FDA ADVISORY COMMITTEE MEETINGS AND THE ROLE OF THE INDUSTRY REPRESENTATIVE: QUESTIONS AND ANSWERS
FDA ADVISORY COMMITTEE MEETINGS AND THE ROLE OF THE INDUSTRY REPRESENTATIVE: QUESTIONS AND ANSWERS

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GENERAL

What is an advisory committee?

The Federal Advisory Committee Act defines a public advisory committee as any group that a federal agency calls to obtain advice or recommendations and that is not composed wholly of full-time government officers and employees. The advisory committee framework permits agency decision making on important matters to be conducted in the open, for public consideration and scrutiny.

FDA operates 32 advisory committees, 5 of which are standing committees within the Center for Devices and Radiological Health (CDRH). All of FDA's advisory committees are scientific and technical committees. They provide independent, expert scientific advice to FDA to help it make sound decisions based upon the reasoned application of good science.

In general, advisory committees include a chair, members, and a consumer, industry, and sometimes a patient representative. Additional experts with special knowledge may be added for individual meetings as needed. Although advisory committees provide advice and input to FDA, final decisions are made by the Agency.

Advisory committee meetings are announced in the Federal Register at least 15 days in advance. Most committee meetings are open to the public, but some meetings may be closed or partially closed to review and discuss confidential information.

CDRH advisory committees provide independent, professional advice from outside experts on the development, safety and effectiveness, and regulation of medical devices. Committee members weigh available evidence and provide scientific and medical advice on the safety, effectiveness, and appropriate use of products under FDA's jurisdiction. They can also advise on general criteria for evaluation and on broad regulatory and scientific issues that are not related to a specific product (e.g., guidance development and safety and effectiveness criteria).

CDRH's five advisory committees include the Medical Devices Advisory Committee, which is comprised of 18 panels that cover medical specialty areas (see Attachment 1). In regulating medical devices, FDA may refer a matter to an advisory committee panel for the following reasons:

A. Advice on a Premarket Submission

Most advisory committee panel meetings to review premarket submissions concern premarket approval (PMA) applications. However, FDA may take any type of premarket submission to an advisory committee panel, including a humanitarian device exemption application, a De Novo classification request, a premarket notification (commonly referred to as a 510(k) submission), a proposed product development protocol, or any scientific or regulatory dispute. Scenarios in which CDRH may seek panel input include:

- a novel technology may have a significant impact on clinical practice;

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1 The five standing committees are the: (1) Medical Devices Advisory Committee; (2) Patient Engagement Advisory Committee; (3) Technical Electronic Product Radiation Safety Standards Committee (TEPRSSC); (4) Device Good Manufacturing Practice Advisory Committee; and (5) National Mammography Quality Assurance Advisory Committee. This document applies to CDRH advisory committees other than the TEPRSSC.
• study results provide significant uncertainty about whether the probable benefits of the device outweigh its probable risks; and
• significant study data quality or data integrity issues or questions exist.

CDRH considers the panel’s nonbinding recommendations as part of its decision whether to provide marketing authorization for the device.

B. Regulatory Issues

CDRH may refer a matter to an advisory committee panel for advice on regulatory actions or to discuss general scientific matters. These types of meetings include:

1. Classification/Reclassification

FDA will seek a panel’s input as part of the classification of a pre-amendments device or to reclassify such a device. FDA will also seek panel input as part of an action to call for PMAs for a pre-amendment class III device. FDA may also, for good cause shown, refer a petition requesting reclassification of a post-amendment device to a panel.

2. General Issues

CDRH may seek the panel’s expertise on complex or contested scientific issues that relate to a device type or a general topic of medical device safety and effectiveness, but not related to a particular device. For example, CDRH may request expert input in formulating recommendations for companies wishing to conduct a clinical trial of a device type, to inform the development of a guidance document, or to develop regulatory strategies to mitigate certain device risks. CDRH may also take postmarket safety issues to a panel meeting for recommendations.

What is the make-up of a medical device advisory committee panel?

Generally, Medical Device Advisory Committee panels are comprised of seven standing members, including the chair and non-voting industry, consumer, and patient representatives. All panel members, other than industry representatives (IRs), are either special or regular government employees and are subject to FDA conflict of interest regulations. A Designated Federal Officer (DFO) oversees the management and operation of each panel.

When a device is the subject of review by a panel, CDRH will ensure that adequate expertise is represented on the panel to assess the disease or condition for which the device is intended, as well as the technology of the device. Adequate expertise means that the panel includes two or more voting members with a specialty or other expertise clinically relevant to the device and at least one voting member who knows about the device’s technology. Thus, a panel may include voting or non-voting consultants with expertise to review and give recommendations on the panel topics. CDRH must give the device sponsor the chance to recommend the expertise needed by the panel’s voting members.

A list of panel members and the DFO can be reviewed by going to the device advisory committee landing page, [https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm](https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm), selecting the relevant panel on that page, and then selecting
the roster link on the panel’s landing page.

How is the integrity of the advisory committee panel program monitored?

Within CDRH, the Committee Management Branch monitors advisory committee panel integrity. Branch members determine the eligibility of all panel members (apart from IRs) for participation in advisory committee meetings. This is an intensive task that involves multiple levels of review, including assessment of potential conflicts of interest.

How does FDA manage conflicts of interest?

To protect the credibility and integrity of advisory committee advice, FDA will carefully screen advisory committee members (apart from IRs), consultants, and regular government employees for two categories of potentially disqualifying interests or relationships:

1. current financial interests that may create a recusal obligation under federal conflict of interest laws; and
2. other interests and relationships that do not create a recusal obligation under federal conflict of interest laws, but that may create the appearance that a member lacks impartiality, known as “appearance issues.”

A conflict of interest occurs when an individual selected to serve on an advisory committee panel has financial interests that may be impacted by the individual’s work on the panel. Financial conflicts involve any financial remuneration between panel members and companies whose products are discussed at a panel meeting. Examples of financial remuneration are payment of expenses for attending conferences, speaker fees, and salary or other payment for services rendered. The financial conflict may be with a company whose product is under consideration at a panel meeting, or with a competitor of that company.

Under federal conflict of interest laws, advisory committee panel members who do not have conflicts may be disqualified from participation if their interests or relationships create the appearance that the individual lacks impartiality. This appearance might exist, for example, for an advisory committee panel member who supervised research that supports a product application before the panel. FDA and the panel member must review and resolve these appearance issues before the panel meeting.

Without a waiver or equivalent authorization from FDA, a member may not participate in a panel meeting if he or she has a conflict of interest or the appearance of a conflict. The waiver or authorization usually permits the member to fully participate but, in some cases, the member may participate in the discussion but not vote. FDA applies multiple standards in determining whether to grant a waiver. These include whether the member’s participation is necessary to provide expertise to the panel and whether the need for the member’s services outweighs the potential for a conflict of interest. FDA may authorize participation of a member with an appearance issue based on its decision that the government’s interest in the member’s participation outweighs the concern that a reasonable person may question the integrity of the agency’s programs and operations.

Note that IRs are not subject to conflict of interest screening. But as discussed below, in some situations, IRs may be recused from panel meetings based on the appearance of a conflict.
What if the industry representative has a conflict of interest?

Regulations permit an IR who works for a company directly affected by an advisory committee panel deliberation to still serve on the panel and participate fully in the discussion. In these cases, it is best practice for the IR to disclose the conflict of interest at the beginning of the panel meeting. The IR may also wish to disclose relationships with consultants or other presenters to the panel.

In some cases, an IR may want to recuse himself or herself from a meeting, for example because the IR works for a direct competitor of a company whose product will be discussed. Likewise, a sponsor may request the IR’s recusal if there are concerns about conflicts of interest. The sponsor should make this request early enough to permit selection of an alternate IR for the meeting.

Who may talk to whom?

Except for the IR, FDA imposes strict rules barring private communications between advisory committee panel members and manufacturers with products under discussion at a meeting. This ensures that no panel member relies on information outside the administrative record or has, or is perceived to have, any bias in the proceedings. The rules do not apply to general or unrelated conversations.

The IR is not under any of these constraints and holds the only exemption from this policy. Sponsors should engage IRs in discussions before advisory committee panel meetings. The sponsor determines which materials are sent to the IR and provides that information to the DFO for distribution. The sponsor is not obliged to provide all material to the IR and may withhold some information. Any material that is considered confidential and is to be discussed in closed session should not be provided to the IR. The DFO should send non-confidential briefing materials to the IR, but the sponsor should also send the materials directly to the IR as soon as it learns that a relevant matter is pending consideration.

The DFO provides the IR with relevant briefing materials at the same time as other panel members, as well as the issues or questions to be discussed at the meeting. The IR should not share any briefing materials with any other entity in the IR’s company or elsewhere. The IR should consult the DFO for questions on this or related points.

Sponsors should actively engage the IR in the weeks before a panel meeting. By sharing materials and discussing relevant issues and concerns, sponsors can help the IR be an effective representative at the meeting. Many times, the IR may have additional and unique advisory panel experiences. IRs should share this experience with sponsors to help them prepare for panel meetings.

Industry members besides the sponsor with an interest in the outcome of the advisory panel are also encouraged to engage the IR before the meeting. This will help ensure that the IR is fully prepared and appropriately represents the entire medical device industry.
How do I contact the industry representative?

Sponsors and other companies affected by a pending advisory committee panel meeting should contact the DFO to get the contact information for the IR for that panel. Also, interested parties may access the following link to obtain contact information for the DFO and the industry representative:
https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm.

MEETING CONDUCT

How often are meetings held?

FDA’s Medical Devices Advisory Committee Charter provides that each advisory committee panel shall meet a minimum of once a year or as necessary at the call of the DFO. In practice, all 18 panels do not meet every year; they average 15-20 meetings per year spread across 7-10 panels.

FDA publishes annually a list of prescheduled, tentative committee meeting dates in the Federal Register, but the meeting dates are subject to change. FDA schedules advisory panel meetings 12-14 weeks in advance and IRs can check CDRH’s Advisory Committee Calendar, https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm, to learn about upcoming panel meetings. FDA updates this calendar every month.

Agency staff will advise IRs about meetings well before they are publicly announced, but IRs should not share this information before the public announcement.

Who runs the meetings?

The DFO is responsible for the meeting and develops the agenda (consulting with appropriate CDRH review staff); arranges for expert consultants to join the panel (to discuss issues and possibly vote); arranges for expert speakers to present topics before the panel; ensures that panel members receive appropriate briefing materials; and acts as liaison between FDA, panel members, affected companies, and interested members of the public. The DFO monitors the meeting to ensure it meets agency policy.

Each panel has a chair who is the presiding official at the meeting. Usually, this is a qualified voting panel member who runs the meeting and shapes its course, but occasionally an expert consultant may act as chair. The chair must follow the agenda and determine who can and cannot speak at a meeting. A panel meeting can be called to order or terminated (for cause or at its logical conclusion) by either the chair or the DFO. If the chair is excluded from participating in a matter because of a conflict of interest, the DFO will designate another voting panel member to serve as acting chair for that issue.

What happens at a meeting?

Advisory committee panel meetings occur either at FDA or a private facility (e.g., a hotel or conference center), depending on space availability and needs. All meetings are tape-recorded, with
transcripts available for purchase or through Freedom of Information Act requests. FDA also posts transcripts of panel meetings on the Agency website, along with related panel materials. Meetings may also be webcast, meaning that IR actions and statements during the meeting may be publicly visible in real time.

The meeting is called to order by the chair or, sometimes, the DFO. The first action is the reading of the Conflict of Interest statement. This indicates whether certain panel members are eligible to participate based on their conflicts of interest, and it identifies panel members who have a waiver to participate. The DFO will state for the record who can vote on matters before the panel.

The order of presentations that follows does not necessarily reflect the order of presentations at a panel meeting.

A. Medical Device Industry Presentations

Any sponsor whose device is the subject of review by a panel has the same opportunity as FDA to participate in the panel meeting. This includes – subject to the chairperson’s discretion – participating by designating a representative to correct misstatements of fact or provide clarifying information. The sponsor or the sponsor’s representative may call on experts within the sponsor’s organization to address specific issues in the time provided.

For premarket submission panel meeting presentations, an applicant will generally have 60 minutes, or up to 90 minutes if (1) the applicant submits a request and the DFO accepts that request; or (2) the CDRH presentation is scheduled for 90 minutes. Following initial presentations, the panel may pose questions to a designated representative and consider the responses in reviewing the device.

Industry presentations for regulatory issues panel meetings are encouraged. If industry stakeholders request time to speak in advance, the 60 or 90-minute presentation slots described above will generally apply. However, the timeslot for industry presentations may be divided among those who requested time to present. Industry stakeholders who wait until the day of the panel meeting to request time to speak will be allowed to speak at the discretion of the panel chair.

B. CDRH Presentation

CDRH presents necessary regulatory background and its review and assessment of the scientific and clinical information for which panel input is requested. CDRH's presentation is generally 60 minutes, but it may extend to 90 minutes depending on the complexity of the review or other issues. Following the CDRH presentation, the panel may pose questions to a CDRH presenter and consider the responses in reviewing the device.

C. Open Public Hearing

Every advisory committee panel meeting includes an open public hearing (OPH) session, during which interested persons may present relevant information or views orally or in writing. FDA regulations require a minimum of 60 minutes per meeting for an OPH session for oral presentations, unless public participation does not last that long.

Advisory committee panel members, including the IR, can question any speaker on any of the material presented. Once the formal presentations are complete, further audience input is not permitted, and the panel members discuss the issues at hand. If an affected trade or professional group has not been invited to make a formal presentation, but wishes to provide testimony for the record, it can do so by requesting
time during the open public hearing.

D. Advisory Committee Panel Deliberations and CDRH Questions

There should be about 1 hour designated for general panel deliberations. During deliberations, and before addressing the CDRH questions, the panel may require clarification or ask questions about the information presented. In such cases, CDRH and the sponsor have an equal opportunity to respond to questions. The panel may pose questions to the sponsor’s designated representative and consider the responses.

Once the general panel deliberations are complete, CDRH should ask specific questions to the panel. Additional input from interested parties, including a sponsor, should be allowed at the discretion of the panel chair. CDRH will generally request that the panel members provide their scientific opinions and recommendations without interruption.

If any confidential commercial, financial, or trade secret information is to be discussed, FDA will announce in the Federal Register, before the panel meeting, that a portion of the meeting will be held in closed session. FDA will empty the room for the closed session of all parties who are not permitted to participate, including the IR.

Before any voting, the applicant, FDA, IR, consumer representative, and patient representative should have an opportunity to present viewpoint summations.

E. Advisory Committee Panel Voting

In general, matters are considered by all voting members present; a member who leaves before the vote should not vote. All voting should occur in public view. The consumer representative, patient representative, and IR do not vote.

1. When to Vote

The formal voting process is typically used for advisory committee panel meetings involving a specific device marketing submission, i.e., premarket submission meetings. For regulatory issues meetings, the panel should be asked to discuss the issues and provide recommendations on questions asked by CDRH, but generally no formal vote will be taken.

2. Voting Procedure for Premarket Submission Panel Meetings

The voting members of a panel are typically asked to respond to three questions relating to safety, effectiveness, and benefit versus risk for devices that are the subject of a PMA application:

Voting Question 1:
Is there reasonable assurance that X device is safe for indications A (and B, etc.)?

Voting Question 2:
Is there reasonable assurance that X device is effective for indications A (and B, etc.)?
Voting Question 3:

Do the probable benefits of X device for indications A (and B, etc.) outweigh the probable risks of device X for indications A (and B, etc.)?

When other submission types are the subject of a premarket submission panel meeting, questions relevant to those submissions should be presented to the panel (e.g., for a 510(k), the panel may vote on substantial equivalence).

The voting occurs electronically and simultaneously, then the DFO reads aloud the total number of responses to each question (i.e., yes, no, abstain) before discussion.

After voting, panel members should state how they answered each question and explain their answers. The panel may discuss labeling changes, use restrictions, longer term follow-up, or other controls that may alter the benefit-risk calculus to give the applicant constructive feedback. If the evidence provided is insufficient to allow for any determinations, then the voting panel member should state this as the reason for answering “no.” A description of any remedial or mitigating studies or actions should be given.

3. Indications for Use and Voting

The Indications for Use to be voted on should be the indications described in the FDA Executive Summary in the Panel Pack. After voting, the panel may discuss whether a change in the indications could have an impact on the benefit-risk calculus. Such discussion should also include what additional pre- or postmarket data or scientific information would be needed to pursue a new indication. If the original Indications for Use receive any unfavorable votes, then the voting members of the panel should answer the following question: “If you answered ‘no’ to any question, please state whether changes to the indications, restrictions on use, or other controls, would make a difference in your answer.” A formal vote on the changes is not necessary and will not generally occur.

F. Post Meeting Activities

FDA should post a brief summary of the meeting on the Agency website no later than 2 business days after the meeting. FDA should post an official transcript of the proceedings on the website as soon as it is available, and no later than 60 days after the meeting.

The DFO prepares a meeting summary and minutes, which are available by going to the device advisory committee landing page, (https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm), selecting the relevant panel on that page, and then selecting “Past Meeting Materials.”

How are issues presented?

Generally, FDA review staff describes issues and submits them in advance to the advisory committee panel members through the DFO. Often, FDA will frame these issues as questions for the panel members to discuss (and vote on). Generally, the DFO also provides the questions to the IR (if the sponsor permits). The IR should communicate regularly with the DFO to ensure that he or she has the most recent copy of the questions.
A. **Briefing Materials for Premarket Submission Meetings**

Regardless of the submission type, CDRH intends to provide to the advisory committee members and the applicant a prepared panel package of briefing materials, referred to as the “Panel Pack,” which may include:

- FDA’s agenda;
- FDA’s executive summary;
- FDA’s draft questions for panel consideration;
- FDA’s voting questions;
- any information deemed relevant by the FDA (e.g., publications/literature); and
- applicant-provided briefing materials.

B. **Briefing Materials for Regulatory Issues Meetings**

For regulatory issues panel meetings, CDRH intends to provide to the advisory committee panel members a Panel Pack that contains:

- FDA’s agenda;
- FDA’s executive summary;
- FDA’s questions for panel consideration; and
- any information deemed relevant by the FDA (e.g., manufacturer material, such as relevant portions of a reclassification petition; publications/literature).

CDRH intends to make available on its website, no later than 2 business days in advance of a panel meeting, the publicly-available briefing information from the Panel Pack.

**What about discussions about financial matters?**

Discussion of financial matters (for example, the cost of a device, or insurance coverage for a treatment) is not under FDA's jurisdiction. Therefore, the chair and the DFO should limit any discussion of such matters during an advisory committee panel meeting.

**Who votes?**

Standing advisory committee panel members vote. Often, CDRH will invite members or consultants of other advisory committees or panels to join a panel because they have unique expertise for the meeting, and to ensure that the panel has a quorum. In these cases, the individuals may be permitted to serve as Temporary Voting Members for the duration of the meeting. IRs and consumer and patient representatives cannot vote (except on meeting minutes approval and future meeting dates); however, the chair will solicit their opinions before the vote.

While lacking voting authority, an IR can make motions on issues. For example, if the IR believes that the panel is discussing information unrelated to a device’s safety and effectiveness or outside the panel’s purview (e.g., discussions about reimbursement or off-label use), then the IR may move that the information not be considered by the panel members when they vote.
STANDING ADVISORY COMMITTEE MEMBERS

FDA publishes Federal Register announcements for vacancies on advisory committees that are expected for the following 12 months. Anyone may nominate himself or herself or another individual for committee membership. FDA may also identify candidates during discussions with the current chair and members of the affected committees. FDA may also contact professional, scientific, and trade associations to solicit nominations, or solicit nominations indirectly through notices in journals.

Individuals may not serve simultaneously on more than one advisory committee, and they may not serve for more than four continuous years on a specific advisory committee. Individuals may not serve more than 8 combined years during a 12-year period. These restrictions may be waived by FDA in exceptional circumstances.

Appointments to an advisory committee are usually for a four-year term. Extensions beyond a four-year term must be requested and are not routinely granted. Members are special government employees (SGEs) and they sign confidentiality agreements that permit them to see confidential documents for advisory committee meetings. A standing member on one committee or panel may be called upon to serve as a consultant on another committee or panel if their expertise is needed.

A member may resign or be terminated before the expiration of his or her term. Reasons for termination include: failure to adhere to conflict of interest requirements; failure to attend regularly-scheduled meetings; failure to submit necessary paperwork; demonstrated bias in rendering advice; and a change in an employment or a professional affiliation that was considered important for the initial appointment.

THE INDUSTRY REPRESENTATIVE

How are industry representatives nominated?

FDA periodically publishes a notice in the Federal Register requesting nominations for certain panels of the Medical Devices Advisory Committee for which a nonvoting IR is to be appointed. Nominations are accepted for current and upcoming vacancies effective with the notice. A 30-day period is provided for submission of nominations for each panel listed in the notice. Information about vacancies is also available at:

https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/CommitteeMembership/AdvisoryCommitteeVacancies/default.htm

Any interested party (person, group, company) can nominate themselves or a colleague, provided that the nominated person or entity agrees with the nomination. The Federal Register notice specifies what information is needed to submit a nomination, which at minimum includes a nomination letter, the candidate's current curriculum vitae, and his or her work address and telephone number. Candidates should have appropriate industry experience and knowledge of FDA regulations.
How does an industry representative get selected?

FDA will forward all nominations to individuals who submitted a nomination and to organizations expressing interest in participating in the selection process for the panel. The nominators are asked to consult with each other to identify a consensus candidate. Individuals who nominate themselves may not participate in this selection process. The nominators must submit the name of the consensus nominee within 60 days of receiving the list. If no consensus is reached, then FDA will make the selection. The IR is generally not an SGE and cannot participate in closed committee deliberations of confidential materials.

Upon official notification that he or she has been selected, the new IR should request from the DFO a current list of all panel members and their affiliations. The new IR also should contact the previous IR (address and telephone number should be provided by the DFO) and hold a transition meeting or conference call. The previous IR should brief the IR on recent issues that have been presented to the panel and answer questions and offer suggestions about how the new IR can be most effective in his or her role on the panel.

AdvaMed hosts working groups and product sectors whose work covers topics that may be relevant to advisory panel meetings. We recommend that the IRs request an introductory meeting with relevant working groups and product sectors after selection and before panel meetings. IRs can contact Steve Silverman, Vice President for Technology & Regulatory Affairs, ssilverman@advamed.org, to arrange these introductory and follow-on meetings.

What is the industry representative’s term?

IRs are appointed to a term not to exceed four years. If appointed to fill an unexpected vacancy due to retirement or otherwise, the newly appointed IR serves only the remaining part of the four-year term.

Whom does the industry representative represent?

Even when a specific manufacturer's product is the subject of an advisory committee panel meeting, an IR must represent all of regulated industry. The advice and comments offered by the IR during a panel discussion should reflect this industry-wide perspective. In addition, the IR should watch for specific recommendations that may have industry-wide implications. Where the benefit to one manufacturer does not coincide with the best interests of all, the IR’s role is to best represent the views of the entire regulated industry.

What is the industry representative's role and responsibility in the proceedings?

The IR ensures that the discussion, advisory committee panel recommendations, and any potential requirements that arise out of the proceedings are based on what is needed to show device safety and effectiveness; are related specifically to the issues under discussion at the meeting; and satisfy FDA's statutory authority and regulations.

The IR can help by ensuring that he or she has the latest version of the issues and questions that the panel will consider. The IR can track the discussion to ensure that votes are taken on all needed
issues, as discussions sometimes can move to a new subject without closure of the previous one. The IR also can highlight points of agreement and areas needing further discussion.

To be effective, the IR should communicate regularly with the DFO, who is the key FDA contact on panel-specific matters, and with all manufacturers whose products or issues come before the panel. The IR also must understand FDA laws, regulations and policies, as he or she may be the only voice on the panel with that expertise. The IR can help to ensure that the panel members clearly understand the regulatory threshold for reasonable assurance of safety and effectiveness. The IR can do this by explaining the following concepts:

- There is reasonable assurance that a device is safe when it can be determined that the probable benefits to health outweigh the probable risks. Considerations related to this standard include valid scientific evidence and proper labeling, and recognition that safety data may be generated in the laboratory, in animals, or in humans.

- There is reasonable assurance that a device is effective when it can be determined, based on valid scientific evidence, that the device provides a clinically significant result in a significant portion of the target population. Labeling – in the form of adequate directions for use and warnings against unsafe use – is important to this determination.

- Valid scientific evidence consists not only of well-controlled investigations, but also partially-controlled studies, studies and objective trials without matched controls, well-documented case histories, and reports of significant human experience with a marketed device. While a well-controlled investigation may be the highest order of evidence, the IR can remind the panel that other types of valid scientific evidence may provide a reasonable assurance of safety and effectiveness.

Sometimes, panel members may try to interject personal preferences or beliefs about how to treat patients into final panel recommendations. IRs should be ready to educate panel members about what is scientifically and technically possible (from an industry perspective) regarding matters under discussion.

Panel members may also criticize a manufacturer’s performance of a clinical study or offer wrong interpretations of applicable regulatory standards. The IR can assist the manufacturer by asking FDA to explain why staff recommended a study design and to explain other relevant instructions that the sponsor received. The IR can also ask the chair or FDA staff to remind the panel of the correct regulatory standard for the panel’s recommendation. In consultation with the sponsor, the IR can assist by asking questions of FDA staff that the sponsor might be reluctant to ask (e.g., because of concerns about biasing the outcome of the deliberations).

IRs can also be effective by asking the sponsor to clarify salient points that might otherwise get lost in the discussion; referencing typical clinical studies conducted for similar device types in the same medical specialty area (particularly regarding acceptable length of follow-up, clinical endpoints, and other relevant factors); reiterating postmarket requirements that PMA sponsors must meet after approval of the PMA (such as postmarket clinical follow-up studies); identifying questions better suited for postmarket instead of premarket studies; and discussing quality system requirements.
What training is available for new industry representatives?

Before an advisory committee panel meeting, CDRH provides an electronic training to new members, consultants, and IRs who are attending their first meeting. The training covers: the composition and function of Medical Device Advisory Committee panels; medical device law and pathways to market; panel membership, roles and responsibilities; and panel meeting overview and procedures.

While not mandatory for IRs, they are encouraged to take the training.

Depending on the complexity of the regulatory issues being discussed, CDRH may AdvaMed (including any non-voting industry, consumer, or patient representatives). This training could include discussion of general regulatory and statutory terminology and the applicability of CDRH regulations to the meeting topic. Any pre-meeting training should provide general background and should not include information specific to any devices discussed at the panel meeting. The panel should not deliberate on any material brought before the panel during pre-meeting training, nor provide any advice to CDRH on the training materials. Subject to FOIA, the training materials should be made available for public disclosure. IRs should attend all such pre-meeting training sessions so that they can join discussions that would benefit from an industry perspective.

How is confidential information handled?

Materials sent to the IR should be treated as confidential, unless otherwise specified, and the IR must protect them. This includes storing the materials in a secure place to prevent others accessing them. In addition, the IR may not discuss the materials, except for conversations with the sponsor and as allowed during the panel meeting.

After the meeting, the IR must return advisory committee panel materials to FDA. If the IR is unable to attend the meeting, he or she must return the materials by mail or by destroying them, such as by shredding or burning. Disposition must be confirmed by email sent to the DFO.

THE CONSUMER REPRESENTATIVE

How is a consumer representative (CR) selected?

FDA issues a Federal Register notice listing all CR vacancies. FDA provides at least 3 CR nominees for each vacancy. Consumer groups participating in the selection process review and rank the candidates, then FDA takes the top-rated candidate for each vacancy.

As with other panel members, the term of office for a CR is four years.

What is the CR’s role?

The CR represents the consumer perspective on issues and actions before the advisory
committee; serves as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitates dialogue with the advisory committees on scientific issues that affect consumers. The CR is a special government employee.

Do CRs get to vote?

CRs do not vote on medical device marketing applications.

THE PATIENT REPRESENTATIVE

How is a patient representative (PR) selected?

The PR Program is managed by the Advisory Committee Oversight and Management Staff within the Office of the Commissioner. PRs serve as the patient’s “voice,” and they typically have direct experience – as patients, primary caregivers, or member of a patient advocacy organization – with particular diseases. This may mean that a PR serves in connection with specific advisory committee meeting topics. The PR is a special government employee.

What is the PR’s role?

The PR provides the unique perspective of patients and family members who are affected by the issues and actions before the advisory committee, asks questions, and give comments to assist the committee in making recommendations. PR roles can include: (1) participating in discussions between FDA and a company that is developing a new product; and (2) as a participant in an advisory committee meeting reviewing a medical product or public health policy.

Do PRs get to vote?

PRs do not vote on medical device marketing applications.³

³ PRs who serve on advisory committees that review drug and biologic therapies are usually voting members.
ADDITIONAL INFORMATION SOURCES

1. 21 CFR 14: Public Hearing before a Public Advisory Committee
2. Medical Devices Advisory Committee, Information and Materials: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/default.htm
SUMMARY OF KEY POINTS

- Information about FDA’s Medical Devices Advisory Committee is available at: https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm.

- FDA may refer a matter to an advisory committee panel for:
  - Advice on a premarket submission – FDA may take any type of device premarket submission to panel; or
  - Regulatory issues – FDA may refer a matter to a panel for advice on regulatory actions or to discuss general scientific matters.

- Upon notification of selection, the IR should request from the DFO a current list of all advisory committee panel members and their affiliations.
  - The new IR should also contact the previous IR to arrange a transition meeting.
  - The new IR should hold an introductory meeting with relevant AdvaMed working groups and product sectors, and additional meetings before panel sessions relevant to those working groups and product sectors.

- The IR must represent the concerns of all industry stakeholders and not one particular entity.

- The IR can contact the sponsor and vice-versa on matters to be presented to the panel.
  - The IR should speak early and frequently with sponsors that have an interest in advisory committee panel deliberations.
  - The panel's DFO should facilitate communications between the IR and the sponsor.

- A sponsor can request that an IR be recused from an advisory committee panel meeting because of conflict of interest concerns. This must be done early to enable FDA to recruit a substitute IR for that meeting.

- To the extent possible, sponsors should share all briefing materials with IRs. Sponsors choose which briefing materials to send to the IR and may choose not to share all materials.

- Although the IR does not vote on any issue, he or she can contribute to the discussion and submit motions for voting.
  - During the advisory committee panel meeting, the IR can question any speaker on any of the materials presented.
  - Before any voting, the IR has an opportunity to present viewpoint summations.
  - The IR is often the only advisory committee panel member with expertise in FDA law, regulations, and policy. The IR should monitor the discussion and recommendations to ensure that they are based on what is needed to show device safety and effectiveness; are related specifically to the issues under discussion at the meeting; and satisfy FDA's statutory authority and regulations.
# Attachment 1
## CDRH Device Advisory Committees and Panels

**Medical Devices Advisory Committee Panels:**

- (AN) Anesthesiology and Respiratory Therapy Devices Panel
- (CV) Circulatory System Devices Panel
- (CH) Clinical Chemistry and Clinical Toxicology Devices Panel
- (DE) Dental Products Panel
- (DR) Medical Devices Dispute Resolution Panel
- (EN) Ear, Nose, and Throat Devices Panel
- (GU) Gastroenterology and Urology Devices Panel
- (SU) General and Plastic Surgery Devices Panel
- (HO) General Hospital and Personal Use Devices Panel
- (HE) Hematology and Pathology Devices Panel
- (IM) Immunology Devices Panel
- (MI) Microbiology Devices Panel
- (CG) Molecular and Clinical Genetics Panel
- (NE) Neurological Devices Panel
- (OB) Obstetrics and Gynecology Devices Panel
- (OP) Ophthalmic Devices Panel
- (OR) Orthopaedic and Rehabilitation Devices Panel
- (RA) Radiological Devices Panel

**Additional Device Committees:**

- (GM) Device Good Manufacturing Practice Advisory Committee
- (MA) National Mammography Quality Assurance Advisory Committee
- (TE) Technical Electronic Product Radiation Safety Standards Committee
- (PEAC) Patient Engagement Advisory Committee