

**Abigail Alliance for Better Access to Developmental Drugs**  
**March 4, 2008**

**Recommendations for Reform of the Advisory Committee Process**

**Structural**

1. Remove the advisory committee nominating and selection process from the Centers and create a new Advisory Committee Office (“the Adcomm Office”) located in the Office of the Commissioner, or in the Office of the Ombudsman. The office should be led by an Associate Commissioner and would administer and supervise all FDA advisory committees and advisory committee staff.

**Nominations**

2. Make all nominations and the person(s) and/or organizations making the nominations a matter of public record. Post nominating information on the FDA webpage within 14 days of receipt of each nomination. No nominee should be appointed to a committee unless his/her nominating information has been posted on the webpage for at least 14 days. Posted information should include the date of receipt of each nomination, the name of the nominee, the name and address of the nominee’s employer(s), the area(s) of expertise of the nominee, the advisory committee to which the individual is nominated, the name and address of the nominating organization(s) or individual(s), and a link to relevant associated documents (e.g., curriculum vitae).
3. Post upcoming vacancies on the FDA’s web page a minimum of six months prior to the vacancy opening. Post a closing date for receipt of nominations for a vacancy 45 days prior to the effective date of the vacancy opening (which should coincide with the day following the last day of an expiring term.)
4. Advisory Committee members should not be appointed to consecutive terms on any advisory committee, and continuing paid relationships with FDA after completion of a term should be fully disclosed on the agency’s web page for a period of one year from the end of any permanent advisory committee member’s term.
5. Timely notify both the nominee and the nominating person/organization of any actions including appointments, rejections, etc. regarding each nomination. Post the notification dates and actions taken on the nomination information webpage within 14 days of the action taken, except that appointments to advisory committees shall be posted within 5 business days following the appointment.
6. Post on the FDA’s website a detailed description of the nomination process *and the selection process*, including detailed descriptions of every step of the process, including how the nominations are compiled and reviewed, how decisions are made, and who

within the FDA handles each step and makes each decision. The information posted on the webpage should be updated coincident with any changes in the process.

7. Center personnel should have no formal role in the nomination or selection processes for advisory committee members or chair persons. Under no circumstances should the process of reviewing or selecting members be administered or conducted by any office in a Center, or by Center personnel.

### **Advisory Committee Membership**

8. Advisory committee membership should be technically diverse and representative of medical, scientific, and patient stakeholder interests. For example, ODAC presently consists entirely of clinical researchers who conduct clinical trials at academic clinical research or similar centers. The only exceptions are generally a statistician (who also works at a research center) and a non-permanent patient representative. This causes the ODAC to mirror almost exactly (with the occasional exception of an aggressive, well-informed patient representative) the expertise and perspective of the OODP's current Division Director. Providing a perspective so close to that of the FDA and in the case of the ODAC, the primary FDA decision maker (the Division Director) is not the purpose of advisory committees.

An example of a more balanced and appropriate membership would be an ODAC including no more than three clinical researchers from large academic oncology research institutions; at least three oncologists that work in practices or organizations that do not routinely participate in the conduct of clinical research with one of the three from a geographic area "remote" to medical oncology research centers; a permanent, well-informed and qualified patient representative/advocate that represents only patients (not, for example, a person from a non-profit organization that receives funding from ASCO, and drug companies, or someone from the medical oncology community, etc.); and, several biomedical researchers who are non-MDs practicing basic medical research in the fields of genetics, proteomics and other relevant scientific fields. A non-voting biostatistician and a non-voting industry representative should be permanent members of the committee. Voting statisticians should be included as voting consultants only if significant and meaningful disagreements about statistical methodology are anticipated. The committee should continue to include a meeting-specific voting patient representative – in addition to the permanent patient representative - with relevant knowledge and experience regarding the subject matter of the meeting.

## **Oversight and Supervision of Advisory Committees and Meetings**

9. Division directors should be required to request and receive authorization from the Adcomm Office to hold an advisory committee meeting. The request should be reviewed by the Adcomm Office and either approved or denied by the associate commissioner, in writing. Approvals should be posted on the web page. The authorization review and approval process should not be a “pro-forma” process. Each request should be evaluated for merit and need. Meetings should not be called unless matters of sufficient importance to merit advisory committee input arise. The written request for authorization should include the proposed date(s) and subject of the meeting, a detailed rationale for why the meeting is needed (which should include clear identification of the issues to be discussed and questions to be put to a vote), and a request for inclusion of voting or non-voting consultants. If the meeting is being held to consider matters of direct concern to a sponsor’s application, investigational product, or approved product, the sponsor should be notified and provided with the same meeting request documentation. The Adcomm Office should allow the sponsor 7 days to submit additional information. The Adcomm Office should then make the final decision regarding whether the meeting is needed, whether consultants are needed, etc. To the extent allowed by law, all requests for advisory committee meetings and actions taken on those requests should be timely made part of the public record.
10. A sponsor and other affected parties (e.g., an incorporated patient group) should also be allowed to request an advisory committee meeting and should receive the same consideration as the division director for such requests.
11. Advisory committee meetings should not be held simply because there is a slot for a meeting once per quarter, nor should meetings to consider specific actions regarding any IND be held to make “policy points.” IND meetings should be specific to questions regarding the product(s). Meetings to discuss policies should be clearly identified as “policy meetings” and should be held as separate, stand-alone meetings. Advisory committee policy meetings should be held when FDA needs advice from advisory committees on specific policy matters under consideration by FDA. Advisory committee members should not be bound by agency, Center or Division policy with regard to the advice they provide as part of the advisory committee process, nor should “policies” created by divisions or supported by advisory committees be applied with the force of regulations or even guidance. Regulatory flexibility should be maintained in the consideration of all actions, including decisions to approve, defer or deny applications for all drugs, biologics and devices, to ensure that “best possible” decisions are made even when guidance and policy don’t strictly support the best possible decision in protecting and/or promoting the public health. In other words, one-size-fits-all thinking should not be imposed on the deliberations or votes of advisory committee members, or advisory committees as a whole. Advisory committee members should receive training regarding the need for advisory and regulatory flexibility, and their role in that flexibility (e.g., their

advice is not limited to conformance with existing agency guidance or policy on, for example, a specific approval endpoint).

12. Agency and sponsor briefing materials for all advisory committee meetings should be posted on the agency webpage a minimum of 72 hours before the meeting, including identification of all FDA and advisory committee members and consultants (both voting and non-voting) that will be participating. Briefing materials for advisory committee policy meetings should be made available to the public no less than 7 days prior to the meeting. The current practice of making briefing materials available the day before a meeting makes it virtually impossible for anyone wishing to comment during the public participation portions of meetings to adequately review the briefing materials. The result is a process that is inadequately transparent, and that places the public at a severe disadvantage in offering substantive input to the FDA and the advisory committee.
13. Prior or ongoing FDA consulting relationships of voting and non-voting consultants participating in any advisory committee meeting should be fully disclosed on the FDA's web page prior to participation in the meeting, and should be noted at the start of any meeting.

#### **Advisory Committee Member Work for FDA Outside the Formal Meeting Process**

14. Involvement of an advisory committee member in the review process, either informally (e.g., phone calls, e-mails, casual conversations), or formally by assignment or request (e.g., assistance with data review, advice on disease and treatments, analysis, reports, attendance at meetings other than publicly noticed and open advisory committee meetings) should be disallowed unless fully disclosed to the public prior to initiation of the activity, and again fully disclosed to the public prior to any advisory committee consideration of the subject matter at issue. The purpose of the advisory committees is to provide outside, independent advice to FDA. Any involvement of members or consultants in the FDA review or policy development process that occurs outside the formal meeting process could have a bearing on the consideration of specific matters that come before the committee; thus compromising the purpose of the advisory committee to provide outside, independent advice, and creating a clear and direct conflict of interest.

#### **Obligations of Advisory Committee Members**

15. It should be made clear to all nominees before they are appointed to any committee that accepting a nomination or invitation to serve constitutes: (1) acceptance of employment by the federal government; (2) acceptance of a code of conduct (to be timely developed by FDA); and (3) a commitment to preserve the integrity of the advisory committee process including, but not necessarily limited to, compliance with the code of conduct.

They should be made aware that violations of the code of conduct and/or compromising the integrity of the advisory committee process may result in dismissal from service.

16. Advisory committee members should be required to certify over their signature that they will conduct themselves in a manner that preserves the integrity of the advisory committee process, and will not undermine that obligation by campaigning outside the formal, public advisory committee process for, or against, a pending or completed matter that will or has come before their committee (e.g., they will not wage letter writing campaigns or express opinions in the media regarding matters scheduled to come before their committee, or that have come before their committee with an FDA decision still pending based on the subject matter of a meeting in which they participated.) Violating this obligation (which should be an explicit provision of the code of conduct) should result in immediate suspension from service as a member of any and all FDA advisory committees on which the person may either permanently or temporarily sit.
17. Evidence of improper actions by any advisory committee member or participating consultant should be investigated by the Adcomm Office and, if warranted, should result in corrective counseling (with documentation to the member's personnel file) and/or dismissal from service as an advisory committee member and/or consultant, depending on the severity and effect of the improper or inappropriate actions. Improper actions would be defined as any action that materially violated the code of conduct (including but not limited to failure to disclose financial or other potential conflict of interest information), threatened the integrity of the advisory committee process (e.g., taking, or participating in, any action outside the committee process intended to influence a matter under consideration by FDA that was the subject of an advisory committee meeting or meetings, or that is scheduled to be considered in a meeting or meetings), or violation of any regulation or law relevant to their continued service on an advisory committee. This provision would not be an abridgement of First Amendment rights provided a nominee accepted them in writing prior to acceptance of federal employment as an appointee to an advisory committee. Actions taken under this provision would be subject to employment confidentiality laws, regulations and policies.
18. Any and all communications between advisory committee members and/or voting and non-voting consultants that take place in the interim between notice of the scheduling of an advisory committee meeting and completion of pending action regarding the subject matter of the meeting, excluding communications that take place as part of the formal public meeting in full view of the public, shall be made part of the public record at the same time as posting of the meeting transcript, which should in all cases be posted on the agency web page within 14 days of the last day of an advisory committee meeting on a specific matter.
19. All advisory committee meetings, in their entirety, should be recorded, and a complete recording of the meeting (accessible and viewable for no charge by the public over the internet) should be posted on FDA's web page within 24 hours of the completion of the

last day of an advisory committee meeting on a specific subject. The only exception to this practice would be a properly convened closed meeting. Closed meetings should in every case be recorded in their entirety; however, transcripts and recordings need not be posted if the reasons for closing the meeting remain valid and proper after completion of the meeting. In the case of any closed meeting, full notice, including a description of the matter(s) to be discussed and the reason(s) for closing the meeting(s), should be fully disclosed prior to the meeting(s) and reviewed within 72 hours after completion of the meeting to determine if the reason(s) for closing the meeting(s) remain valid. Upon completion of the review, any portion of a meeting that can reasonably be disclosed to the public in transcripts and recordings should be posted on the FDA's web page in transcript and video formats.

### **Obligations of FDA Staff**

20. Division directors and all other FDA staff should not discuss advisory committee meeting subject matter with advisory committee members except as specifically allowed as part of the briefing and meeting process. Under no circumstances should FDA staff discuss strategy or potential outcomes of any potential or planned discussion(s) or vote(s) before or after scheduled or completed meetings and prior to FDA action on the matter(s) discussed, with advisory committee participants.

*[We also would comment on communications between advisory committee members and sponsors during the "briefing" period (the time between receipt of briefing documents and the meeting) and the post-meeting period when FDA has yet to act on the matters discussed, but given the near complete opacity of FDA's administration of adcomms, we have no idea how this is currently handled. Every aspect of the FDA's administration of advisory committees should be transparent. We would be happy to review and provide input on how we think FDA should handle communications between committee members and sponsors, if you will inform us of the agency's current policies on this subject].*