



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

CHARTER

ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY

PURPOSE

The Secretary is responsible under Sections 301, 351, and 361 of the Public Health Service Act, as amended (42 U.S. Code 241, 262, 264), and various provisions of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*), for carrying out research in health fields including diseases involving blood and blood products, and for issuing and enforcing regulations concerning the collection, preparation, and distribution of these products, and regulations related to the transmission of communicable diseases. The Advisory Committee on Blood Safety and Availability shall advise, assist, consult with, and make policy recommendations to the Secretary and the Assistant Secretary for Health regarding these broad responsibilities.

AUTHORITY

42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Advisory Committee on Blood Safety and Availability is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2) which sets forth standards for the formation and use of advisory committees.

FUNCTION

The Advisory Committee on Blood Safety and Availability shall provide advice to the Secretary and to the Assistant Secretary for Health. The Committee shall advise on a range of policy issues to include:

(1) definition of public health parameters around safety and availability of the blood supply and blood products, (2) broad public health, ethical and legal issues related to transfusion and transplantation safety, and (3) the implications for safety and the availability of various economic factors affecting product cost and supply.

STRUCTURE

The Committee shall consist of 20 voting members; 14 public members, including the Chair, who will be selected from State and local organizations, advocacy groups, provider organizations, academic researchers, ethicists, private physicians, scientists, consumer advocates, legal organizations, and from among communities of persons who are frequent recipients of blood or blood products. While this document sets no prescribed formula for distribution of membership, every attempt will be made for equal and diverse representation. The public voting members shall be classified as special Government employees (SGEs). In addition, there will be six (6) individuals designated to serve as official representative members of the blood and blood products industry or professional organizations. These representative members shall be from the AABB (formerly the American Association of Blood Banks),

Advisory Committee on Blood Safety and Availability

the Plasma Protein Therapeutic Association (PPTA), one of the two major distributors of blood on a rotating basis, a trade organization or manufacturer of blood, plasma or other tissue test kits or equipment, and a major hospital organization that purchases blood and blood products. Where more than one company produces a specified product or process, representatives from those companies shall rotate on the same schedule as public members. All members and the Chair shall be selected by the Secretary or designee.

The Committee shall also consist of not more than six non-voting *ex-officio* members to represent the Centers for Disease Control and Prevention; the Centers for Medicare and Medicaid Services; the Food and Drug Administration; the National Institutes of Health, including the National Heart, Lung, and Blood Institute; and the Department of Defense. Other Federal departments/agencies shall be invited to participate as non-voting *ex-officio* members, as the Secretary or designee, deem necessary to effectively carry out the Committee's function.

Members shall be invited to serve for overlapping terms of up to four years. Terms of more than two years are contingent upon renewal of the Committee's charter by appropriate action prior to its expiration. Any member appointed to fill a vacancy for an un-expired term shall be appointed only for the remainder of that term. A member may serve no more than 180 days after the expiration of the member's term if a successor has not taken office.

In carrying out its function, the Committee may establish temporary subcommittees that must be composed of two or more members of the ACBSA, to address specific issues within the Committee's jurisdiction, with the approval of the Secretary or designee. The subcommittees make preliminary recommendations regarding specific issues for subsequent action by the ACBSA. Where appropriate, advice also may be sought by the Committee or subcommittees from non-member special consultants/advisors, with the approval of the Secretary or designee. The Department Committee Management Officer will be notified upon establishment of each subcommittee, and will be given information regarding its name, membership, function, and estimated frequency of meetings.

Management and support services for Committee operations and activities shall be provided by staff within the Office of Public Health and Science.

MEETINGS

Meetings shall be held not less than once a year. Meetings shall be held at the call of the designated Federal officer (DFO), who is responsible for developing the meeting agenda. Development of the meeting agenda may be done in collaboration with the Committee Chair. The DFO or other official to whom the authority has been delegated shall be present at all meetings of the full Committee and any subcommittees that have been established to assist the Committee. A quorum for the conduct of business by the full Committee shall consist of a majority of the Committee's voting members.

Meetings shall be open to the public except as determined otherwise by the Secretary or designee, in accordance with the guidelines under Government in the Sunshine Act at 5 U.S.C. 552b(c) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations and policies.

COMPENSATION

Members shall be paid at the rate not to exceed \$200.00 per day, plus per diem and any applicable travel expenses, as authorized by Section 5703, Title 5, U.S.C., for persons employed intermittently in the Government service. Members who are officers or employees of the United States Government shall not receive compensation for their services on the Committee.

Members who serve as representative of a particular interest group or industry shall serve without compensation, pursuant to advance written agreement, but may be allowed per diem and any applicable expenses for all Government-directed travel.

ANNUAL COST ESTIMATE

Estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is \$274,500. Estimated person years of staff support required is 4.0, at an estimated annual cost of \$475,000.

REPORTS

In carrying out its functions, the Committee may be asked to prepare reports on a broad range of subjects. When a meeting is to be closed or partially closed to the public, as determined by Secretary or designee, in accordance with Government in the Sunshine Act at 5 U.S.C. 552b(c) and the Federal Advisory Committee Act, then a report shall be prepared that will contain, at a minimum, a list of the members and their business addresses, Committee's functions, dates, places of meetings, and a summary of committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

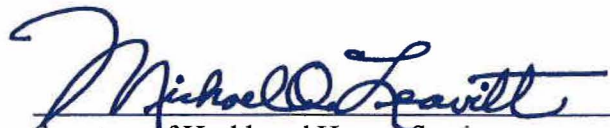
TERMINATION DATE

Unless renewed by appropriate action prior to its expiration, the Advisory Committee on Blood Safety and Availability will terminate on October 9, 2010.

APPROVED:

SEP 25 2008

Date


Secretary of Health and Human Services



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

NOTICE OF RENEWAL
OF THE
ADVISORY COMMITTEE ON BLOOD SAFETY AND AVAILABILITY

I have determined, after appropriate consultation between this Department and the General Services Administration, that renewal of the Advisory Committee on Blood Safety and Availability is in the public interest. Performance of duties imposed on the Department by law can best be performed through the advice and counsel of such an advisory group. The Committee is authorized to continue until October 9, 2010.

I deem that it is not feasible for the Department or any of its existing committees to perform these duties. A satisfactory plan for appropriate balance of the Committee membership has been submitted.

SEP 25 2008

Date


Secretary of Health and Human Services



OCT 9 2008

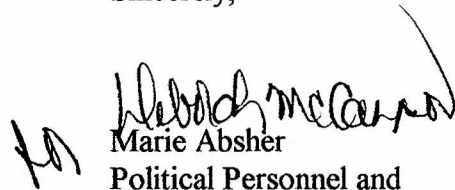
Library of Congress
Federal Advisory Committee Desk
Government Documents Section
101 Independence Avenue, S.E.
Washington, D.C. 20540-4174

A copy of the charter for the following committee is enclosed for your committee file in accordance with Section 9(c) of Public Law 92-463:

Advisory Committee on Blood Safety and Availability

The Act requires the Department to file a copy of the charter for each advisory committee it utilizes with the standing committees of the Senate and the House of Representatives having legislative jurisdiction of the Department, and with the Library of Congress.

Sincerely,


Marie Absher
Political Personnel and
Advisory Committee Specialist, DCMO

Enclosure



OCT 9 2008

The Honorable Edward M. Kennedy
Chairman, Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, D.C. 20510

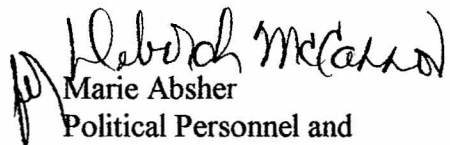
Dear Mr. Chairman:

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OCT 9 2008

The Honorable John D. Dingell
Chairman, House Energy and Commerce Committee
U.S. House of Representatives
Washington, D.C. 20515

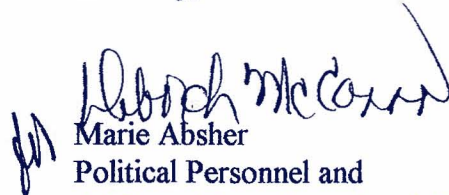
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