Washington University in Rockville, Maryland, to undergo an initial evaluation. Those individuals who remain eligible and interested would be assigned by the DSCC to one of the three centers (Vanderbilt University medical Center in Nashville, the University of California at San Francisco, and Children's Hospital of Philadelphia) where final evaluation and screening will be performed. Patient selection to the three Management of Myelomeningocele Study (MOMS) Centers would be based on convenience to the individual as well as the need to divide evenly the participants among the three centers.

E. Costs

Patients who choose to participate in the clinical trial will have no additional costs for prenatal care beyond what is normally paid by the beneficiary. If TRICARE beneficiaries have other health insurance, the other health insurance is required to pay first before TRICARE to the extent the health care is a benefit under the other plan as stated under 10 U.S.C. 1079(j)(1). If patients are in a prenatal surgery group, the travel, meal and lodging costs for the patient and a relative or friend will be covered by NICHD grant support or the grantee institution until delivery and after delivery, until the patient and baby go home.

If patients are in a postnatal surgery group, travel back to the center for the patient and a support person will be covered by NICHD grant support or the grantee institution, as well as meals and lodging before and after delivery, until the baby and patient are able to go home. The cost of the study follow up, returning at one year and two and a half years of age will also be covered. Meals and lodging will be covered for those visits as well.

Dated: February 5, 2003.

Patricia L. Toppings,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 03–3512 Filed 2–12–03; 8:45 am]

BILLING CODE 5001–08–M

DEPARTMENT OF DEFENSE

Department of the Air Force

HQ USAF Scientific Advisory Board

AGENCY: Department of the Air Force, DoD.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Pub. L. 92–463, notice is hereby given of the forthcoming meeting of the 2003 S&T Review and the Chief of Staff and Secretary of the Air Force. The purpose of the meeting is to allow the SAB leadership to advise the Air Force leadership on the outcome of the 2003 Review. Because classified and contractor-proprietary information will be discussed, this meeting will be closed to the public.

DATES: February 20, 2003.

ADDRESSES: Room 4E869, The Pentagon.

FOR FURTHER INFORMATION CONTACT: Maj John Pernot, Air Force Scientific Advisory Board Secretariat, 1180 Air Force Pentagon, Rm 5D982, Washington DC 20330–1180, (703) 697–4811.

Pamela D. Fitzgerald,

Air Force Federal Register Liaison Officer.

[FR Doc. 03–3638 Filed 2–12–03; 8:45 am]

BILLING CODE 5001–05–U

DEPARTMENT OF DEFENSE

Department of the Air Force

HQ USAF Scientific Advisory Board

AGENCY: Department of the Air Force, DoD.