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Food and Drug Administration
Rm. 1-23, 12420 Parklawn Dr.
Rockville, MD, 20857

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By Federal Express

Docket No. _____

CITIZEN PETITION

Public Citizen, Inc. submits this petition to request that the Commissioner of Food and Drugs refrain from convening the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee until adequate public notice is given of the Panel's membership in accordance with the Federal Advisory Committee Act and the Food and Drug Administration's regulations.

A. Action Requested.

This petition requests that the Commissioner of Food and Drugs refrain from convening the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee on October 14, 2003 until adequate public notice is given of the Panel's membership, consistent with the requirements of the Federal Advisory Committee Act (5 U.S.C. Appendix 2) and 21 C.F.R. Part 14. This petition further requests that, pursuant to 21 C.F.R. 14.7, "the Commissioner will expedite the review of the petition and make a reasonable effort to render a decision before the action concerned in the petition."

B. Statement of Grounds.

1. FDA Has Not Disclosed The Membership of the General and Plastic Surgery Devices Panel.

The General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee does not have a set membership, but instead is composed of up to seven voting members and two non-voting members who vary from meeting to meeting.[1] The Panel is scheduled to meet on October 14, 2003 to discuss, make recommendations, and vote on a premarket approval application for Silicone Gel-Filled Breast Prostheses.[2] As of September 19, 2003, only three members of the panel were identified by the FDA on its public website: voting

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1 www.fda.gov/cdrh/panel/charter/charter-mdac.doc.

2 "General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting," 68 Fed. Reg. 52775-02 (September 5, 2003).

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members Michael A. Choti, M.D., and Michael J. Miller, M.D., and non-voting consumer representative LeeLee Doyle, Ph.D.[3]

If FDA follows its previous practice, it will appoint additional members to the Panel but will not publicly announce the identity of those members until the date of the meetings. Meetings of the General and Plastic Surgery Devices Panel typically involve more than two voting members. For example, at both its July 24, 2003, meeting and its February 28, 2003, meeting, the Panel consisted of two voting members and four "temporary voting members."[4] Thus, it appears that the Panel usually consists of six members, not including non-voting consumer and industry representatives. The Medical Devices Advisory Committee's charter, which states that a panel may "consist of a maximum of seven standing voting members," also suggests that Panels are usually more than two members.[5]

In the past, the temporary voting members added to the Panel apparently have not been publicly announced in advance of the meeting. Presumably, FDA decides who will serve as members of the General and Plastic Surgery Devices Panel at least by the time it issues its Federal Register notice giving the time and date of the meeting, because FDA will have identified qualified individuals who can prepare for and attend a meeting on that date. Yet FDA apparently does not publicly disclose the identity of these members until the start of a Panel meeting. The transcripts from both July's and February's meetings reveal that the temporary voting members were not officially and publicly appointed to those positions until the start of those meetings.[6] The Federal Register notices announcing each meeting also did not include a list of members.[7] In light of this past practice, it is likely that more voting members will be added to the Panel sometime before its October 14, 2003, meeting, but that the public will not be informed of the identity of these voting members until the meetings have begun.

FDA's failure to inform the public of the Panel's membership in advance of meetings makes it impossible to determine whether the Panel complies with the requirements of the Federal Advisory Committee Act (FACA),[8] that Act's implementing regulations, and other federal law and regulations concerning qualifications for committee membership. Thus, withholding the identity of committee members until the date of the meeting undermines federal law requiring that advisory committees be competent, balanced in viewpoint, and free from conflicts of interest.

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3 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfAdvisory/paneldetail.cfm?panel=14&details=1

4 Tr. July 24, 2003, http://www.fda.gov/ohrms/dockets/ac/03/transcripts/3973t1.htm; Tr. Feb. 28, 2003, www.fda.gov/ohrms/dockets/ac/03/transcripts/3934t1-am%20session.htm.

5 www.fda.gov/cdrh/panel/charter/charter-mdac.doc.

6 Tr. July 24, 2003, http://www.fda.gov/ohrms/dockets/ac/03/transcripts/3973t1.htm; Tr. Feb. 28, 2003, www.fda.gov/ohrms/dockets/ac/03/transcripts/3934t1-am%20session.htm.

7 68 Fed. Reg. 38067-01 (June 26, 2003); 68 Fed. Reg. 7127-01 (Feb. 12, 2003).

8 Pub. L. 92-463, passed on October 5, 1972, as amended September 13, 1976.

2. Failure to Inform the Public of the Panel's Membership in Advance of Its Meeting Prevents the Public From Ensuring that the Panel Complies with FACA's Fairly Balanced Membership Requirement.

Unless the identity and background of additional voting members are made available at least fifteen days before the meeting, the public will not have a chance to review the Panel membership to determine whether it complies with the requirements of FACA's "fairly balanced" membership requirement.

FACA mandates that advisory committee membership be "fairly balanced in terms of the points of view represented and the functions to be performed."[9] A committee is "functionally balanced" if its members have the expertise necessary to accomplish the tasks assigned. "Point-of-view balance" requires committee members to represent the perspectives of all groups directly affected by the committee's work.[10]

In its implementing regulations, the General Services Administration requires agencies establishing or renewing advisory committees to have a "plan" to attain "fairly balanced membership." As GSA explained:

> The plan will ensure that, in the selection of members for the advisory committee, the agency will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the advisory committee. Advisory committees requiring technical expertise should include persons with demonstrated professional or personal qualifications and experience relevant to the functions and tasks to be performed.[11]

The courts have confirmed this essential function of the Act in ensuring the integrity and effectiveness of federal advisory committees. As the Fifth Circuit declared, "FACA is designed to ensure that advisory committees are fairly constituted and properly monitored so that they will provide sound advice."[12]

To ensure that the Panel's members satisfy the "fairly balanced" membership requirement, FDA must provide the public with information about the identity and background of advisory committee members. Indeed, FACA declares explicitly that "the public should be kept informed with respect to the . . . membership . . . of advisory committees," and GSA's implementing regulations provide that Committee Management Officers must maintain "membership lists for each advisory committee."[13] This information will only be useful,

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9 5 U.S.C. Appendix 2 § 5(b)(2), (3).

10 *See Cargill*, 173 F.2d at 336

11 66 Fed. Reg. 37728-01, at 37739 (July 19, 2001).

12 *Cargill, Inc. v. United States*, No. 97-31190, 1999 WL 225205, at *2 (5th Cir. April 19, 1999).

13 5 U.S.C. App. 2 § 2(b)(5); 41 C.F.R. § 102-3.115(a).

however, if provided to the public *before* the Panel meets, deliberates, and votes on the issues it is to address.

Disclosing the membership of the Panel at the time of its first meeting is insufficient, because once the Panel has met, taken evidence, deliberated, and voted, it will be far more difficult to reconstitute the panel and, in any case, it may be too late to undo the damage caused by a biased or conflicted Panel. For example, if the Panel is challenged as not being "fairly balanced" *after* it has met, discussed, and voted upon the issue under consideration, it is almost impossible to rectify the error. As one district court noted, "once a committee has served its purpose, courts generally have not invalidated the agency action even if there were earlier FACA violations."[14] Even if an individual with a different viewpoint or area of expertise is added, post hoc, to the Panel, that new member will not have the same influence as if he or she had been a member of the Panel from the outset.

3. Failure to Inform the Public of the Panel's Membership in Advance of Its Meetings Prevents the Public From Ensuring that the Panel Members Do Not Have Conflicts of Interest.

Failure to provide advanced disclosure of the Panel's membership raises the equally serious prospect that FDA is not fully complying with its conflicts of interest policy for advisory committee members. Under FDA's regulations, prior to each advisory committee meeting, committee members must complete an FDA Form 3410, "Conflict of Interest Disclosure Report for Special Government Employees." "Form 3410 relates and is accompanied by a list of sponsors, affected firms, competitors, parent firms, and other information, for each topic to be covered at the upcoming meeting. Financial interest is defined in the regulations as the potential for gain or loss as a result of government action on the particular matter (18 U.S.C.208 and 5 C.F.R. part 2640). The types of interests screened are stocks and investments, primary employment, consultant work, contracts, patents, grants, trademarks, expert witness activities, speaking engagements, and other information."[15] Without timely and rigorous evaluation of this information, the potential for serious or unresolved, unidentified or incompletely characterized conflicts may remain in the Panel's membership.

As in the case of FACA's "fairly balanced" requirement, conflict of interest disclosures must be made in *advance* of meetings to allow the public to review the information to determine whether any of the panel members are conflict.

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14 *Seattle Audubon Society v. Lyons*, 871 F.Supp. 1291, 1309 (W.D. Wash. 1994). *Cf. Northwest Forest Resource Council v. Espy*, 846 F.Supp. 1009, 1015 (D.D.C. 1994) (declining to enjoin agency from relying on committee's report, despite FACA violations by committee, because such relief would "exceed injury to be redressed").

15 www.fda.gov/ola/2000/advcomm.html (Statement of Senior Associate Commissioner Linda Suydam, House Committee on Government Reform, June 14, 2000).

4. Last Minute Appointment of Panel Members Undermines FDA's Claim That It "Carefully Screens" Panel Members.

Eleventh hour announcements of panel membership make it impossible to determine whether FDA is complying with its own requirements to assure that Panel members are fully qualified "in the subject matter with which the committee is concerned and have diverse professional education, training, and experience so that the committee will reflect a balanced composition."[16] Last-minute appointments also cast doubt on FDA's claims that:

> In screening nominations for prospective standing committee members for scientific and technical expertise and competence, FDA has a thorough, and consistently applied, process. This ensures that we obtain qualified members who are able to provide the Agency advice... Candidates should be carefully screened to ensure that they possess expertise relevant to the particular subject matter on which their advice will be sought. Attention also should be paid to reputation and leadership qualities. Whenever possible, nominees should be acknowledged experts in their fields whose credibility is beyond question . . . The responsible office is expected to seek diligently, and document external evaluation of, the credentials of the nominee.[17]

Announcing Panel members only once the meeting has started, when it is too late to obtain public input on the quality of these members, conflicts with FDA's stated intention of ensuring that candidates are "thorough[ly]" and "carefully screened" before being appointed.

FDA typically appoints several "temporary voting members" to the General and Plastic Surgery Devices Panel. Temporary voting members are selected from standing members of other FDA advisory committees and consultants to FDA.[18] Presumably, members of other committees have been screened before being appointed to those committees. However, the screening that FDA conducts before appointing an individual to one committee does not automatically qualify that individual to serve as a member of another committee examining different issues. When FDA composes a new panel, it must ensure that each individual is competent to address the specific issues before that panel and that the panel as a whole is "fairly balanced" in light of the "functions to be performed." Thus, FDA is not fulfilling its obligation to screen members when it makes last-minute appointments to the General and Plastic Surgery Devices Panel.

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16 21 C.F.R. § 14.80(b)(1)(i).

17 www.fda.gov/ola/2000/advcomm.html (Statement of Senior Associate Commissioner Linda Suydam, House Committee on Government Reform, June 14, 2000).

18 www.fda.gov/ola/2000/advcomm.html (Statement of Senior Associate Commissioner Linda Suydam, House Committee on Government Reform, June 14, 2000).

5. Failure to Give Advance Notice of the Panel's Membership Undermines Public Confidence in the Integrity of the Committee's Deliberations.

The FDA's advisory committee system was established "to provide independent expertise and technical assistance related to the development and evaluation of products regulated by FDA; to lend credibility to the product review process... and to provide a forum for public discussion on matters of significant public interest."[19] The agency relies upon over 1,500 external experts with highly specialized expertise to advice and inform the decisions of its medical and scientific staff.

The FDA has no greater need for objective, credible scientific and credible advice than in its review of "a premarket approval application for Silicone Gel-Filled Breast Prostheses." The regulation of breast implants has been one of the most controversial areas of practice for the FDA in the post-war era.

The FDA and other federal public health agencies have been the focus of intense public scrutiny over question of whether individuals have been appointed to their advisory committees for their political or ideological views, or their relationships with regulated industries, rather than their scientific or medical expertise.[20] As the *Lancet* recently observed:

> Expert committees need to be filled, by definition, with experts. That means those with a research record in their field and in epidemiology and public health. Members of expert panels need to be impartial and credible, and free of partisan conflicts of interest, especially in industry links or in right-wing or religious ideology. Any further right-wing incursions on expert panels' membership will cause a terminal decline in public trust in the advice of scientists.[21]

Deviations from compliance with FACA, and with FDA regulations and policy, cast doubt on the credibility and integrity of the advisory committee process. The delays and lack of transparency in naming members to the General and Plastic Surgery Devices Panel could be construed to constitute an explicit strategy to shield FDA's decision-making from public scrutiny and accountability. Such appointments, as one editorial recently noted, "go against the Federal Advisory Committee Act, which requires that committees be 'fairly balanced in terms of points of view represented' and that advice 'not be inappropriately influenced by appointing authority or by any special interest.'"[22]

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19 Id.

20 See, e.g., David Michaels et al, "Advice Without Dissent" (editorial), *Science* 2002;298:703; "HHS Seeks Science Advice to Match Bush Views," *Washington Post*, September 17, 2002, A-1; Dan Ferber, "Environmental Health: Critics See a Tilt in a CDC Science Panel," *Science* 2002;297:1456-7; "On Health and Medicine: When Politics Trumps Science" (editorial), *San Francisco Chronicle,* January 5, 2003.

21 "Keeping Scientific Advice Non-Partisan," *Lancet,* 1525 (Nov. 16, 2002).

6. Conclusion

For the aforementioned reasons of law, regulation and policy, the Commissioner should refrain from convening the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Committee until adequate public notice is given of the Panel's membership in accordance with Federal law and regulations.

C. Environmental Impact.

This petition qualifies for categorical exemption under 21 C.F.R. § 25.15, 25.30-32 from the preparation of an environmental assessment.

D. Economic Impact.

A statement of the economic effect of the requested action may be submitted upon request by the Commissioner.

E. Certification.

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

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[22] "Science fiction: Bush's ideological skewing of research is no way to make good public policy" (editorial), *Philadelphia Inquirer,* August 24, 2003.