



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Office of Policy, Planning, and  
Legislation HF-22  
5600 Fishers Lane  
Rockville, MD 20857

AUG 14 2000

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Indianapolis, IN 46204-1782

Re: Docket No. 97P-0150/CP

Dear Mr. Thompson:

This responds to your petition, dated April 8, 1997, filed on behalf of the Indiana Medical Device Manufacturers Council, Inc. Your petition requested that the Food and Drug Administration (FDA) amend the advisory committee regulations at 21 CFR Part 14 by creating a new § 14.37 titled, "Meetings addressing issues unrelated to submissions." The new provision you requested would:

- \* apply to "any meeting of an advisory committee at which the FDA plans to pose questions to the committee that do not directly relate to a product submission received by the FDA" (see petition at page 1);
- \* require the agency to publish a *Federal Register* notice at least 60 days before the meeting, identifying the precise questions that FDA would present to the advisory committee, including the text of any "regulatory proposals such as any guidance or guidelines" that FDA would submit to the committee, identifying "with particularity the data that underlie the FDA's questions or the FDA's concerns that prompted the questions" (id.);
- \* require the agency to place any data underlying FDA's questions on display at the Dockets Management Branch (id.);
- \* require the agency to ensure "that the voting membership of such committee is equally balanced with regard to its representation of consumers, medical

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professionals, industry, and any other sectors with an interest in the subject to be discussed” (id.);

- \* require the agency to organize and conduct meetings subject to §14.37 to “[a]llow the proponents of a particular technology opportunity to rebut any adverse data or testimony” (id.); and
- \* require the agency to organize and conduct meetings subject to §14.37 in a manner that would “[c]reate a logical flow of the information presented so that the committee receives adequate background on the regulatory issues involved” (id. at page 2).

Your petition further requested that FDA amend the charters of advisory committees that would consider issues under a new § 14.37 to conform to the requirements found in that requested regulation. In addition, your petition asserted that the Medical Devices Advisory Committee does not comply with the Federal Advisory Committee Act (FACA) when it considers issues unrelated to product applications, and requested that FDA change the committee’s charter to comply with your requested regulation (id. at pages 2, 14-16).

For the reasons stated below, your petition is granted in part, and denied in part.

#### *The Request for 60-Day Notice*

Your petition requested that FDA provide at least 60 days notice of a meeting “whenever the agenda includes a discussion on a general policy issue” (id. at page 11). Your petition asserted that greater notice is “essential” to public participation and to forming appropriate committee recommendations. Currently, FDA regulations state that it will provide notice at least 15 days before a meeting (see 21 CFR 14.20(a)). This time period is consistent with government-wide regulations at 41 CFR 101-6.1015(b).<sup>1</sup>

The agency agrees that earlier notice of any advisory committee meeting is desirable, but an absolute, 60-day advance notice requirement would be impractical given FDA’s time constraints when scheduling meetings. A major purpose of some FDA advisory committee meetings is to solicit the committee’s scientific and technical advice on an issue or issues

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<sup>1</sup> Most agency regulations also require at least 15 days notice before an advisory committee meeting. See, e.g., 10 CFR 7.12(c) (Nuclear Regulatory Commission); 16 CFR 16.9(a) (Federal Trade Commission); 16 CFR 1018.22(b) (Consumer Product Safety Commission); 22 CFR 8.9(c)(2) (Department of State); 22 CFR 214.33(a) (Agency for International Development); 29 CFR 1912.27 (Occupational Safety and Health Administration); 41 CFR 105-54.301(i) (General Services Administration); 44 CFR 12.11(a) (Federal Emergency Management Agency).

pertaining to a pending marketing application. When a meeting is primarily to address a marketing application and to discuss “policy issues” only inasmuch as they are ancillary to the submission, the status of the application, rather than other issues such as guidance documents, is the critical factor in scheduling a meeting. If FDA were required to delay an advisory committee meeting to provide for a full 60-day notice period as requested by your petition, completion of the application review could be delayed, and the product could be delayed from reaching consumers. Delayed meetings would also have an adverse effect on the agency’s ability to meet application review performance goals for certain products.

FDA also convenes some advisory committee meetings in response to sudden or important public health developments. These instances are rare so that issuance of a new rule dealing exclusively with such meetings is not warranted, and, in any event, the need for prompt consideration of the underlying scientific issues would make an absolute, 60-day advance notice requirement impractical.

FDA further notes that the Food and Drug Administration Modernization Act of 1997 (“FDAMA”) (Pub. L. 105-115) amended section 505 of the Federal Food, Drug, and Cosmetic Act (the “Act”) to require the agency to “ensure that scientific advisory panels (for drugs and biologics) meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review....” FDAMA also provides that “[c]lassification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.” These statutory requirements make it difficult, if not impossible, for FDA to provide extensive notice before advisory panel meetings while simultaneously ensuring that the meeting does not preclude FDA from complying with its statutory deadlines.

Additionally, in preparing for any advisory committee meeting, FDA must perform numerous planning activities, such as contacting the members, formulating the agenda, identifying appropriate consultants, conducting conflict-of-interest screening, drafting the *Federal Register* announcement of the meeting, and handling logistical arrangements. The agency works constantly on all these activities 30, 60, and 90 days before a meeting. The time required for these tasks, as well as the time required to publish the *Federal Register* notice, often results in publication of the notice 15-30 days before the meeting is to occur.<sup>2</sup> Consequently, for the agency to adopt a rule requiring 60-days advance notice in all instances would require the agency to begin its preparations for the meeting weeks and probably months before publication of the 60-day notice. Such long delays between when the need for an

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<sup>2</sup> A preliminary announcement of an advisory committee meeting usually appears earlier, on average 30 days before the meeting date, on FDA’s Internet site. Early information about advisory committee dates and topics also may be obtained from the Advisory Committee Information Line, 1-800-741-8138.

advisory committee develops and when the agency may call the meeting would severely hamper FDA's ability to fulfill its responsibilities efficiently.

*The Request to Publish the Text of Guidances and to Identify Questions*

Your petition requested that FDA publish the text of any "regulatory proposals," such as guidance documents, submitted to an advisory committee. Your petition further requested that FDA identify the precise questions that it would present to the advisory committee.

FDA is already publishing the text of its guidance documents as a result of its "Good Guidance Practices." As you know, under the Good Guidance Practices, FDA solicits public input on "level 1" guidance documents before their implementation (see 62 FR 8961, 8968 (Feb. 27, 1997)).<sup>3</sup> The only exceptions to this general practice are when there are public health reasons for immediate implementation; when a new statutory requirement, executive order, or court order requires immediate implementation and the guidance document is necessary for such implementation; and when the guidance document presents a less burdensome policy that is consistent with public health (id.). In situations where greater public input is desired, the agency may even hold public workshops to discuss a draft guidance document or present a draft to an advisory panel (id.). Furthermore, the agency will accept comments at any time for level 1 and level 2 guidance documents. Thus, publication of a guidance document under FDA's Good Guidance Practices<sup>4</sup> should be sufficient for purposes of soliciting public comment on a guidance document.<sup>5</sup>

FDA will make an effort to publish the questions to be presented to advisory committees that will be addressing general scientific and technical issues. The agency

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<sup>3</sup> Level 1 guidance documents generally include guidances directed at applicants/sponsors or other members of the regulated industry that set forth first interpretations of statutory or regulatory requirements, changes in interpretation or policy that are of more than a minor nature, unusually complex scientific issues, or highly controversial issues. Level 2 guidance documents include all other guidance documents.

<sup>4</sup> You may be aware that, under section 405 of FDAMA, Congress essentially codified FDA's Good Guidance Practices as an amendment to section 701 of the Act. FDAMA requires FDA to promulgate regulations specifying the agency's policies and procedures for developing, issuing, and using guidance documents no later than July 1, 2000. FDA published its proposed rule on Good Guidance Practices on February 14, 2000 (65 FR 7321). The comment period on this proposed rule closed on May 1, 2000.

<sup>5</sup> On occasion, FDA does present preliminary drafts or concepts to an advisory committee before it publishes a draft document. In such cases, the agency makes these documents available on its web site.

acknowledges that providing advance notice of the questions could help interested persons to decide whether to attend the meeting or how to prepare for the meeting, but in preparing a *Federal Register* notice of an advisory committee meeting and in preparing for the meeting itself, FDA usually continues to work on and to refine the issues and questions to be presented until shortly before the meeting. Thus, publishing the questions in the *Federal Register* is impractical as FDA constantly prepares for a meeting, adds or rephrases questions or revises the previously published questions. Nevertheless, FDA has been publishing such questions for many advisory committee meetings on its web site (where the agency may make information publicly available much more quickly and easily). Additionally, in an effort to disseminate more information about non-approval type issues discussed at advisory committee meetings, FDA is making available written information for consideration at an advisory committee meeting, whenever practicable, before or at the time of the meeting.

The agency does note, however, that, for device classification panels, FDAMA amended section 513 of the Act to require FDA to provide, to any person whose device is specifically the subject of a classification panel review, the “same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under [5 U.S.C. 552]) as [FDA]”. This new statutory requirement will give device sponsors whose device is the subject of a classification panel access to the draft questions submitted to the device classification panel.

#### *The Request for Publication of Relevant Data or Concerns*

Your petition requested that FDA identify, in its *Federal Register* notices, the data underlying FDA’s questions or FDA’s concerns that prompted FDA’s questions (id. at pages 1 and 11). It claimed that current FDA practice “inhibits the public from supplying the kind of quality data that the panels need to make informed recommendations on policy issues” (id. at page 11).

For advisory committee meetings that will address general and scientific issues, the agency grants your request to the extent that the data is publicly available, the availability or disclosure of that data is within copyright laws, and the agency has obtained and analyzed the data in time to publish it. No regulatory amendment is necessary to implement this decision. The agency is also examining the legal and policy issues associated with public disclosure of more data and information for an advisory committee meeting, and so, to the extent that your request includes data and information that are currently not publicly available, FDA is deferring that portion of your request.

Moreover, as stated earlier, FDAMA amended section 513 of the Act to require any person whose device is under review by a classification panel to have access to the same “data and information submitted to the classification panel” (except for data and information that are not available for public disclosure) (see section 513(b)(6)(A)(i) of the Act). FDAMA also amended the Act to require any person whose device is under review by a classification panel

to have the opportunity to submit information based on that data or information to the panel for its review, and to have “the same opportunity as the Secretary to participate in meetings of the panel.” Thus, insofar as sponsors and device classification panels are concerned, implementation of this amendment should provide sponsors greater access to data and information as sought by your petition.

As for your request to identify the agency’s concerns in the *Federal Register* notices, FDA cannot grant your request because, as in the case of questions for an advisory committee, the agency is constantly preparing and rephrasing the issues and concerns to be presented at the meeting. Consequently, it is not always feasible for the agency to publish the concerns it may present to the advisory committee when the agency publishes a notice announcing a meeting. Instead, FDA will try to make information available (through its web site or through other means), whenever practicable, before or at the time of an advisory committee meeting.

#### *The Request Regarding Committee Membership*

Your petition requested that FDA reconstitute its advisory committees to “diversify” the backgrounds of their members “if these committees are to be used as sounding boards for broad regulatory or enforcement issues” (id. at page 12). It added that “[m]edical device regulatory questions often involve scientific, medical, human factors, legal, policy, and other issues, and can be adequately addressed only by a group of people with a broad range of backgrounds, including manufacturers, physicians and other health care professionals, patients, hospitals and other health care facilities, attorneys, compliance experts, and academics and other researchers” (id. at page 13).

The agency agrees that a diverse group may enhance discussion of a regulatory issue, but disagrees with your petition’s implicit notion that regulatory issues can *only* be *adequately* addressed if FDA expands its advisory committees to include persons representing the different constituencies identified in your petition. If an advisory committee’s membership was based on affiliation (e.g., industry, physician, public health group), the advisory committee’s size might become unwieldy and questions would arise as to whether all parties were adequately represented. The agency notes that, in 1992, the Institute of Medicine (IOM) reviewed the agency’s use of advisory committees and issued a report titled *Food and Drug Administration Advisory Committees*. In this report, the IOM rejected an interpretation of the FACA that would require committees to consist of representatives or advocates of specific constituencies.<sup>6</sup>

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<sup>6</sup> The provision at issue is at 5 U.S.C. App. II § 5(b)(2), which requires that an advisory committee’s membership be “fairly balanced in terms of the points of view represented and the functions to be performed....”

The IOM's rationale was that the primary role of advisory committees is to provide the best scientific advice and interpretations and not to represent specific constituencies.<sup>7</sup>

In some cases, the Act provides specific guidance on advisory committee membership. Section 513(b) of the Act states that persons appointed to device classification panels should be "qualified by training and experience to evaluate the safety and effectiveness of the devices to be referred to the panel and who, to the extent feasible, possess skill in the use of, or experience in the development, manufacture, or utilization of, such devices." It also requires that the panels consist of "members with adequately diversified expertise in such fields as clinical and administrative medicine, engineering, biological and physical sciences, and other related professions" and nonvoting members representing consumer interests and industry interests.

FDAMA provided additional guidance on advisory committee membership, but only with respect to two types of advisory panels. Section 120 of FDAMA amended section 505 of the Act to require expert panels providing advice on clinical investigations of drugs or marketing approval of drugs to consist of:

- (A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;
- (B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoconomics, biological and physical sciences, and other related professions;
- (C) a representative of consumer interests, and a representative of the interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and
- (D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels.... (See section 505(n)(3) of the Act.)

This membership requirement is narrower than the membership sought by your petition because it pertains to expert panels on drug issues only and does not mandate membership for representatives of hospitals, other health care facilities, attorneys, compliance experts, academics, or other researchers.

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<sup>7</sup> See also 21 CFR 14.80(a)(1) which states, in part, that members of a policy advisory committee shall have diverse *interests*, education, training, and experience.

Section 127(d) of FDAMA amended the Act to prescribe the composition of the advisory committee on drug compounding. Under section 503A(d)(1) of the Act, that advisory committee must include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and “other experts selected by the Secretary.” Again, this membership requirement is limited in its application and is narrower than the membership sought by your petition. Nevertheless, to comply with the spirit of FDAMA and to further diversify the backgrounds of committee members, both the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) are in the process of modifying their committee charters to include non-voting industry representation on their advisory committees.

In the absence of statutory requirements regarding membership on advisory committees and because the representational membership sought by your petition would not necessarily determine whether an advisory committee would adequately address issues placed before the committee, FDA declines to impose the membership requirements requested by your petition on all advisory committees.<sup>8</sup>

#### *The Requests Regarding Committee Meeting Organization and Format*

Your petition requested that, as part of a proposed rule, FDA require advisory committee meetings to provide “the proponents of a particular technology opportunity to rebut any adverse data or testimony” (petition at page 1) and to “create a logical flow” of information (id. at pages 2 and 13-14). Your petition asserted that the order of presentations and time allocated for a presentation “significantly influences the outcome of a panel’s recommendations” (id. at page 13) and that the quality of information presented would be increased if the proponents of a technology could rebut adverse data or arguments (id.). Your petition further requested that the structure of the meetings themselves be revised so that public participation would not be “artificially” clustered at the beginning of the meeting (id. at page 14).

The agency declines to grant your requests because existing regulations and recent statutory changes provide sufficient flexibility to address your concerns. FDA regulations expressly allocate at least 1 hour of each advisory committee meeting to open public participation and give the committee chairperson discretion as to further public participation (21 CFR 14.29(a)). The chairperson’s discretion extends to allocating more time for public participation during the course of the meeting; in other words, public participation is not necessarily “clustered” at or confined to the beginning of the meeting. In fact, for many meetings, the public participation phase is scheduled later on the agenda after the sponsor and FDA have made their presentations, but before the advisory committee begins its discussions.

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<sup>8</sup> It is important to note that advisory committees have retained consultants in order to add specific expertise.

Additionally, the regulations allow any interested person to request the opportunity to make an oral presentation at an advisory committee meeting (21 CFR 14.29(b)). Thus, existing FDA regulations and advisory committee practice provide the opportunity for interested persons to participate in all phases of the meeting when such a format is appropriate to the given topic at hand.<sup>9</sup>

Additionally, for device classification panels, section 208 of FDAMA amended section 513(b) of the Act to require such panels to provide any person whose device is under panel review “the same opportunity as the Secretary to participate in meetings of the panel” and “adequate time for initial presentations and for response to any differing views.” Thus, persons whose devices are the subject of a device classification panel must, under section 513(b)(6)(A)(iii) of the Act, be given adequate time for an initial presentation and time to respond to differing views.

Section 208 of FDAMA also amended section 513(b) of the Act to require classification panel meetings to “encourage free and open participation by all interested persons” (see section 513(b)(6)(B) of the Act). As part of implementing this provision, device classification panels conduct the open public session in two segments: approximately 30 minutes at the beginning of each panel meeting for general or specific issues and 30 minutes near the end of the panel deliberations, prior to the vote, for interested persons to address issues specific to the submission before the panel.<sup>10</sup>

Section 404 of FDAMA requires FDA to promulgate regulations under which sponsors, applicants, and manufacturers of drugs or devices may seek review of scientific controversies between themselves and the agency if neither the Act nor FDA regulations already provide for such review. The request for review may include review by an appropriate scientific advisory panel described in section 505(n) of the Act or an advisory committee described in section 515(g)(2)(B) of the Act. While this may not give persons the opportunity to respond to differing views during an advisory panel or committee meeting, it does give them an additional opportunity to submit the subject of a scientific dispute with the agency to independent review by an advisory panel or committee. As part of the implementation of section 404 of FDAMA,

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<sup>9</sup> FDA acknowledges that 21 CFR 14.29(a) states that the public participation portion of a meeting “ordinarily” is the first portion of a meeting. However, the term “ordinarily” does *not* mean that the public participation portion *must* occur first, and, as stated above, advisory committees have scheduled the public participation portion to occur later in the meeting. FDA is considering whether to amend § 14.29 to clarify this position.

<sup>10</sup> On January 26, 1999, the agency issued a guidance document titled, “Guidance on Amended Procedures for Advisory Panel Meetings” (64 FR 3954). The guidance document is intended to establish operating procedures for CBER and CDRH in implementing section 513(b)(6) of the Act, as amended by section 208 of FDAMA.

the Center for Devices and Radiological Health (CDRH) has established the Medical Devices Dispute Resolution Panel, which will operate as one of the panels under the Medical Device Advisory Committee. The Dispute Resolution Panel will follow the procedures described in the guidance document titled, "Resolving Scientific Disputes Concerning the Regulation of Medical Devices: An Administrative Procedures Guide to Use of the Medical Devices Dispute Resolution Panel." The Dispute Resolution Panel will serve as a useful forum for sponsors to seek review of scientific controversies between themselves and the agency.

As for creating a "logical flow" of information, the current regulation gives FDA sufficient flexibility in the structure of meetings to allow adjustments depending on the subject matter to be presented. FDA works with the advisory committees to organize the meetings as best it can, yet the "logical flow" of information may vary from meeting to meeting, and individuals can and often do differ as to how a meeting or topic should be organized. For example, the organization could be based on major and minor topics, on chronological sequence, or on specific and general issues. In each instance, the result may be "logical" to some persons yet confusing to others. Consequently, FDA declines to incorporate in its regulations an express requirement of a "logical flow" of information.

*The Request to Create a New § 14.37 and  
the Request to Amend the Advisory Committees' Charters*

Your petition requested that FDA create a new § 14.37 to codify the changes sought by your petition and to amend advisory committees' charters to conform with the requirements of such a new regulation.

As discussed above, the agency does not agree that regulatory changes are necessary. FDA declines to initiate rulemaking to create a new § 14.37. Furthermore, because the agency declines to initiate such rulemaking, FDA also declines to grant your request that FDA amend its advisory committee charters to conform with a new § 14.37.

*The Claim That the Medical Device Advisory Committee  
Does Not Comply with Federal Laws*

Your petition requested that FDA amend the charters of all FDA advisory committees to conform to your suggested regulatory changes, and charter the Medical Devices Advisory Committee (MDAC or the Committee) as a nonstatutory committee. You asserted that the charter of the MDAC purports to charter activities not authorized by the Act and requested that CDRH follow the procedures prescribed by the FACA and regulations of the General Services Administration (GSA) for chartering nonstatutory committees.

For the reasons discussed below, your request is denied.

The particular provisions of the current MDAC charter your petition objects to are those authorizing panels to:

- \* “advise[] on any possible risks to health associated with the use of devices;”
- \* “make recommendations on specific issues or problems concerning the safety and effectiveness of devices;”
- \* “review[] guidelines and guidance documents;” and
- \* “make appropriate recommendations \* \* \* on the quality in the design of clinical studies regarding the safety and effectiveness of marketed and investigational devices.”

The Act authorizes the MDAC to perform each of these activities.<sup>11</sup>

As your petition points out, the FACA and the GSA regulations describe two means of establishing advisory committees other than presidential advisory committees. See FACA § 9, 41 CFR §§ 101-6.1007, 101-6.1013; see also 21 CFR § 14.40(a). When an agency wishes to vest an advisory committee with functions not mandated by statute, the agency must go through the procedures outlined in 41 CFR 101-6.1007 for nonstatutory committees. Your petition reads into the distinction the FACA draws between statutory and nonstatutory committees a requirement that a federal agency follow the procedures in section (9)(a)(2) of the FACA and 41 CFR 101-6.1007 when chartering statutory advisory committees to perform unspecified advisory activities undertaken as a means to statutorily mandated functions.<sup>12</sup>

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<sup>11</sup> In response primarily to FDAMA, the agency recently amended the MDAC charter. FDA’s Senior Associate Commissioner signed the amended charter on August 18, 1999. Few changes were made to the description of the MDAC’s functions; however, to clarify the statutory basis for such functions as advising on a broad range of health risks, review of guidance documents, and making recommendations concerning safety and effectiveness, the latest version of the MDAC charter includes the sentence: “The panels engage in a number of activities to fulfill the functions the FFDC Act envisions for device advisory panels.”

<sup>12</sup> The requirements in the FACA for advisory committee charters cast doubt on this construction. Under subparagraph 9(c)(F), so long as a committee serves a purely advisory role, its charter need not reference the statutory authority for the committee’s chartered functions. Although the FACA does distinguish statutory from nonstatutory committees on the basis of whether statutory authority for the committee exists, it does not support the rigid rule that whenever a statutory advisory committee engages in an activity not named by statute as one of or the only means of fulfilling the committee’s mandate, the agency seeking advice must recharter the committee as a nonstatutory advisory committee.

The construction your petition urges runs counter to the principle in administrative law that a statutory delegation of congressional authority to carry out named goals includes the authority to perform the reasonable means of achieving those goals. See, e.g., *Wyoming Hospital Association v. Harris*, 527 F. Supp. 551, 556 (D.Wy. 1981) (“[w]here delegation of power is made to an administrative agency, authority to take appropriate action to effectuate that power will be implied”), *aff’d*, 727 F.2d 936 (10th Cir. 1984), citing *Morton v. Ruiz*, 415 U.S. 199 (1974). This principle makes sense: a common reason for delegating congressional authority is that the agency to which Congress delegates has greater expertise and better ability to determine the best course for implementing a legislative objective. This reasoning applies equally to advisory committees such as the MDAC, which FDA uses in an advisory capacity to supplement the internal expertise of the agency. In addition, the principle that a statutory grant of authority also authorizes reasonable means of exercising that authority is especially compelling for the Act, which courts construe broadly to effect the congressional purpose of protecting the public health. See, e.g., *United States v. Bacto-Unidisk*, 394 U.S. 784, 798 (1969). The Act, then, mandates that the MDAC perform certain functions. In doing so, the Act also authorizes the Committee to undertake activities necessary to performing those functions.

The Act’s mandates on the Committee include some of the activities to which your petition objects, at least when performed in furtherance of certain of the Committee’s advisory functions. Many functions the Act prescribes for the advisory panels that comprise the MDAC<sup>13</sup> concern reviewing and making recommendations on product submissions and the classification of devices. Several provisions require that the panel provide the reasons for its recommendations. See, e.g., sections 513(c)(2), 513(f)(2)(B)(i), and 515(c)(2) of the Act. Given that safety and effectiveness are critical components of many product review and classification decisions, the reasons for a panel’s recommendation will almost invariably incorporate a discussion of the possible health risks presented by the device. When a risk to health is the reason for a panel recommendation on classification of a preamendment device, reclassification of a post amendment device, or approval of a premarket approval (PMA) application, the Act not only allows but requires such a discussion.

Similarly, the Act expressly authorizes panels to make recommendations on issues or problems with devices as part of panels’ classification and reclassification functions. For example, section 513(c)(2)(B) of the Act charges device classification panels that have recommended a device be classified into class I with making recommendations on whether the device should be exempt from any of the general controls normally applicable to class I devices. Making such a recommendation requires evaluation of whether the device

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<sup>13</sup> The Act mandates functions for device classification panels. Under the 1990 charter, all the classification panels constitute the MDAC. Because, under section 3(2) of the FACA, an “advisory committee” includes advisory committee subcommittees and subgroups, the FACA applies equally to the MDAC and the classification panels. *Cf.* 21 CFR § 14.40(d).

recommended for class I presents a risk, and if it does, whether registration including premarket notification, reporting, and good manufacturing practices are necessary to control that risk, or whether the device can be exempted from one or more of those general controls. Making recommendations concerning issues or problems with a device, then, is a required function of a device advisory panel recommending a device for inclusion in class I.

Several of the Act's provisions governing medical device panels implicitly authorize the panels to give advice on health risks posed by devices and make recommendations on device issues or problems. For example, panels must discuss in their classification and reclassification recommendations for certain devices "an identification of the risks to health (if any) presented by the device with respect to which the recommendation is made." See sections 513(c)(2)(a) and 513(f)(2)(b)(i) of the Act. In addition, the decision to place a device in class I, II, or III entails an assessment of the risks a device presents and the regulatory mechanisms - - whether general controls by themselves, or in combination with special controls or premarket approval -- necessary to control those risks. A panel's recommendation of the controls appropriate for a given device would have little value to the agency officials responsible for classifying and assigning controls to a device without an explanation of the reasoning of the panel, including the types of problems presented by the device and a discussion of the controls necessary to address those problems. The authority of a panel to make recommendations on issues associated with use of a device, then, is an inherent part of the panel's advisory function in recommending a device's classification.

The review of guidance documents is also an intrinsic part of the panels' device review and classification functions. Special controls frequently take the form of guidance documents. See section 513(a)(1)(B) of the Act. A panel cannot intelligently recommend a device's classification into class II unless it has reviewed the controls proposed to obviate the need for premarket approval. Some FDA guidances contain information on good manufacturing and design control practices. Reviewing and evaluating such information can assist panel members in making informed, useful recommendations to FDA on product classification and submissions.

The Act's provisions establishing the device submission functions of the panels also authorize the charter provision addressing the panels' role in making recommendations on the quality of clinical studies of marketed and investigational devices. See, e.g., sections 515(c)(2) and 515(f)(2) of the Act. The evaluation of any submission that relies on clinical data requires an evaluation of the quality of the data and the studies that produced the data. Those studies may be the subject of an investigational device exemption pursuant to section 520(g) of the Act or they may involve devices already manufactured. When such studies are submitted as part of a PMA, PDP or other submission for which the Act provides panel review, assessment by the panel of the quality of those studies is appropriate, and, in some instances, unavoidable and necessary.

Finally, your petition argues that FDA uses the Committee, which the agency has chartered as a technical committee, to decide policy issues, and thus should recharter the Committee as a policy committee. The MDAC does not reach decisions on agency policy. The Committee's role is solely advisory; its purview is technical, scientific, and medical matters. In a science-based regulatory agency, policy decisions inevitably depend upon scientific findings and opinion, and the Act expressly contemplates FDA's use of advisory panels to inform the scientific basis for specified agency programs. The distinction FDA's regulations draw between policy and technical committees does not prohibit the FDA from using technical committees to address technical issues that have implications for how the agency decides policy matters.

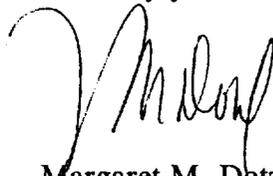
For the reasons discussed above, your request to recharter the MDAC is denied.

*Conclusion*

In summary, FDA grants your requests to publish the texts of guidance documents and to identify data underlying the agency's questions or concerns (to the extent that such data are publicly available and its disclosure would be legally permissible and feasible). The agency denies your requests to require publication of *Federal Register* notices at least 60 days before advisory committee meetings, to revise advisory committee membership criteria, to create a new § 14.37 concerning "meetings addressing issues unrelated to submissions," and to impose certain organization and format requirements on meetings. The agency also disagrees with your assertion that the Medical Devices Advisory Committee does not comply with FACA.

FDA appreciates your interest in this area.

Sincerely yours,



Margaret M. Dotzel  
Associate Commissioner for Policy

cc: HFA-305  
GCF-1