

in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

The Commissioner has determined for the reasons stated that those portions of the advisory committee meetings so designated in this notice shall be closed. The Federal Advisory Committee Act (FACA) (5 U.S.C. app. 2, 10(d)), permits such closed advisory committee meetings in certain circumstances. Those portions of a meeting designated as closed, however, shall be closed for the shortest possible time, consistent with the intent of the cited statutes.

The FACA, as amended, provides that a portion of a meeting may be closed where the matter for discussion involves a trade secret; commercial or financial information that is privileged or confidential; information of a personal nature, disclosure of which would be a clearly unwarranted invasion of personal privacy; investigatory files compiled for law enforcement purposes; information the premature disclosure of which would be likely to significantly frustrate implementation of a proposed agency action; and information in certain other instances not generally relevant to FDA matters.

Examples of portions of FDA advisory committee meetings that ordinarily may be closed, where necessary and in accordance with FACA criteria, include the review, discussion, and evaluation of drafts of regulations or guidelines or similar preexisting internal agency documents, but only if their premature disclosure is likely to significantly frustrate implementation of proposed agency action; review of trade secrets and confidential commercial or financial information submitted to the agency; consideration of matters involving investigatory files compiled for law enforcement purposes; and review of matters, such as personnel records or individual patient records, where disclosure would constitute a clearly unwarranted invasion of personal privacy.

Examples of portions of FDA advisory committee meetings that ordinarily shall not be closed include the review, discussion, and evaluation of general preclinical and clinical test protocols and procedures for a class of drugs or devices; consideration of labeling requirements for a class of marketed drugs or devices; review of data and information on specific investigational or marketed drugs and devices that have previously been made public; presentation of any other data or information that is not exempt from public disclosure pursuant to the FACA, as amended; and, deliberation to formulate advice and recommendations to the agency on matters that do not independently justify closing.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: February 14, 1995.

Linda A. Suydam,

Interim Deputy Commissioner for Operations.

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National Institutes of Health

Technology Assessment Conference on Gaucher Disease: Current Issues in Diagnosis and Treatment

Notice is hereby given of the NIH Technology Assessment Conference on "Gaucher Disease: Current Issues in Diagnosis and Treatment," which will be held February 27-March 1, 1995, in the Masur Auditorium of the National Institutes of Health, 9000 Rockville Pike, Bethesda, Maryland 20892. The conference begins at 8:30 a.m. on February 27 and 28 and at 9 a.m. on March 1.

Gaucher disease, the inherited deficiency of the enzyme glucocerebrosidase, is the most common lysosomal storage disease and the most frequently inherited disorder in the Ashkenazic Jewish population. In the past decade there has been much progress both in our understanding of the molecular biology of the disease and the ability to treat Gaucher patients. However, many issues regarding diagnosis, population screening, and therapy for Gaucher patients do not have clear consensus. Gaucher disease is characterized by a remarkable degree of clinical heterogeneity, ranging from severely affected infants to totally asymptomatic adults. Patients with Gaucher disease have been classified into three major types on the basis of clinical signs and symptoms: Type 1—non-neuropathic; type 2—acute neuropathic; and type 3—subacute neuropathic.

All types of Gaucher disease result from the deficiency of the same enzyme, glucocerebrosidase, and the diagnosis can be made by measurement of enzyme activity obtained from a tube of blood. The most striking difference between the types is the presence of neurologic manifestations and the rate of progression. Even within the different types there is not a unique clinical presentation. Some patients with type 1 Gaucher disease, which is by far the most common type, may display anemia, low platelets, massively enlarged livers and spleens, and extensive skeletal disease, while others have no symptoms and have been recognized only during screening or evaluation for other diseases.

The gene for glucocerebrosidase on chromosome 1q21 has been characterized and sequenced. Multiple mutations have been identified in the glucocerebrosidase gene in patients' DNA, several of which are encountered frequently. While some patients with similar clinical courses share the same genotype, there are other examples where patients with the same DNA mutations have very different clinical manifestations. It is still not clear to what extent a person's phenotype or prognosis can be accurately predicted on the basis of current DNA mutation analysis. Furthermore, while the availability of molecular techniques has made possible early prenatal diagnosis, heterozygote detection and population screening for Gaucher disease, the advisability and usefulness of these techniques remains unsolved.

Gaucher disease has been traditionally managed by supportive therapy including total and partial splenectomy, transfusions, and