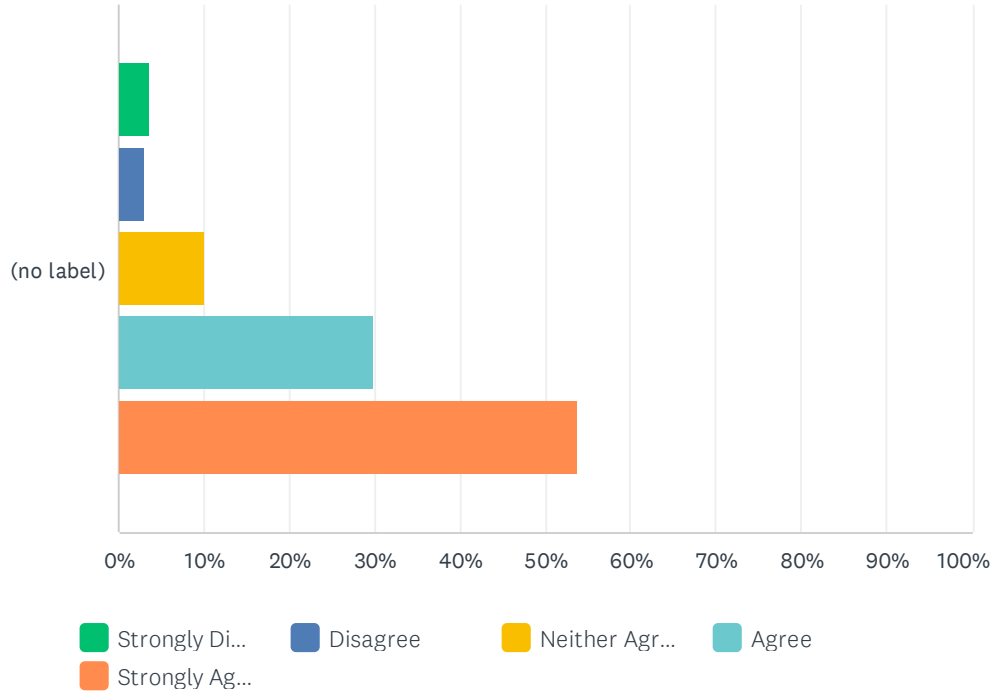
Q1 FDA should include subject matter experts (SME) who are treating physicians with therapeutic expertise as voting members at advisory committee meetings.

Answered: 413 Skipped: 1



	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
(no label)	3.63% 15	2.91% 12	9.93% 41	29.78% 123	53.75% 222	413	4.27

#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	These advisory committees also need to include one or more biostatisticians with clinical trials expertise.	7/23/2024 12:45 PM
2	SME are valuabe to have but no matter how many forms completed, there is inherent bias in their work.	7/21/2024 11:44 PM
3	not all experts should be based in academic institutions	7/19/2024 12:44 AM
4	However, there need to be constraints which keep these individuals arm’s length as if too close to the agency, they could be a tool to advance agendas.	7/18/2024 7:17 AM
5	voting members should be qualified to evaluate (from a scientific and public health perspective) the risk/benefit tradeoff in the specific disease/indication setting. These are often includes such treating physicians, although it is not necessarily the case.	7/17/2024 9:12 PM
6	I also strongly believe that nurses who have "treatment-related" expertise should also be voting members	7/17/2024 7:09 PM
7	While I believe they would provide very important perspectives from a clinical perspective, I would be somewhat concerned about being a voting member without the experience and background that comes with standing members	7/17/2024 6:00 PM

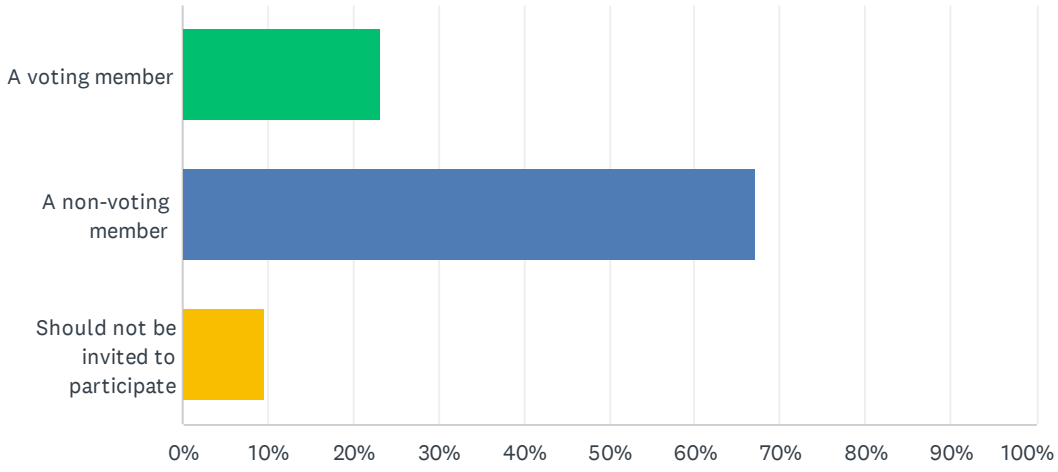
8	These experts are caring for the patients and know the challenges more than most would assume	7/17/2024 5:44 PM
9	FDA should also include SMEs who are not treating-physicians. This includes other MDs, PhDs, and other doctoral level personnel (e.g., PharmDs)	7/17/2024 5:33 PM
10	Would provide additional expertise to the committee.	7/17/2024 4:45 PM
11	There should also be other healthcare providers and scientists/engineers with relevant expertise.	7/17/2024 2:55 PM
12	In some contexts this can be good, but not always. "Experts" with N of 1 experiences are only of limited value	7/17/2024 2:23 PM
13	There should sldo be some voting members who are not treating physicians	7/17/2024 1:53 PM
14	This is too general a statement. The need/value of this expertise depends on the specifics of the topic/setting.	7/17/2024 1:34 PM
15	FDA should include physicians or PhDs who have the expertise needed and who do not have relevant COIs	7/17/2024 1:13 PM
16	Providers without practical experience may not be able to provide the most appropriate input	7/17/2024 12:48 PM
17	SMEs maybe other caregivers than Physcians and should be included on voting	7/17/2024 11:52 AM
18	Sometimes PhDs are needed in advisory committee meetings. Physicians should participate of course, but sometimes you need PhD expertise.	7/17/2024 11:08 AM
19	It is important to have a broad range of expertise on the panel - including experienced clinicians, safety experts, statisticians and informed patients and	7/17/2024 11:01 AM
20	This should include the patient rep who is well-versed in the disease and treatment landscape	7/17/2024 10:53 AM
21	some committees lack the right expertise	7/17/2024 10:29 AM
22	Only if they have research experience	7/17/2024 10:17 AM
23	Been on lots of FDA AdComms. Difficult to find non-conflicted people and most non-conflicted do not understand the science/issues.	7/17/2024 10:01 AM
24	They could be "treating physicians" or SMEs who conduct research relevant to the topic being discussed.	7/16/2024 11:41 PM
25	SHould include but not ALL members need to be treating physicians	7/16/2024 11:03 PM
26	It depends on the subject and the Advisory Committee	7/16/2024 12:40 PM
27	These experts bring very practical experience to the meeting. When integrated with permanent members and under the management of a strong chair, they are a strong addition.	7/15/2024 6:04 PM
28	Yes but not only physicians with therapeutic expertise. Others can add valuable opinions.	7/15/2024 5:27 PM
29	Benefits - treating providers know the disease. Risks - treating providers not focused on drug risk or safety	7/15/2024 3:31 PM
30	It is essential to have input from practicing physician's input.	7/14/2024 8:21 PM
31	As long as there is no conflict of interet.	7/14/2024 9:33 AM
32	Can provide results (neg or pos) with treatments prescribed to their clients. Must not have any coflicts with matter being voted on (speaker for drug/treatment, not a share-holder, etc.)	7/13/2024 10:51 AM
33	It has been my experience that this category of person has always been present.	7/13/2024 8:56 AM
34	Yes, we need to have active clinicians in the field who are treating patients on a regular basis. From my perspective, we have too many people involved in advisory committees who are not actively involved inpatient care, but are making decisions in that realm.	7/12/2024 4:37 PM
35	ODAC already does this from my experience	7/12/2024 3:12 PM
36	Some treating physicians	7/12/2024 3:05 PM

37	but limit this to 1-2 per meeting (But SME cannot have financial ties w/ sponsor)	7/12/2024 1:42 PM
38	In my session as an ad hoc member of a broad DAC, I found myself as one of the only voting members with clinical content expertise.	7/12/2024 12:29 PM
39	Though I definitely think that SME's should not be the sole voting members--it's critical that non-SME's who are on the core committee also vote, because they have no "skin in the game."	7/12/2024 12:14 PM
40	SMEs are there to inform the committee	7/12/2024 12:00 PM
41	I think this could be a positive but not necessary. Any treating physician is likely to bring their own perspective and bias, but wider academic reviews are usually more beneficial.	7/12/2024 11:47 AM
42	ideally with some analytic expertise	7/12/2024 11:35 AM
43	treating physicians as well as scientists for a balanced group	7/12/2024 11:06 AM
44	SME provide unique considerations unknown to other ad committee members	7/12/2024 10:27 AM
45	When appropriate to the topic	7/12/2024 9:47 AM
46	To clarify, I mean treating oncologists broadly regardless of disease type. I don't believe it should be 12 thoracic oncologists for a lung cancer drug.	7/12/2024 9:29 AM
47	Not at the expense of statistician/epidemiologists	7/12/2024 3:54 AM
48	There should be a mix but practice physician experience is important	7/11/2024 10:53 PM
49	I think that past and/or present experience is sufficient.	7/11/2024 10:15 PM
50	Physician perspective not really necessary for the particular committee on which I served.	7/11/2024 9:25 PM
51	This question assumes FDA actually cares what the panel vote outcome is.	7/11/2024 9:17 PM
52	SMEs should not have to be physicians. Other disciplines may be better informed.	7/11/2024 8:04 PM
53	This must also apply to non-physican members (ParmD, laboratory scientists, etc)	7/11/2024 6:50 PM
54	ODAC members in different disease areas may not understand the landscape of other, especially uncommon, diseases.	7/11/2024 6:26 PM
55	Should have representation from multiple fields. Ie if a chemo drug, to include surgical and radiation oncologists as well. Medical oncologists may be biased if they are all giving specific chemo, then there is no balance views	7/11/2024 6:15 PM
56	With expert recognition by peers with equally recognizable publication record (h index or other)	7/11/2024 6:07 PM
57	Just need to ensure no bias or COI	7/11/2024 6:00 PM
58	although including only those physicians with research experience or expertise.	7/11/2024 5:52 PM
59	Also helpful to have outside experts in statistics not from FDA.	7/11/2024 5:48 PM
60	It depends on the questions/topics of discussion.	7/11/2024 5:24 PM
61	They should be thoroughly vetted for conflict and they should have an active practice (preferably also conducting research in the area).	7/11/2024 5:19 PM
62	The data to be reviewed are the most important thing; the value of the treating clinician is in the risk benefit evaluation and should be encompassed by clinician voting members already	7/11/2024 5:17 PM
63	But not all members need to be treating physicians	7/11/2024 5:11 PM
64	Generally SME are patients / families affected so might as critical to include a well informed patient.	7/11/2024 5:10 PM
65	Depends on the topic	7/11/2024 5:07 PM
66	Assume it is not restricted but also includes others such as biostatisticians, nurses etc as warranted.	7/11/2024 5:03 PM
67	They already do	7/11/2024 5:00 PM

68	Physians are not the only content experts and may not have the expertise	7/11/2024 4:59 PM
69	Also must include a knowledgeable biostatistician	7/11/2024 4:50 PM
70	In general active physicians bring value, but they must also have requisite background knowledge of the process of an advisory board and of domains (stats, clinical trial theory, regulatory science) that are critical to weigh in on policy. A danger is over reliance on a single voice that represents all clinicians, as practice sites and patient populations may vary.	7/11/2024 4:49 PM
71	They provide an important perspective.	7/11/2024 4:36 PM
72	They are important but need other expertise.	7/11/2024 4:35 PM
73	not necessarily physicians, but relevant health care provider who is SME	7/11/2024 4:33 PM
74	They should be invited to provide expertise but the voting should be limited to the panel members	7/11/2024 4:31 PM
75	when i was on a committee, i was a practicing physician with drug safety expertise.	7/11/2024 4:23 PM
76	As long as they are not conflicted	7/11/2024 4:20 PM
77	this should be a rigorous process with a thorough review of conflicts the same. as for panel members. the danger is is that the bias sees of pro or anti-sentiment would land on his advisory committees if they're being picked on an ad hoc basis rather than using a consistent membership	7/11/2024 4:13 PM
78	It depends on the question, of course, but therapeutics is central to FDA's mission and practitioners often have important experience to bring to the discussion.	7/11/2024 4:03 PM
79	In addition, need members who understand clinical trials and postmarketing studies	7/11/2024 4:02 PM
80	sometimes non-physicians who are subject matter experts are also qualified based on their expertise	7/11/2024 3:56 PM
81	My experience has been that they do this routinely, I was one of such members	7/11/2024 3:51 PM
82	dfdgfdsgsdfsd	7/10/2024 12:11 PM

Q2 In some cases, subject matter experts (SMEs) with no conflicts of interest (COIs) can be difficult to recruit for advisory committee meetings (e.g., in rare disease settings). For an SME who has a COI that is fully disclosed, what do you think would be an appropriate role for them at an advisory committee meeting?

Answered: 406 Skipped: 8



ANSWER CHOICES	RESPONSES	
A voting member	23.15%	94
A non-voting member	67.24%	273
Should not be invited to participate	9.61%	39
TOTAL		406

#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	This depends on the nature of the COI and the ability to identify other experts having lesser levels of COI	7/23/2024 12:45 PM
2	SME is very important to committee members	7/21/2024 11:44 PM
3	Depending on the matter and the extent of their COI they could even be considered as voting members.	7/21/2024 4:16 PM
4	The information is needed, and the committee and other medical experts have the job of discerning if there is any manifest COI...	7/20/2024 11:02 AM
5	Depends upon nature of conflict	7/18/2024 1:50 PM
6	I have concerns if COI but it is also dependent on the COI	7/18/2024 12:30 PM
7	Under no circumstance can they vote and probably shouldn't be allowed to participate	7/18/2024 7:17 AM
8	I'm torn -- If included as a voting member the COI must be sufficiently managed soas to avoid the appearance of biasing the committee's deliberations.e of bias	7/17/2024 9:12 PM
9	The nature of the conflict could be considered and if determined not to be in direct conflict, the	7/17/2024 9:05 PM

	SME participation could be considered on a case-by-case basis. If the is a direct commercial or competing research conflict, but the individual's expertise is essential to the panel, then this person could serve as a non voting participant	
10	The perspective and experience of a SME with conflicts should have input that can be shared with other voting members	7/17/2024 8:14 PM
11	I think at least having them involved in the conversation would be valuable. COIs, as long as disclosed, should not be an absolute contraindication to participation	7/17/2024 8:08 PM
12	It might be more important to assess what the actual COI is -- is there a financial conflict? Or other -	7/17/2024 7:09 PM
13	I think would entirely depend upon the nature of the COI - e.g. past, current, financial, etc - in some cases, would not recommend inviting them to participate	7/17/2024 6:00 PM
14	this could depend on the type of conflict	7/17/2024 4:41 PM
15	I would consider a meeting structure that allows presentation, but includes a closed session of voting members for confidential discussion	7/17/2024 3:46 PM
16	If there is a clear conflict, they should only be advisory.	7/17/2024 2:55 PM
17	Like many conlict of interest related issues, it depends on the nature of the conflict and on how confident we can be of a fair and impartial vote by the individual	7/17/2024 2:05 PM
18	Non-voting members have virtually the same impact as voting members, but this is a way of mitigating concerns regarding COI.	7/17/2024 1:34 PM
19	Most academic physicians, if they are being fully transparent, received funding for research, external community programming or personal consulting. If I applied for a community programming support, or research funding via grantsmanship, this should NOT be a prohibition	7/17/2024 12:48 PM
20	public comments are permitted and these can be from individuals with COI that would be disclosed	7/17/2024 12:33 PM
21	If the SME offers an attestation that there is not a conflict either real or perceived, the SME should be granted voting priveldges	7/17/2024 11:52 AM
22	This should depend on the nature of the COI. A person with an immediate financial, intellectual, or a longstanding or strong personal or contractual relationship should not participate	7/17/2024 11:39 AM
23	Voting membership may be appropriate depending on the nature of the conflict of interest.	7/17/2024 11:02 AM
24	It is so important to have clinical expertise on the panel that having an expert with declared conflicts is acceptable	7/17/2024 11:01 AM
25	Especially in rare diseases this is important to retain	7/17/2024 10:53 AM
26	Could be a non-voting member or a person who offers expertise in the area but would be excused for particular aspects of the discussion and meeting. Often these people are the right ones to provide the best information and that may be why they have COIs - they are the ones who are developing the products due to their expertise.	7/17/2024 10:49 AM
27	At some level it would depend on the amount of conflict involved	7/17/2024 10:39 AM
28	This really depends on the nature of the conflict, the rarity of the disease and magnitude of expertise	7/17/2024 10:39 AM
29	Depends entirely on conflict	7/17/2024 10:35 AM
30	Voting/non-voting depends on significance of conflict and perception.	7/17/2024 10:01 AM
31	Their insights are valuable, but the general public might not understand the COI rules--hence non-voting.	7/16/2024 11:41 PM
32	IMportant to have experts who are knowledgeable	7/16/2024 11:03 PM
33	The purest approach to this would be to include them as a non-voting member but I think that if the COI is fully disclosed, then those individuals would be better as voting members who know the issues rather than someone who is not a SME.	7/16/2024 7:29 PM

34	This depends on the nature of the conflict of interest, e.g. distinguishing the case of owning some stock in a pharmaceutical company from sitting on the board of that company.	7/16/2024 10:28 AM
35	It depends on the extent of the conflict of interest.	7/15/2024 8:30 PM
36	With a clear COI disclosed, their input reflects a likely strong bias. Still, the input could be valuable but I would recommend no ability of vote to these members with COI.	7/15/2024 6:04 PM
37	So long as conflicts noted they should be able to serve	7/15/2024 3:31 PM
38	Of course depends on what the conflict is	7/15/2024 11:56 AM
39	it depends on the situation if there is a very rare condition but I believe most situations can be reviewed by members of the advisory committee if the appropriate information is given.	7/15/2024 10:03 AM
40	Even though they disclose their relationship, voting should probably be avoided. Having them be able to provide expertise to the committee may still be very helpful so long as their testimony is base in evidence.	7/15/2024 9:29 AM
41	Answer based on the clarification that all COIs are "fulled disclosed"	7/15/2024 9:18 AM
42	COI should be explained at the beginning of session	7/14/2024 12:11 PM
43	I think their expertise is valuable but I do not think they should be able to vote.	7/14/2024 9:33 AM
44	Every effort should be made to identify SMEs without conflicts or without significant conflicts	7/14/2024 6:41 AM
45	whether impartial or not, the optics of including persons with COI in decision making that can have tremendous financial implications would not be advised. they can present during the public portion if desired	7/13/2024 11:35 PM
46	Discretion of the committee organizer	7/13/2024 6:53 PM
47	The nature of a conflict of interest can vary considerably. If the SME doesn't stand to gain financially, then that person could ve a voting member. If there are no SME as voting members, then SMEs with a financial conflict should still serve as non-voting members.	7/13/2024 4:17 PM
48	Advisory members can inquire about treatments and whether met standards of care, etc. which would affect efficacy of drug/treatment	7/13/2024 10:51 AM
49	This is obviously a difficult issue in the realm of rare disease interventions. A strong voice of a (biased) investigator can swing the whole committee, sometimes inappropriately. If usual COI restrictions are waived it should be done only rarely, and these people should not be allowed to vote.	7/13/2024 8:56 AM
50	Many of the best experts have conflicts of interest because the best are asked by pharma to consult. I think it is good to continue the exchange between experts and pharma. Personally I would draw the line to exclude people who had patents or stock/stock options in companies directly involved in the product or those who received above a certain amount annually from any given pharmaceutical company--maybe more than $20,000? And of course everything needs to be declared.	7/12/2024 8:58 PM
51	The risk is the bias the cmte member with the fully disclosed COI can impart and unduly influence the committee. Having them as a non-voting member would allow them to share their expertise yet not directly affect the vote.	7/12/2024 8:00 PM
52	From my perspective, there are a variety of COIs. Some are minor, some are major. It is very hard to get excellent experts, who have no conflict. Even then, many people have their own bias. I think it's reasonable to have these people as non-voting members, and they should be encouraged to mention their possible COI when they are offering perspectives and opinions.	7/12/2024 4:37 PM
53	As long as it is fully disclosed this should be fine. It is insulting to think that medical experts can't separate their involvement in a study (for example) and the objective utility of a drug to treat other patients with a rare disease.	7/12/2024 3:57 PM
54	depending on nature of conflict	7/12/2024 3:05 PM
55	Not all with COI should be allowed to be a voting member. I think that people who do consulty, Ad board meetings, give talks etc on behalf of companies should NOT be allowed to vote.	7/12/2024 2:46 PM
56	The degree of COI should be assessed prior to recruitment as a voting member.	7/12/2024 2:39 PM

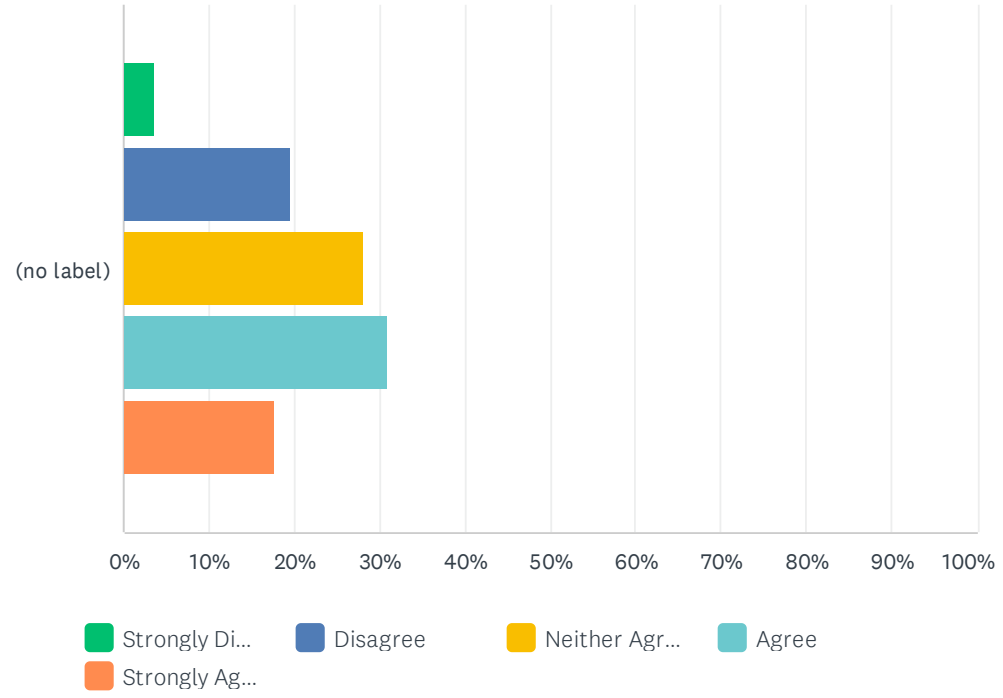
57	They may still have some important information to discuss	7/12/2024 2:08 PM
58	I guess I would challenge the FDA to do a better job of finding SMEs with no conflicts of interest. I think having people in these committees with conflicts is highly problematic. It's a very bad look.	7/12/2024 12:56 PM
59	The COI should be vetted and graded as to relevance to the topic being voted upon. The assignment to voting or non-voting membership could then be decided.	7/12/2024 12:29 PM
60	depending on the degree of COI	7/12/2024 12:08 PM
61	As long as COI are disclosed, the committee can take that into account.	7/12/2024 12:00 PM
62	provide clarification information only	7/12/2024 11:38 AM
63	HOwever, the conflicts should be reviewed by the agency before the meeting and this would require a judgement	7/12/2024 11:37 AM
64	The potential COI needs to be fully evaluated in the context of the the topic[s] of the topics being evaluated by the FDA; if significant the SME should be a non-voting member..	7/12/2024 11:22 AM
65	A SME with a COI can be present prior to the voting to provide their opinion regarding their area of expertise and then be asked to recuse themselves when the vote is taken.	7/12/2024 11:10 AM
66	in specific situations - e.g., rare diseases, can provide their perspective to the group without voting and with full disclosure.	7/12/2024 11:06 AM
67	Conflicts are very liberally considered, hence I believe that those with "conflicts" are often unnecessarily excluded. They can be recused from voting, but their opinion is often helpful.	7/12/2024 9:54 AM
68	It depends on the COI. If the SME has received institutional grant support, I would not consider that a disqualifying conflict. But, if they have equity in a company or receive personal payments from the company for consulting or advisory boards, I would consider that a conflict unless the amounts are relatively small (less than a few thousand dollars).	7/12/2024 9:42 AM
69	if they have a COI they can recuse themselves	7/12/2024 9:08 AM
70	There is no way to answer this question properly without knowing the nature of the conflict of interest.	7/12/2024 8:49 AM
71	no more than two per committee	7/12/2024 7:34 AM
72	While the COI should limit voting on approval, if there are not relevant SMEs without COI, having them present but not voting would be helpful to committee deliberation process.	7/12/2024 7:28 AM
73	Depends on the nature of the conflict	7/12/2024 3:54 AM
74	There is always a concern that a physician with a COI is corrupted but the are often the physician with the most knowledge and experience with the product and most times honest about that experience which is better than someone who has never used the product.	7/11/2024 10:53 PM
75	This would allow for their commentary, but avoid the issue of COI and voting.	7/11/2024 10:15 PM
76	depends on the nature of COI; if a major stakeholder in a competing therapeutic agent, should not be invited. If the COI of ownership of a few thousand dollars worth of stock, non-voting or even voting member may be appropriate (<$50k I think would be permissible ; >$500k would be problematic).	7/11/2024 9:48 PM
77	The FDA has process to allow voting members with a COI to vote. When I was chair of the AC for the PCNS, we had members who had conflicts.	7/11/2024 9:28 PM
78	All the expertise available should be on the panel, with COI disclosed, whether or not FDA follows or cares about the outcome.	7/11/2024 9:17 PM
79	It really depends on the COI. If it is a significant COI, they should not participate at all since that could bias the discussion and would certainly give the impression of being a problem. If it is a minor COI, then they could participate as a non-voting members. Those with a COI should not vote.	7/11/2024 8:44 PM
80	There may also be times when the conflict is direct enough they can only be a non voting member	7/11/2024 6:47 PM

81	Depends on the nature of the conflict	7/11/2024 6:39 PM
82	On a case by case basis, as not every COI is the same.	7/11/2024 6:37 PM
83	I think would depend on the exact COI, but for example someone who was just on a clinical trial, etc. as long as this is disclosed is reasonable from my standpoint.	7/11/2024 6:26 PM
84	If there are no other experts available.	7/11/2024 6:19 PM
85	Only for rare diseases. Otherwise I don't think a COI , even if disclosed, is appropriate	7/11/2024 6:15 PM
86	Unless you can create a process to ensure someone with COI will have no bias, I think having them as non-voting member is good. That person should have a platform to speak and the voting members can then use this information along with their own intelligence to take into account the specialists point of view without the conflict. Basically the voting member would have to be able to weed out the bias. This might mean special training for the voting member to teach them how to see through the bias	7/11/2024 6:00 PM
87	Depends on what the conflict is and how substantial it is.	7/11/2024 5:58 PM
88	Many or most physicians with real expertise have some COIs	7/11/2024 5:52 PM
89	With full disclosure of COI to the Advisory Committee	7/11/2024 5:31 PM
90	if conflict only as PI of competing study product would be ok; would exclude those with paid consultancy/speaker/boards	7/11/2024 5:29 PM
91	They can add a lot of value to the discussion but not vote.	7/11/2024 5:24 PM
92	As long as COI is clearly declared and there are limited alternatives	7/11/2024 5:22 PM
93	I understand the challenge particularly for some narrow indications, orphan conditions and devices. It is not possible to avoid all conflicts. Maybe the middle ground is to not allow them to vote.	7/11/2024 5:19 PM
94	It really depends on how serious the conflict is. Very serious; don't invite. Moderately: non-voting	7/11/2024 5:11 PM
95	consider establishing a 2nd voting tier with SMEs with COIs, or a weighted system with lower weight for them	7/11/2024 5:09 PM
96	The expertise should be considered and if there is a clear COI, they should not be able to vote, even if disclosed fully	7/11/2024 5:04 PM
97	though exclusion may be preferable if COI present there likely would need to be exceptions e.g. for rare disease settingsfor	7/11/2024 5:03 PM
98	If the COI is financial, they should not be included	7/11/2024 5:00 PM
99	A non voting member to add to deliberations only in cases of conflict	7/11/2024 4:59 PM
100	I think the current protocol of disclosure and selling of equity that may be in conflict is an appropriate action	7/11/2024 4:52 PM
101	A potential conflict is a potential issue that can be easily made public. An underqualified board member is more of a danger, and one much less immediately visible to the public.	7/11/2024 4:49 PM
102	We nee dot learn top deal with COI rather than avoid it. Also the rules are much stringent than other parts of the government and those for other officials.	7/11/2024 4:44 PM
103	I disagree that the FDA can NOT find SME with no conflicts of interest. We have provided a list before to FDA.	7/11/2024 4:44 PM
104	Physician only when no nonconflicted MDs available.	7/11/2024 4:38 PM
105	Given the stakes involved, only those without significant COIs should vote.	7/11/2024 4:36 PM
106	That may include me in prior meetings. COI degree varies greatly.	7/11/2024 4:35 PM
107	They should be permitted to provide expertise but the voting should be limited to the panel members	7/11/2024 4:31 PM
108	Should be a last resort.	7/11/2024 4:23 PM

109	with significant caution that the CO I does not unduly influence voting members of the committee	7/11/2024 4:20 PM
110	although I said they should not be a member, this gets to the vagueness of your question. there are conflicts at varying degrees, some with more simple potential than actual conflict. some of these conflicts are not just whether or not they have any financial conflict with the devices in question, but whether they do other work in the industry. this varies from significant remuneration to relatively inconsequential activities and this question needs to be worded more carefully	7/11/2024 4:13 PM
111	COIs or appearance of COI should be avoided if at all possible. I would definitely them from exclude voting.	7/11/2024 4:03 PM
112	depends on the type of conflict - often the conflict is minor and they could be a voting member	7/11/2024 4:02 PM
113	depends on the nature of the COI	7/11/2024 3:56 PM
114	adfdfadsfad	7/10/2024 12:11 PM

Q3 All advisory committees should have both a voting patient representative and a voting consumer representative.

Answered: 412 Skipped: 2



	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
(no label)	3.64% 15	19.66% 81	28.16% 116	30.83% 127	17.72% 73	412	3.39

#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	One or both should be included.	7/21/2024 11:44 PM
2	Not sure about difference between patient representative and consumer representative	7/18/2024 1:50 PM
3	Having served as both, I feel the distinction and role of each need to be more clearly defined and explained.	7/18/2024 9:00 AM
4	The patient rep is most important	7/18/2024 1:52 AM
5	As in question number 1: committee members should be qualified to evaluate the scientific and public health consequences of the risk/benefit decisions. In some committees the patient or consumer representatives have provided an important perspective for committee consideration.	7/17/2024 9:12 PM
6	I am not entirely sure of the distinction so would depend on the difference in role and perspective	7/17/2024 6:00 PM
7	People in these categories should be non-voting, as they can be viewed as having COIs.	7/17/2024 5:33 PM
8	I think these roles could be combined, however, also appreciate the opinion of patients/consumers.	7/17/2024 4:45 PM
9	i think patient and consumer input are important, however, data analysis and interpretation are a skill set that should be used to address scientific questions. patient and consumer input can	7/17/2024 4:41 PM

	be taken into account in different ways than voting.	
10	While rules (“All…”) allow for standardization, they can introduce inflexibility	7/17/2024 3:46 PM
11	The distinction between patient and consumer needs to be clearly defined.	7/17/2024 2:55 PM
12	These representatives always seemed duplicative to me, but there must have been a reason for including both. This reasoning was never clarified at least to me.	7/17/2024 1:54 PM
13	This FAR to absolute a statement and the need for this representation--which may be great--depends on the specifics.	7/17/2024 1:34 PM
14	I'm not clear about the distinction between a patient and a consumer representative	7/17/2024 12:57 PM
15	Important to encourage cross communication to understand and resolves challenges for healthcare	7/17/2024 12:48 PM
16	In my experience, these individuals have not really provided valuable input as they are not subject matter experts and usually just follow the advice of the SME's on the panel. In rare specific situations, there may be a role for positions of this type so I would not structure their involvement for "all" committees but would have them on an "as needed" basis depending upon the topic or device being evaluated.	7/17/2024 12:05 PM
17	Carefully vetted and not representing advocacy groups	7/17/2024 11:56 AM
18	The consumer representative must attest they hold no conflict regarding the issue under the vote.	7/17/2024 11:52 AM
19	AS a patient representative, I believe it's a disservice to patients to not have a voting patient representative and a voting consumer representative.	7/17/2024 11:40 AM
20	I do not see the value of a “consumer representative”, nor is it clear how that differs from the patient representative	7/17/2024 11:39 AM
21	Patient representative is most important.	7/17/2024 11:02 AM
22	in my experience the consumer representative has never contributed in even a small way, usually saying nothing. patient representative (with appropriate experience/knowledge) is far more valuable as voting member.	7/17/2024 10:53 AM
23	I think it depends on the context and the issues. Voting for patient/family representatives should be included. Voting for consumer reps could have more potential for COI and should be discussed on a case-by-case basis.	7/17/2024 10:49 AM
24	define "consumer representative" - not who this person is or what they actually bring to the discussion.	7/17/2024 10:35 AM
25	i would lean towards just one vote from either patient rep or consumer rep - those roles seem redundant	7/17/2024 10:17 AM
26	As a physician, patient, and consumer, I find that most of the voting pt and consumer reps to not fully understand the issues at hand and unable to perceive purpose of AdComm or risks/benefits.	7/17/2024 10:01 AM
27	Helpful but not necessary to have both	7/16/2024 11:03 PM
28	Agree with the voting patient representative but neutral on the need for a voting consumer representative.	7/16/2024 7:29 PM
29	subject to availability pool and selection process; strong risk for bias; advisory panel of patients to inform work of FDA and/or advisory committee is another thought	7/16/2024 4:36 PM
30	The patient representative often has no clue what is really at stake	7/15/2024 11:16 PM
31	Where possible this would likely be valuable. If difficulty persists in filling, this should not prevent the meeting from happening.	7/15/2024 6:04 PM
32	Good idea	7/15/2024 3:31 PM
33	sometimes the size of our committee is so small that 2 more voting members makes a big difference. I suggest 1 voting member and 1 non-voting member.	7/15/2024 10:03 AM

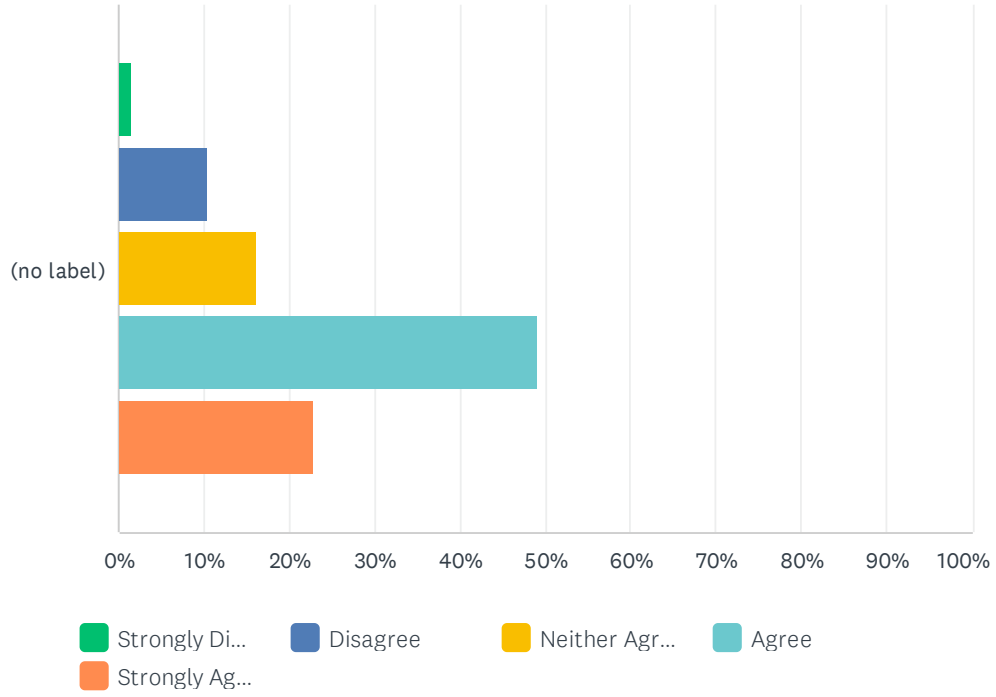
34	Both these perspectives add to the richness of the discussion. While at times it may be a bit exasperating, on the whole it is a perspective that should receive some consideration.	7/15/2024 9:29 AM
35	I am not sure of the difference between consumer and patient	7/15/2024 5:26 AM
36	I strongly agree with having patient representatives but not consumer representatives.	7/14/2024 8:21 PM
37	this is essential	7/14/2024 5:58 PM
38	voting pt not consumer- but not sure what you mean by consumer	7/14/2024 12:37 PM
39	the patient and consumer perspectives are important to counter balance the scientists and medical providers	7/13/2024 11:35 PM
40	Both parties could have good information/perspectives which may be beneficial in consideration of approval	7/13/2024 10:51 AM
41	I have never been aware of the difference when attending a meeting.	7/13/2024 8:56 AM
42	unclear of rationale to have both patient and consumer rep. Prefer patient rep. Not sure what consumer adds.	7/13/2024 8:51 AM
43	The patient representative should have a vote. Not sure that a consumer representative should	7/13/2024 7:52 AM
44	Although I am not sure what a the difference is. I think a patient representative is exceedingly helpful but may not understand the science well enough to be a voting member.	7/12/2024 8:58 PM
45	Advisory committee decisions affect the public at large. Having patient and consumer reps with voting privileges would enhance openness and transparency of the process.	7/12/2024 8:00 PM
46	Patient representatives and consumer representatives provide different perspectives and each viewpoint is valuable to the overall discussion.	7/12/2024 6:04 PM
47	Yes, we have that on the CDC ACIP and this is a very important perspective. It would be important to pick someone who has significant medical literacy and knowledge.	7/12/2024 4:37 PM
48	They can have a voice but I am not sure their vote should be equal to other experts. I could go along with one voting patient rep or advocate (eg parent for a childhood disease).	7/12/2024 3:57 PM
49	I am not sure about this	7/12/2024 2:46 PM
50	NOt sure of the background of a consumer rep	7/12/2024 2:31 PM
51	Parent or patient yes, not sure what a consumer representative really is	7/12/2024 2:08 PM
52	I think the interests of patients can be represented by either a pt representative or a consumer representative. I have no objection to having non voting consumer or patient representatives	7/12/2024 1:48 PM
53	one patient representative only	7/12/2024 1:42 PM
54	I think their COIs should be handled the same way as investigators. If they are receiving travel reimbursement from the industry sponsor, they should not vote	7/12/2024 1:37 PM
55	Once again, I think this is also a bad look. People on this committee need to be able to impartially review the science, as well as the arguments from patients and consumer reps. Having people with a vest interest in the outcome on these committee's dilutes their relevance.	7/12/2024 12:56 PM
56	I don't know what a consumer representative brings to the table, different from that of a patient rep.	7/12/2024 12:14 PM
57	Not sure about how these non-medical/science folks would be vetted and selected	7/12/2024 12:00 PM
58	Consumer advocates or representatives should always be included to balance the potential impact of finding.	7/12/2024 11:47 AM
59	they are essentially the same constituencies	7/12/2024 11:38 AM
60	I think their perspectives are important for the deliberations, but don't think they necessarily have the tools to evaluate the safety and population impact of the products/devices being considered.	7/12/2024 11:06 AM
61	One or two consumers cannot possible represent the universe of potential consumers. Having one is simply window dressing.	7/12/2024 10:58 AM

62	similar to SME treating physicians, this unique perspective provides additional context to meetings/voting	7/12/2024 10:27 AM
63	one or the other should suffice	7/12/2024 10:14 AM
64	Support their inclusion but not as voting member. Nothing is binding, so it is mostly moot anyway. The goal is to get the opinions.	7/12/2024 9:54 AM
65	It would be useful to know where these stakeholders stand on a decision, so a vote would be helpful. Votes from ACs are not binding; FDA still has the final decision.	7/12/2024 9:42 AM
66	They can add an important perspective.	7/12/2024 8:49 AM
67	Ned to define "patient representative" and "consumer" since every is a patient and be clear what sort of "consumer" is meant..	7/12/2024 7:31 AM
68	for some topics, there may not be much difference between a patient representative and a consumer rep.	7/12/2024 7:28 AM
69	A single patient maybe as biased by personal experience without a typical experience which could bias there comments	7/11/2024 10:53 PM
70	Patients are commonly influenced by just their own experience and therefore do not represent the opinion of all the patients with a disorder.	7/11/2024 10:29 PM
71	I think they should be non-voting, but their perspectives are critically important to the process.	7/11/2024 10:15 PM
72	The consumer representative has the appearance of conflict regardless of their actual COI. For the sake of the public, it would not be good to have voting members that appear to have a conflict.	7/11/2024 9:28 PM
73	As far as I remember, this is part of the law so it's necessary. If not part of the law, it couldn't hurt.	7/11/2024 9:17 PM
74	The vote is only part of the process. The FDA does not need to approve a drug based on a majority vote.	7/11/2024 8:47 PM
75	Most patient representatives and consumer representitives are not actually representative of a large group. They tend to represent themselves and their personal experiences and should not be included on advisory committees. The advisory committees may take comments/suggestions from such people.	7/11/2024 8:44 PM
76	These members should be allowed to speak, but not vote.	7/11/2024 8:04 PM
77	Having the perspective of patients is very important but in my field of inflammatory bowel diseases there is wide patient heterogeneity and varied perspectives and it would be difficult to have balanced representation from 1-2 voting patient representatives. Disease advocacy societies would provide vaulable input but should not be voting members in my opinion	7/11/2024 7:55 PM
78	has to be decided on a case by case basis, depending on the product to be discussed	7/11/2024 7:15 PM
79	The consumer and patient representative should be one and the same person.	7/11/2024 6:36 PM
80	A consumer representative is a reasonable idea to me, but in a non-voting capacity due to COI	7/11/2024 6:35 PM
81	Again, concerned about bias. It just truly depends on the representatives.	7/11/2024 6:15 PM
82	In my experience, "lay" members rarely if ever contributed to the deliberations or decisions	7/11/2024 6:13 PM
83	perhaps a patient rep	7/11/2024 6:04 PM
84	I am not sure what the consumer representative brings. They bring personal experience which is usually anectodal and not based in evidence based practice	7/11/2024 6:00 PM
85	I realize this is a "popular" idea. I think it depends on the committee in question as to how helpful/essential a consumer/patient representative would be.	7/11/2024 5:56 PM
86	Patient yes. Do not necessarily agree with consumer (for all committees).	7/11/2024 5:54 PM
87	consumer representatives often add little value to the discussioins and bring their own (often irrelevant) agendas.	7/11/2024 5:52 PM

88	They are rarely very helpful.	7/11/2024 5:48 PM
89	When practical	7/11/2024 5:31 PM
90	do not understand difference in role between patient rep and consumer rep	7/11/2024 5:29 PM
91	The issues with those voting members is that they are driven by the need and often don't have the subject matter expertise to evaluate technical questions.	7/11/2024 5:24 PM
92	I like have a patient representative and always learned a lot from listening to them. The consumer representative was frequently opposed to everything so that doesn't really add value to the discussion when their position is the same for all meetings.	7/11/2024 5:19 PM
93	I rarely understand the difference. My main complain is that sometimes the patient is 'too educated'. One recently she kept referring to herself as Doctor (a phd in a related field) and repeatedly cited the literature. I'd prefer patients offer a more 'average patient' perspective.	7/11/2024 5:17 PM
94	not sure why you need both	7/11/2024 5:11 PM
95	The patient is critical: what criteria are used for representative??	7/11/2024 5:10 PM
96	Not sure why a voting patient would be meaningful for the focus of TPSAC meetings. Depending on the topic, a voting consumer could provide meaningful input, but it would be challenging to select a single person to represent the likely diversity of perspectives.	7/11/2024 5:07 PM
97	Would have been strongly agree if it was only “patient representative”	7/11/2024 5:05 PM
98	I think the curent system works well.	7/11/2024 5:03 PM
99	They need to have demonstrated expertise in the topic	7/11/2024 5:00 PM
100	These two disciplines provide important balance	7/11/2024 4:52 PM
101	Their contributions are superficial	7/11/2024 4:50 PM
102	Both help to avoid group think. Patients in particular usually do not add much, but occasionally they can point to a key issue not (or under) appreciated.	7/11/2024 4:49 PM
103	There are times when those chosen have no comments - perhaps that is just who volunteers	7/11/2024 4:47 PM
104	not sure a consumer respresentative is necessary all the time	7/11/2024 4:46 PM
105	Would prioritize a patient representative over consumer representative	7/11/2024 4:44 PM
106	consumer rep maybe should be non-voting	7/11/2024 4:42 PM
107	Non conflicted key	7/11/2024 4:38 PM
108	The provide potentially different perspectives.	7/11/2024 4:36 PM
109	not sure what the difference between patient rep and consumer rep so just need one	7/11/2024 4:33 PM
110	They people add little to no value during the scientific conversation, but I guess they should be retained for appearances sake?	7/11/2024 4:31 PM
111	There may be exceptions, but i can't think of any. This should only be if appropriate.	7/11/2024 4:23 PM
112	I think it is good to have these few points represented, but not necessarily as voting members	7/11/2024 4:20 PM
113	Patients and consumers have COIs too, often undeclared.	7/11/2024 4:15 PM
114	having sat on many panels, I think it is good optics to have these folks, but in truth I have not found that they have added much to the panel meetings	7/11/2024 4:13 PM
115	I do not think a patient representative is always required, or a consumer rep. If they are included they should not vote. The evidence-based advice that the FDA is seeking should come from subject experts alone.	7/11/2024 4:03 PM
116	The last committee I was on the patients speaking clearly could not understand critical issues related to the subject.	7/11/2024 3:58 PM
117	Either one is sufficient, not both. I prefer a voting patient representative.	7/11/2024 3:51 PM
118	dfdfadfdf	7/10/2024 12:11 PM

Q4 Advisory committee meetings should be modified to allow for adequate time for sponsors to comprehensively address all questions and concerns raised by committee members.

Answered: 409 Skipped: 5



	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
(no label)	1.47% 6	10.51% 43	16.14% 66	49.14% 201	22.74% 93	409	3.81

#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	It is of critical importance to increase the time provided to the Advisory Committee members to have their questions to the sponsor and FDA properly asked and addressed. This could be achieved in part by reducing the time provided to sponsor presentations, given that the advisory committee already has been provided sponsor and FDA Briefing Documents.	7/23/2024 12:59 PM
2	Committee meetings seem to be running well and participants have time to address questions	7/21/2024 11:45 PM
3	Sponsors' participation in Advisory Committee deliberations should be focused on presentation of study design, data formatting and data analyses, results, and proposed next steps.	7/19/2024 1:31 PM
4	Many issues cannot be comprehensively addressed in meeting because data not available or time is limited	7/18/2024 1:53 PM
5	Generally is OK	7/18/2024 1:53 AM
6	The key questions and concerns should be answerable using materials in the sponsor and agency briefing documents. The committee can always comment and highlight cocerns that were not adequately addressed in the disucssion (and as advice for agency consideration in subsequent decisions).	7/17/2024 9:24 PM
7	Current time limits seem appropriate.	7/17/2024 9:11 PM

8	the tremendous effort and resources required to convene an advisory committee meeting necessitates that the bulk of the work be completed "in one sitting"; advisory cmte members can submit questions ahead of time if adequately prepared and any urgent unanswered questions raised during the meeting can be answered in writing thereafter as needed to inform FDA decision making (if not advisory cmte decision making)	7/17/2024 8:17 PM
9	In my experience with ODAC, I have never come away with the idea that sponsors were ever denied opportunities to address all questions posed by committee members	7/17/2024 7:15 PM
10	within reason, it's possible we would ask questions that could extend the meeting substantially so there needs to be a balance - attention span likely wanes at a certain threshold vs feeling fully informed prior to voting.	7/17/2024 6:03 PM
11	Currently, the time may not be adequate. Consider adding an extra hour or two.	7/17/2024 5:40 PM
12	this sounds reasonable. it would require additional work of the committee.	7/17/2024 4:43 PM
13	Some questions and concerns can only be adequately addressed by allowing sponsors time to gather relevant information	7/17/2024 3:48 PM
14	already does	7/17/2024 3:19 PM
15	My experience has been that adequate time was allotted.	7/17/2024 2:56 PM
16	I would assume that the FDA works through all the details with sponsors, and that not all issues raised by committee members need to be addressed by the sponsor	7/17/2024 2:27 PM
17	I believe that with a well-run meeting, there is adequate time within the current format. Committee members need to limit questions and concerns to the most important issues that would affect their votes. This is an imortant function for the committee chair, and should be communicated by the chair to the committee at the beginning of the meeting.	7/17/2024 2:07 PM
18	This is simply impractical, and the sponsor should know their own data so well that they are prepared. I think it is rare that more time would lead to a qualitatively better response that alters the outcome of the meeting. The Committees are only advisory.	7/17/2024 1:36 PM
19	within reason	7/17/2024 12:59 PM
20	A designated amount of time should be available for comment, though doled out so no one party controls the floor	7/17/2024 11:56 AM
21	I do not understand what “adequate time” means.	7/17/2024 11:45 AM
22	I think the current format works well.	7/17/2024 11:08 AM
23	Not all questions raised by committee members require detailed or studied responses	7/17/2024 11:06 AM
24	sponsors already play games with the process. why give them more opportunity to filibuster and delay?	7/17/2024 10:44 AM
25	To a limit. Perhaps days/ week but not an extended period.	7/17/2024 10:41 AM
26	because these are non-binding recommendations, i think it is most likely adequate for the purposes of the fda to hear the input of the AC members, and to extend it to allow more time for sponsor responses would almost certainly mean extending the meeting past one day which i don't think is practical. a little extension but to keep the meeting one day would probably be ok	7/17/2024 10:19 AM
27	I found that the current time given to Sponsor and FDA adequate.	7/17/2024 10:04 AM
28	I'm not aware that this has been an issue, but I served as a SME and I'm not part of a standing committee.	7/16/2024 11:43 PM
29	Helpful to answer MOST questions but it is not always possible to address ALL questions as time needs to be taken into account	7/16/2024 11:06 PM
30	This should be judged by subject-matter experts as to the meaning of "comprehensively" in this phrase.	7/16/2024 10:30 AM
31	Everyone wants committee decisions based on total disclosure or with as much knowledge as possible.	7/15/2024 6:13 PM

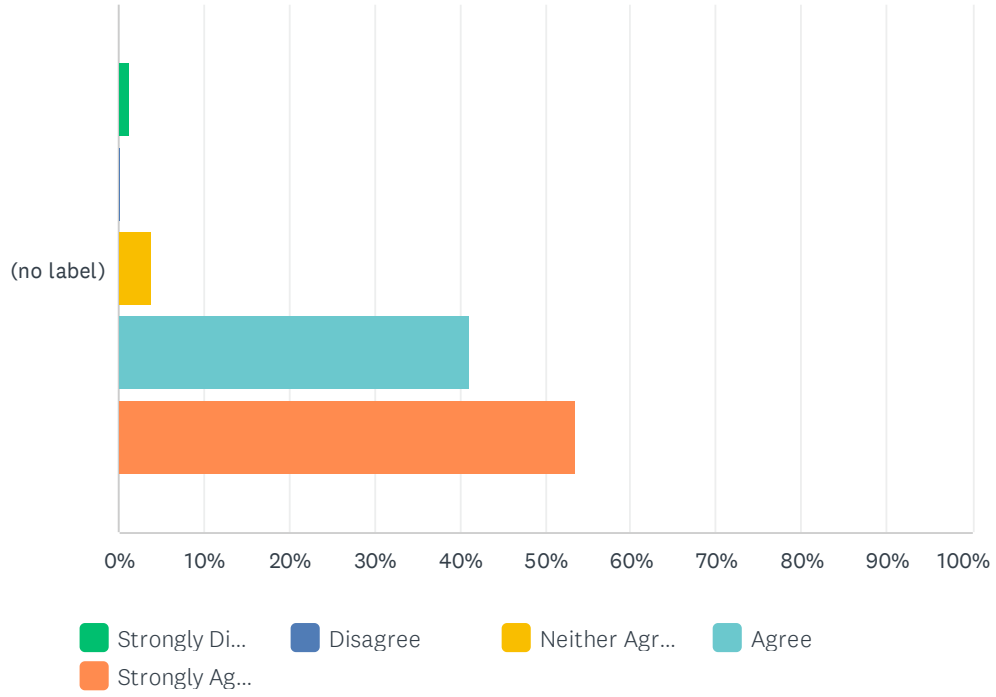
32	Adequate time now	7/15/2024 3:32 PM
33	the sponsors could respond with chat messages but if they had free reign it would be too much time given to them.	7/15/2024 10:07 AM
34	Adequate time for questions is important but the sponsors also need to show some restraint when it comes to presenting only relevant evidence of support for their product.	7/15/2024 9:33 AM
35	Would this occur within the same committee meeting session or a follow-up meeting?	7/14/2024 9:36 AM
36	In order to make the best decision, full knowledge is essential to make the best decision for the public.	7/13/2024 10:57 AM
37	Pre-work is likely essential to a more productive meeting. Review of relevant documents, responses and questions to be addressed should all be done in advance to help focus the objectives for the meeting.	7/13/2024 10:15 AM
38	More time for discussion is a good goal. I would not say "comprehensively address all questions". I would suggest there be more time for committee members to ask specific questions of both the sponsor and the FDA. The sponsors have huge slide sets ready for further explanation of their reading of the data. Committee members can ask for clarification of specific points and the sponsors are glad to give their pitch. To have more of a sponsor lecture in the guise of "comprehensively addressing all questions" is not useful. To have more time for specific answers to specific questions is useful.	7/13/2024 9:13 AM
39	"Comprehensively address all questions" - need to have a time limit and restrictions on how long to continue conversation about an esoteric issue important for one but not the other committee members.	7/12/2024 8:10 PM
40	Yes, this is crucial as I find that many of the sponsors do not reveal important negative aspects of their work, which are often only solicited through questions.	7/12/2024 4:39 PM
41	Time for questioning is currently too short for both SPONSOR and FDA presentations	7/12/2024 3:14 PM
42	some questions are not possible to address at the meeting but can be addressed later if requested byFDA	7/12/2024 3:06 PM
43	I think that the meetings are rushed and very formal, not allowing for ability to ask probative questions.	7/12/2024 2:48 PM
44	I think they have adequate time to address questions.	7/12/2024 1:50 PM
45	more time = more obfuscation	7/12/2024 1:43 PM
46	It been a while since I have been at one of these meetings, but I would say this already happens. Additional time is not needed.	7/12/2024 12:59 PM
47	My question to the sponsor was not addressed prior to voting ("we'll get you that"). No facilitator seemed to be tracking unanswered questions (or any judgement on whether or not the question was important)..	7/12/2024 12:32 PM
48	...within reason. After a point, if the briefing document and the sponsor presentation don't answer the questions along with the Q&A period, there's a fundamental problem.	7/12/2024 12:16 PM
49	Have not had this be an issue,	7/12/2024 12:09 PM
50	How much time is adequate?	7/12/2024 12:03 PM
51	We usually had plenty time for questions and answers. When we did not, they sent follow up responses after the meeting.	7/12/2024 11:50 AM
52	Committee members need to get responses to all their queries/concerns prior to voting.	7/12/2024 11:14 AM
53	Within certain limits, and also with guardrails on the amount of time sponsors have to answer individual questions so that they remain focused.	7/12/2024 11:08 AM
54	I have not attended a committee meeting with inadequate time for comprehensive questions but find it important for all questions and concerns to be addressed.	7/12/2024 10:31 AM
55	It depends, but I generally favor time limits.	7/12/2024 9:56 AM
56	otherwise why have the sponsors present before the committee members?	7/12/2024 9:10 AM

57	I do not know if this means sponsors who's products reach a certain level of review or all sponsors? I also do not know what "adequate time for sponsors to comprehensively address all questions and concerns... "	7/12/2024 8:52 AM
58	In my experience, the FDA takes a very long time to review materials. Adequate time would need to be defined to ensure a timely process.	7/12/2024 8:08 AM
59	for my committee, we have typically always had adequate time to for sponsors to address our questions.	7/12/2024 7:32 AM
60	Yes, but this is not a problem at present	7/12/2024 3:55 AM
61	However time has to be reasonable	7/11/2024 10:56 PM
62	Self-explanatory	7/11/2024 10:17 PM
63	Sponsors often pivot to answer a question different from the one asked. There must be a time limit for practical purposes.	7/11/2024 9:34 PM
64	These concerns should be provided in writing at least two weeks prior to the meeting and not sprung on the Sponsor at the meeting. There is plenty of time to do this.	7/11/2024 9:20 PM
65	In the meetings I attended the sponsors had plenty of time. What was lacking was time for the committee members to present their opinions based on their particular expertese	7/11/2024 8:50 PM
66	Within reason	7/11/2024 8:45 PM
67	presentations should be organized and prioritized for important details. Time to address all questions and concerns may not be possible.	7/11/2024 8:11 PM
68	sponsors should be given questions in advance and provide written responses to the committee prior to the meeting and any outstanding issues can be addressed at the meeting with defined time limits.	7/11/2024 8:10 PM
69	I have not found this to be a problem in the meetings I participated in.	7/11/2024 7:17 PM
70	Within reason-sometimes things can get tangential and there is only so much time. This is where thoughtful moderation is critical.	7/11/2024 6:39 PM
71	I think the current format allows one to get through all the material in a practical time period	7/11/2024 6:36 PM
72	Agree but with need for limitations based on criteria (number of questions proposed, complexity)	7/11/2024 6:12 PM
73	My experience is that this already occurrs.	7/11/2024 6:10 PM
74	The word comprehensive is too ambiguous as it can mean that sponsors would have an infinite amount of time to address questions and concerns. A time-bounded response would be something that I would agree with.	7/11/2024 5:56 PM
75	Time constraints forces the sponsors to be concise and answers questions directly.	7/11/2024 5:53 PM
76	think the sponsor already gets plenty of time	7/11/2024 5:35 PM
77	Now that the meeting is now longer on-site, there does not need to be the constrain of completing within a day. A second partial day is not burdensome logistically and can often allow for proper full discussion.	7/11/2024 5:28 PM
78	This is tough because it is so highly orchestrated- perhaps more time is needed overall for each product.	7/11/2024 5:21 PM
79	With time limits set ahead, similar for each company.	7/11/2024 5:15 PM
80	Most meetings I have attended have allowed adequate time	7/11/2024 5:13 PM
81	this should be a critical part of the advisory process and there should be no limitation of time within reason.	7/11/2024 5:10 PM
82	There is often not adequate time for either members of the committee to address all of their questions. This can be remedied by having fewer members. Not all committee members need to be at every committee- but rather tailor make the committee to have SGE's as appropriate	7/11/2024 5:05 PM

83	there can be flexibility in this matter but would ask advisory panel at the time if more time is indicated based on the discussion	7/11/2024 5:04 PM
84	The operative word is adequately. I worry that a sponsor will run the clock to attempt to weigh an argument. The current approach balances both and is the proper legnth	7/11/2024 4:57 PM
85	FDA doesn't listen to everything - spending the time to address absolutely everything raised has diminishing returns at a point.	7/11/2024 4:46 PM
86	I have never seen a problem with time constraints for Q&A	7/11/2024 4:42 PM
87	Meetings that run too long sap everyone's energy and attention, and may result in worse decision making.	7/11/2024 4:40 PM
88	this could be helped if committee members submitted questions in advance of the meeting and optimally written responses could be submitted.	7/11/2024 4:38 PM
89	Depends -- still needs to be a time limit	7/11/2024 4:34 PM
90	Time is already allotted for this purpose.	7/11/2024 4:34 PM
91	It is unfair that some committee members walk away with unanswered questions and are forced to vote at the end of the day without all of the requisite information.	7/11/2024 4:33 PM
92	within reason	7/11/2024 4:21 PM
93	Sponsors are allotted lots of time already. Questions and concerns are often obvious up front.	7/11/2024 4:18 PM
94	since most of these meetings take all day, I think getting the questions out in the morning and giving the sponsor time to address them during the lunch break is sufficient icient	7/11/2024 4:14 PM
95	I don't fully comprehend the problem, or what "sponsors" means here. The committee members need to have adequate time to review and decide on the issues they are asked to advise on.	7/11/2024 4:06 PM
96	There must be some time limit, the meetings are quite long enough	7/11/2024 4:00 PM
97	My experience has been that the time is sufficient for my questions, so I'm not sure what the problem is.	7/11/2024 3:52 PM
98	asdfadfadfds	7/10/2024 12:11 PM

Q5 FDA should continue to have voting questions on benefit / risk at advisory committee meetings that discuss an application for approval of a product.

Answered: 409 Skipped: 5



	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
(no label)	1.22% 5	0.24% 1	3.91% 16	41.08% 168	53.55% 219	409	4.45

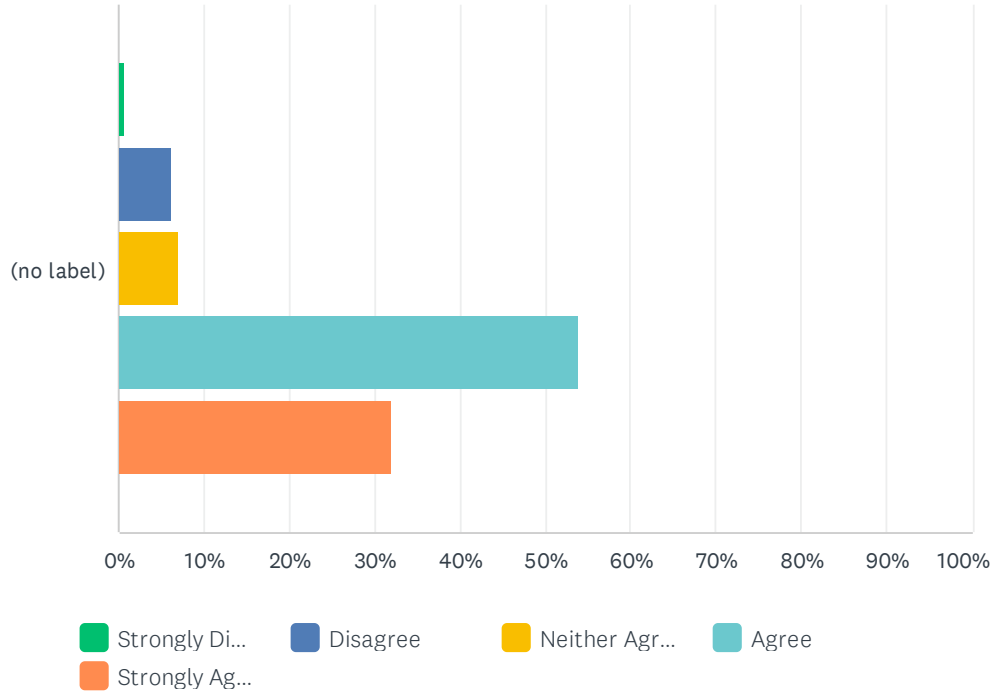
#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	FDA, not the Advisory Committee, is the decision-making body. Hence, what should be of integral importance is not a voting process but rather a process to ensure the Advisory Committee can provide their reasoning in response to questions raise by FDA.	7/23/2024 12:59 PM
2	In my experience, this has been the primary purpose of most meetings. The committee often discusses caveats to their conclusions about risk and benefit that can be considered in agency decisions.	7/17/2024 9:24 PM
3	none	7/17/2024 7:15 PM
4	This seems essential to me.	7/17/2024 5:40 PM
5	Questions need to be written in a way that doesn't bias the results. In my experience the way they have worded leaves the members with only one logical answer	7/17/2024 2:43 PM
6	This is a good idea.	7/17/2024 1:57 PM
7	I believe this is related to regulatory language and thus would be difficult to change.	7/17/2024 1:36 PM
8	This is often the key question for ADCOM members to vote and then provide comments.	7/17/2024 11:08 AM
9	This is the crux of how clinicians and patients make treatment decisions	7/17/2024 11:06 AM

10	Context of risk/benefit is very important in these discussions. Nothing is without risk. Weighing this balance and full disclosure of risk/benefit is important. For patients who have diseases with no realistic cure, for example, there is likely a higher risk tolerance for potential benefit.	7/17/2024 10:51 AM
11	seems self evident.	7/17/2024 10:40 AM
12	Voting questions distort the scientific discussion and are for the press and investors	7/17/2024 10:30 AM
13	Tend to see the b/r voting as a "show" and not a nuanced discussion as most b/r is required to be.	7/17/2024 10:04 AM
14	agree as that is the conceptual framework that FDA uses to make decisions regarding approval.	7/16/2024 7:31 PM
15	The core reason for the AdCom	7/15/2024 3:32 PM
16	This is an important question that clinicians will need to weight post-approval so asking the committee seems appropriate.	7/15/2024 9:33 AM
17	this is a critical role of the advisory committee	7/13/2024 11:38 PM
18	This is a safe-guard that must be an essential responsibility of every decision made by the FDA!	7/13/2024 10:57 AM
19	Transcript of the discussion and/or rationale for pro and con opinions should be publicly available. Similar to the supreme court process of publishing majority and dissenting opinions	7/13/2024 10:15 AM
20	This is an absolutely crucial part of the meeting. People who have been quiet are forced to take a position and explain why. This is the most public part of the whole approval process, and needs to be maintained. If FDA later makes a decision different than the committee vote, they then have the opportunity to say why their suggestions differed from that of the committee. The vote is critical to maintain.	7/13/2024 9:13 AM
21	The FDA leaders who craft the voting questions do a good job and I do not perceive a need to change the process.	7/12/2024 6:13 PM
22	Everything we do in medicine is about risk and benefit. This is an important aspect.	7/12/2024 4:39 PM
23	This is the main point of these meetings!	7/12/2024 3:58 PM
24	no point in committee meetings if this isn't included	7/12/2024 1:38 PM
25	Here I would also add that the FDA should continue to consider "community-based" risks and not just those to the individual.	7/12/2024 12:59 PM
26	And attention paid to differences between the participants within the trial versus the individuals in a society with the condition.	7/12/2024 12:32 PM
27	Benefits/Risks are an important factor in decision making	7/12/2024 12:03 PM
28	though in some cases, FDA can continue to just have discussion without voting if appropriate	7/12/2024 11:08 AM
29	I feel this is one of my most important roles as a member of this committee - to provide a vote on benefit/risk following content discussion.	7/12/2024 10:31 AM
30	the evaluation of benefit and risk is one of the key aspects for most topics my committee discusses.	7/12/2024 7:32 AM
31	Why else have a committee?	7/11/2024 10:56 PM
32	Absolutely yes.	7/11/2024 10:17 PM
33	This is part of FDAs final decision on "reasonable assurance of S & E."	7/11/2024 9:20 PM
34	This question is poorly constructed. From my FDA experience, I cannot make sense of it.	7/11/2024 7:31 PM
35	These are important to keep focus on concerns raised.	7/11/2024 6:10 PM
36	however the degree of benefit and risk should be better taken into account in a more meaningful way. Perhaps a specialist or someone knowledgable can ellucidate if a proposed benefit is really worth it	7/11/2024 6:10 PM

37	The questions should be fair and balanced without steering the vote to the answer they want or avoid questions whose answers they may not want to hear.	7/11/2024 5:56 PM
38	This is usually the crucial point of the decision making.	7/11/2024 5:53 PM
39	Those questions crystallize the voting members input otherwise there is a lot of nuance in what/how they vote. The vote is non-binding but does provide cover for the FDA.	7/11/2024 5:28 PM
40	Totally agree; This makes it harder for FDA to pick and choose which advice they follow and pressures FDA when clinicians want a tool that FDA has been hesitant to approve.	7/11/2024 5:25 PM
41	I think that this leads to some of the best discussion. It is the balance that is critical.	7/11/2024 5:21 PM
42	I don't think it's necessary for AC members to vote. Questions should be constructed so their views are clear	7/11/2024 5:13 PM
43	benefit risk is critical to any future clinical application of a new product, combination, or device(s)	7/11/2024 5:10 PM
44	This is the rubber hitting the road and is a very effective way to assess the pros and cons of a potential drug candidate	7/11/2024 5:05 PM
45	Is that not the advice they are asking for - it is advice, however, and should not mandate FDA action	7/11/2024 5:04 PM
46	These should be broadly tailored and not narrow to encourage discussion all the panel to focus on "the big picture"	7/11/2024 5:03 PM
47	risk/benefit is the core of the regulatory enterprise.	7/11/2024 4:57 PM
48	THere has to be a record of the benefit/risk vote along with explanation of vote.	7/11/2024 4:46 PM
49	Knowing the overall up/down vote for each person and the rationale is important.	7/11/2024 4:40 PM
50	these are advisory anyway; not binding	7/11/2024 4:34 PM
51	Yes, this is very important	7/11/2024 4:33 PM
52	This makes sense. There is not always complete agreement and a vote helps to express the range of agreement or disagreement.	7/11/2024 4:06 PM
53	adfadfdagfad	7/10/2024 12:11 PM

Q6 The FDA should present the proposed verbatim indication (drugs or biologics) or intended use (devices) and ask advisors to vote on the appropriateness of that wording based on the available evidence.

Answered: 409 Skipped: 5



	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
(no label)	0.73% 3	6.11% 25	7.09% 29	54.03% 221	32.03% 131	409	4.11

#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	FDA should ask the Advisory Committee to provide their reasoning, rather than votes, regarding the proposed verbatim indication or intended use.	7/23/2024 12:59 PM
2	Recognizing that most members will not have the legal or regulatory experience to provide exact wording and that label discussions are often later in the process, it still may be useful for the FDA and sponsor to receive input from the advisors.	7/21/2024 4:18 PM
3	Not sure if you are referring to voting on indication or final wording of product insert.	7/18/2024 1:53 PM
4	I would tweak this and give some leeway for FDA to add information that is beneficial to patient safety	7/18/2024 1:53 AM
5	A clear indication (patient population, disease, and intended outcome) is at the foundation of the label and the approval decision. That said, the committee should consider a proposed indication and discuss it implications for the intended use, but it is not necessary that the committee approve the specific wording.	7/17/2024 9:24 PM
6	This is fine to do, it the FDA seems well equipped (without advice of committee) to do this	7/17/2024 9:11 PM
7	Stated indications are often (always?) translated into advertising and marketing, as well as label wording and patient instructions. Attention should be paid to literacy levels of wording	7/17/2024 7:15 PM

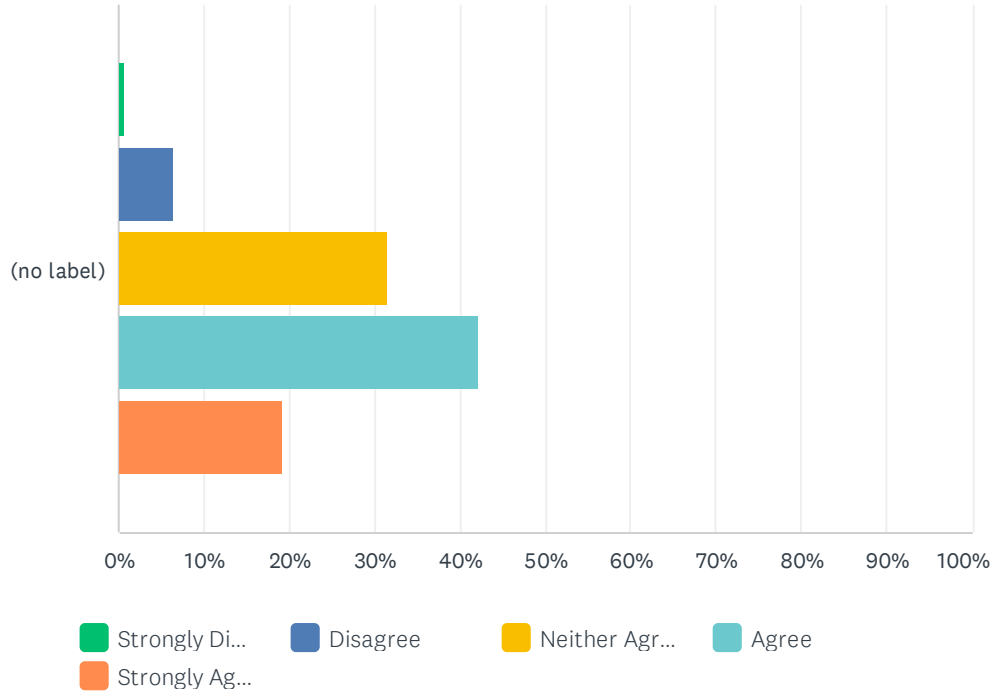
8	within reason - if this approach results in substantial extension focused on wordsmithing, then not necessarily appropriate.	7/17/2024 6:03 PM
9	Voting could result in additional clarity, and it may help address both over-specificity and overgeneralization.	7/17/2024 5:40 PM
10	Presentation of something close to the language may be useful, but the committee could get really lost in wordsmithing and could end up with wording that is inconsistent with policy, precedent, regulations	7/17/2024 2:27 PM
11	Word smithing by a group is always a mistake, but there should be a consensus statement about the outcome of the meeting	7/17/2024 1:57 PM
12	This could turn into a word smithing exercise	7/17/2024 1:08 PM
13	The FDA process begins well before the Advisory Committee hearing, and often extends beyond it. The FDA should only present those questions for which it requires expert advice.	7/17/2024 11:45 AM
14	When the verbatim indication presents a problem or concern, their is ample opportunity for ADCOM members to propose modifications.	7/17/2024 11:08 AM
15	Prescibing indications should not be so detailed that they limit the use in appropriate patients. Approving a drug for use in "high risk" patients is often interpreted in very different ways by payors and prescribers - the former may use that qualification to limit use unreasonably.,	7/17/2024 11:06 AM
16	it is very hard to word smith amd vote at AD board meeting	7/17/2024 10:54 AM
17	This should be a working process that has input from multiple stakeholders including review by patient/parent advocates to ensure that wording is understandable to the public.	7/17/2024 10:51 AM
18	how do we prevent endless wordsmithing?	7/17/2024 10:44 AM
19	When relevant.	7/17/2024 10:38 AM
20	Outside of FDA and sponsors, the actual lang and regs associated with lang in labels is beyond the scope of what AdComm members understand. Think that the lang discussion should focus on concepts, broad vs narrow, etc... rather than actual verbiage.	7/17/2024 10:04 AM
21	agree, unless there is a better, more effective alternative.	7/16/2024 7:31 PM
22	challenging for vaccines with ACIP recommendations to follow; soliciting comments as opposed to voting on appropriateness may be a better avenue to pursue	7/16/2024 4:39 PM
23	I do not think reviewing of verbatim wording is the role of an advisory committee. That is FDA's role.	7/15/2024 6:13 PM
24	This can be completed post AdCom	7/15/2024 3:32 PM
25	does this allow for editing?	7/15/2024 10:07 AM
26	in order to most accurately assess risk/benefit, the specific indication/use that the drug will be used for needs to be crystal clear	7/13/2024 11:38 PM
27	This gives the prescriber the opportunity to weigh whether it is the best Rx for the patient's situation.	7/13/2024 10:57 AM
28	I am not sure that the verbatim indication is agreed upon at the time of the meeting so this question is difficult. I am certainly aware that the way the voting questions are phrased is a huge issue that sometimes itself causes discussion. Standardization of voting questions shold be attempted as much as possible. Questions of safety and efficacy need to be asked. But "exact wording" goes to far in the recommendation.	7/13/2024 9:13 AM
29	Hard to do as a committee, in real time, but better to do when there is more time to reflect and give feedback on the verbage.	7/12/2024 9:00 PM
30	The intended use is proposed and not final. The discussion period should include an open forum concerning who should be treated and what are the indications.	7/12/2024 6:13 PM
31	Yes, details are very important. it would be helpful if the FDA had input from people in the field. I do understand that regulatory agencies have a slightly different goal, so they may not always utilize the input they are given, but I think it is important to solicit information and input.	7/12/2024 4:39 PM

32	There are times when other questions are more important or discussions are not indication specific.	7/12/2024 3:58 PM
33	This would help guide AC questiuons	7/12/2024 3:14 PM
34	committee members don't always have the expertise to parse the wording of the indication/ intended use.	7/12/2024 1:38 PM
35	I agree. But seems very complicated.	7/12/2024 12:32 PM
36	Lay person verbiage should also be included.	7/12/2024 11:23 AM
37	It is fair to ask voting committee members if they approve the verbatim indication or intended use statements.	7/12/2024 11:14 AM
38	YES, as a consumer representative, this is critical information.	7/12/2024 10:31 AM
39	This might be difficult to resolve within the time the Advisory Committee meets.	7/12/2024 10:18 AM
40	Flexibility should be allowed to understand what modifications of the indication would be acceptable to the panel and thus possibly to FDA, to avoid "throwing the baby out with the bath water."	7/12/2024 10:15 AM
41	Because physicians can prescribe off-label, labeling claims are likely overemphasized except with regard to coverage decisions. Unfortunately, that's where labels likely have the most impact on patients.	7/12/2024 9:44 AM
42	But this will also add a lot of time to the discussion	7/12/2024 9:29 AM
43	a "shared decision making" approach since the clinicians are the ones fighting with insurance for "off label" uses	7/12/2024 9:10 AM
44	this serves as opportunity for external feedback from experts who are informed on the data and understand the patient population who may potentially be prescribed the new drugs and biologics.	7/12/2024 7:32 AM
45	Sometimes final labeling might be changed based on the panel discussion	7/11/2024 10:56 PM
46	Absolutely yes.	7/11/2024 10:17 PM
47	Many/most committee members do not have sufficiently detailed knowledge of the indication for other drugs in the class to compare the indication to.	7/11/2024 9:34 PM
48	This won't help. FDA will modify the labeling as they please at the last minute stating it's based on information gleaned from the panel meeting. However, give it a try and do your best. The panel needs this information to provide feedback.	7/11/2024 9:20 PM
49	The exact wording may change based on what happens in the meeting. I don't think that the proposed wording is relevant.	7/11/2024 8:50 PM
50	Getting into wordsmithing is not something advisory committees should do. We focus on bigger picture issues, and FDA staff should do the nitty-gritty work.	7/11/2024 8:45 PM
51	Whether advisors should vote on the indication /intended use is not a yes or no questions; how the vote is used is what is important.	7/11/2024 8:11 PM
52	Committee members should also be able to amend the wording and vote on that as a suitable replacement.	7/11/2024 8:10 PM
53	Yes, but any decision making regarding wording should always include a committee member with training in communication.	7/11/2024 7:31 PM
54	Advisory panels are not experts on language.	7/11/2024 7:17 PM
55	When it can be made available. Sometimes indications from the committee to FDA are good directions for FDA to work with.	7/11/2024 6:10 PM
56	AGree with this 100%, it is ridiculous that indications essentially are verbatim from the trial design.	7/11/2024 6:10 PM
57	That decision should be left to agency staff.	7/11/2024 5:33 PM

58	Somtimes narrowing the patient demographic and / or other modifications allow for a positive result for the project.	7/11/2024 5:28 PM
59	Agree they have to have that; and like the idea of "if no, would any label language change make you say yes".	7/11/2024 5:25 PM
60	If pertinent to the specific discussion and evidence available to include this aspect.	7/11/2024 5:15 PM
61	Comment, but not vote	7/11/2024 5:13 PM
62	Since all patients may not specifically fall into the specific label language, there should be some give and take regarding the appropriate patient population even thought it may not be identical to the label	7/11/2024 5:05 PM
63	The ultimate language is a complex decision and larger than can be addressed in the short time span for committee members to assess. It may also drift with new information	7/11/2024 4:57 PM
64	It is too much to expect FDA to lock down the IFU that early. Things come up based on the panel comments.	7/11/2024 4:52 PM
65	it depends on If available at the time	7/11/2024 4:46 PM
66	I agree in principle, but reviewers can get nitpicky about phrasing. As long as the rationale for each person's vote is recorded, it should be fine.	7/11/2024 4:40 PM
67	Yes, this is exactly what the AdCom should vote on.	7/11/2024 4:33 PM
68	This seems sensible and may obviate problems later on (if the language is not what they were expecting).	7/11/2024 4:06 PM
69	Not all advisors are qualified on all aspects of the indication	7/11/2024 4:00 PM
70	asfsadfafds	7/10/2024 12:11 PM

Q7 The FDA should take more proactive steps to inform patients and consumers of advisory committee meetings and encourage participation during the public comment period.

Answered: 410 Skipped: 4



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(no label)	0.73% 3	6.34% 26	31.46% 129	42.20% 173	19.27% 79	410	3.73

#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	The integrity of the public comment process would be enhanced by having a more balanced representation of the public, rather than speakers essentially being limited to those arranged by special interest groups or the sponsor.	7/23/2024 1:07 PM
2	While this opinion is probably unpopular, I rarely see the patient or public comments being useful in the meetings in which I have participated.	7/21/2024 4:19 PM
3	Agree as long as the patients and consumers have standing to provide relevant and informed comments.	7/19/2024 1:35 PM
4	Meetings of new products I have been involved with have been very well attended indicating that the interested public was aware.	7/18/2024 1:56 PM
5	I agree, but there are times when it will be necessary to limit public comment or to ask that written comments be submitted for consideration by the committee.	7/17/2024 9:29 PM
6	Interested parties and informed stakeholdersare aware of announcements for public comment, but but perhaps more proactive communication about the process would result in better public engagement	7/17/2024 9:20 PM
7	I agree, although locations and timing of actual meetings are not always convenient for	7/17/2024 7:25 PM

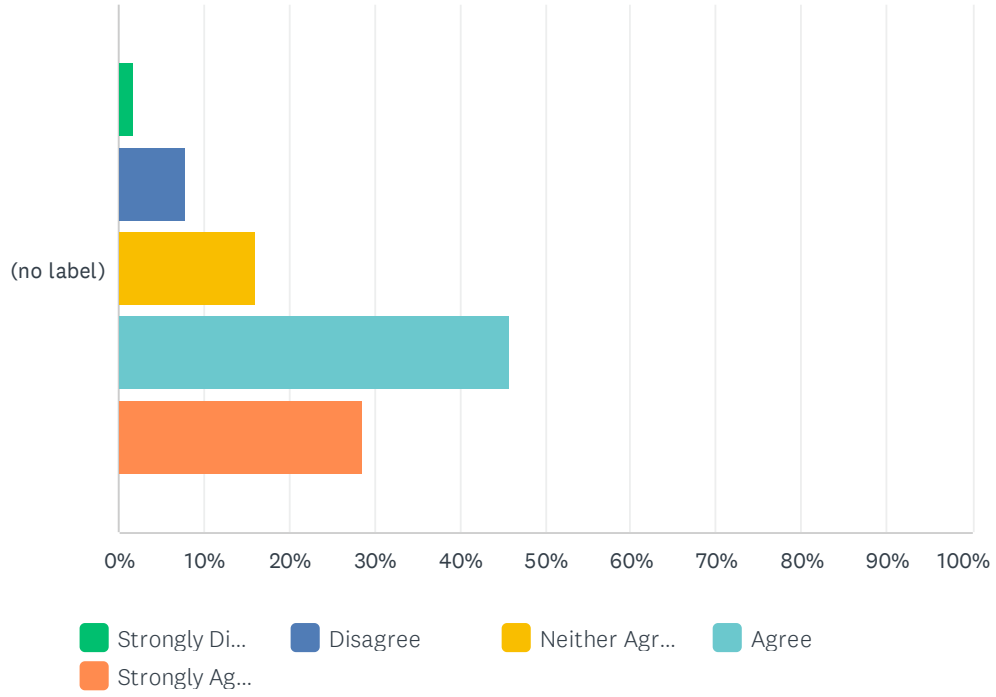
	patients and consumers. Maybe use of digital participation would be beneficial and useful to the public. I'm not informed as to how the public is informed of opportunities to participate. If not in person, then should consideration be made of "in writing" participation.	
8	again, within reason - important for transparency and the mission of serving the public	7/17/2024 6:06 PM
9	I can see both upsides and downsides to greater proactivity. I am concerned, however, that increased participation may result in agenda activism.	7/17/2024 5:53 PM
10	Sometimes this information does not seem widely available.	7/17/2024 4:48 PM
11	FDA already does a good job.	7/17/2024 2:59 PM
12	Turn around time has been too short for meaningful public participation	7/17/2024 2:45 PM
13	If meetings are made more widely public, submitted comments should be written rather than add meeting time to advisory committee meetings.	7/17/2024 2:01 PM
14	The current system seems adequate.	7/17/2024 1:40 PM
15	Who is aware of these hearings besides lobbyists. These hearings should be more broadly and verbally communicated	7/17/2024 12:51 PM
16	It seems like the current workflow and communications are adequate.	7/17/2024 12:12 PM
17	My impression is that the current system is adequate.	7/17/2024 11:24 AM
18	Would be nice to have more than 48 hours to digest FDA briefing before ODAC...	7/17/2024 11:02 AM
19	Awareness is important - partcipation is not always productive so that could be a big can of worms, especially if there were many, many requests for slots -- it could dramatically impact the meeting duration, yet the full assessment is important so that the conclusions are informed and representative of all parties.	7/17/2024 10:55 AM
20	I have not found that public commment period to be useful or informative in understanding the issues. For example, the standard Public Citizen comment is wasteful.	7/17/2024 10:08 AM
21	This would require that there is the chance for interaction with staff for questions/concerns during the public comment period.	7/16/2024 11:44 PM
22	This may depend on the product	7/16/2024 11:09 PM
23	Time limitations for comments should be enforced and they should be present at the meeting to hear the discussion	7/16/2024 12:47 PM
24	This is a good thing.	7/15/2024 6:20 PM
25	it seems to me there is good communication even if there is limited time to talk at these meetings.	7/15/2024 10:10 AM
26	I think this would be helpful for both the general public and for health care providers who do not completely comprehend the process.	7/15/2024 9:36 AM
27	the tremendous amount of public comment seen recently suggests the information is adequately being disseminated	7/13/2024 11:43 PM
28	It is beneficial to have input from the public regarding their own experience/results with a drug/treatment and be aware of what may be available in the future.	7/13/2024 11:04 AM
29	Keeping a record of the public dialogue important as well	7/13/2024 10:17 AM
30	People whol are interested can find out. More public comment is not needed	7/13/2024 9:13 AM
31	I believe that the public comment period is currently adequate and do not believe changes are needed.	7/12/2024 6:29 PM
32	Yes, many people don't know that they have an opportunity to comment.	7/12/2024 4:41 PM
33	In the meetings I attended (and this includes FDA advisory meetings as well as SACHRP meetings) the public comments were never informative and frequently absurd.	7/12/2024 2:08 PM
34	can't determine COI for "public" comment	7/12/2024 1:40 PM

35	On the committee's I have attended, this was not an issue.	7/12/2024 1:01 PM
36	though I don't know how the process works. Do concerned parties monitor the Federal Register for upcoming meetings, so they're prepared to comment? Aren't many of public commenters invited by the sponsor to participate because they derived benefit from the indication? To avoid COI, maybe more active spreading of the word about the meeting would be worthwhile. I was often surprised at how important the public comments were to my thinking about the voting question.	7/12/2024 12:23 PM
37	We had very few patient and consumer input during past meetings. In the past, the allotted time for public statements seemed adequate.	7/12/2024 11:54 AM
38	Public testimony is universally biased, uniformed by data, and presented on behalf of interest groups.	7/12/2024 10:59 AM
39	I am unclear how this would happen but welcome additional patient/consumer participation.	7/12/2024 10:34 AM
40	We should avoid the perception that the public is left out of the deliberations, so I see no problem with providing ample time for public comment. Notifying the public where and when the meeting will take place is reasonable, but I don't think the FDA has to do widespread outreach.	7/12/2024 10:23 AM
41	More systematic, scientifically sound approaches are needed to obtain patients' and consumers' views.	7/12/2024 9:45 AM
42	I suspect that current level of informing patients and consumers is likely adequate. I doubt there would be much impact of expanded efforts on this.	7/12/2024 7:37 AM
43	They’re doing a good job of this right now	7/12/2024 3:56 AM
44	Again, one may get a skewed opinion based on a single patient experience	7/11/2024 11:19 PM
45	Self-explanatory	7/11/2024 10:20 PM
46	I think meetings are sufficiently publicized. If the public comment period were any longer, the meeting would be too inefficient without adding any new opinions.	7/11/2024 9:44 PM
47	FDA will claim they do this, but it's not true because so much of the information is made available so close to the meeting date. To enforce this, you should require FDA to make all public information available at least three weeks before the meeting so everyone can prepare.	7/11/2024 9:25 PM
48	I thought they did this already	7/11/2024 8:51 PM
49	Within reason. Allowing hours of public comment would not be constructive nor a reasonable use of time.	7/11/2024 8:48 PM
50	This is a 'probably agree'. It is not clear what steps the FDA currently takes. Patient and consumer in put can be important.	7/11/2024 8:15 PM
51	I don't have enough knowledge of what FDA is currently doing to answer this question. In any case, the heading "Improving Public Perception..." doesn't have much to do with the question itself.	7/11/2024 7:41 PM
52	Assume include stakeholders such as professional societies	7/11/2024 6:25 PM
53	It is ridiculous that the companies have prepared patient presentations but actual patients at large in communities have no say… again biased	7/11/2024 6:18 PM
54	The public comment opportunities attract persons with "an axe to grind". I have never participated in an advisory committee meeting when the public comments significantly impacted the decision of the committee.	7/11/2024 6:13 PM
55	There have been enough public comments included in meeting in which I participated.	7/11/2024 6:12 PM
56	Current public participation is sufficient in most cases. Multiple public comments are often repetitive.	7/11/2024 5:55 PM
57	the patient comments often seem to come from advocates - sometimes supported by industry - rather than a more objective view	7/11/2024 5:38 PM
58	I think they do this enough already.	7/11/2024 5:27 PM
59	Not sure how this would work. But perhaps doing things to invite participation on social media	7/11/2024 5:26 PM

	would work.	
60	Am unsure how much the public participation has influenced eventual approval . It seems that experiences presented are often emotive or anecdotal	7/11/2024 5:22 PM
61	the sponsoring companies are already active in that campaign, no additional federal action needed	7/11/2024 5:07 PM
62	The current method is adequate and does not detract from the main portion of the meeting but ramains an important part that is now adequately represented	7/11/2024 5:07 PM
63	These parties can make statements in the open session	7/11/2024 4:55 PM
64	Difficult to do in an equitable way	7/11/2024 4:53 PM
65	Resources are limited - a sponsor can do this as can patient groups themselves - this is what the Sunshine Act is for.	7/11/2024 4:48 PM
66	In my experience, the FDA does take proactive steps to inform patients but advocacy groups fail to pass information on to patients. FDA could increase social media platform presence in hopes of increasing patient awareness.	7/11/2024 4:48 PM
67	There is enough commentary as is	7/11/2024 4:44 PM
68	I don't know what the FDA does in this regard now.	7/11/2024 4:43 PM
69	VERY strongly agree. Some AdComm meetings are covered in advance in the press but most fly under the radar, and the press doesn't cover a meeting until it's over.	7/11/2024 4:36 PM
70	I'm really indifferent to consumer participation. I don't find it useful.	7/11/2024 4:35 PM
71	I didn't know this was an issue.	7/11/2024 4:32 PM
72	The public comment period is often more entertaining than data rich.	7/11/2024 4:25 PM
73	I think there is adequate availability/visibility and time for public comments, so I neither agree nor disagree.	7/11/2024 4:10 PM
74	Sure, they could do better outreach directly to patients and consumers. Most of the public comment at meetings I've attended has been 'sponsored' by advocacy groups, not by individuals.	7/11/2024 3:56 PM
75	asfsfsaf	7/10/2024 12:12 PM

Q8 To increase public involvement in the open public comment period, the FDA should continue to allow remote participation, as it did when COVID-19 restrictions were in place.

Answered: 406 Skipped: 8



	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
(no label)	1.72% 7	7.88% 32	16.01% 65	45.81% 186	28.57% 116	406	3.92

#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	It is good but will be very difficult to make decisions about who gets to speak based on the time allotted for comments. Have more time for comments? Or an open line to record them and summarize for the committee.... to	7/20/2024 11:15 AM
2	IMO, little is accomplished with remote participation. People believe it’s a good thing but in many standards organizations that allow this, the quality of the produced standard and the quality of the meeting itself has decreased significantly.	7/18/2024 7:21 AM
3	participants should have to register for involvement	7/18/2024 6:15 AM
4	The physically present and remote public participants should be limited in number	7/17/2024 10:59 PM
5	difficult logistics	7/17/2024 9:37 PM
6	See also my comments on the preceeding question.	7/17/2024 9:29 PM
7	and make such possibilities made with a "splash"	7/17/2024 7:25 PM
8	Not allowing remote participation can lead to wealth-based discrimination.	7/17/2024 5:53 PM
9	former Advisory Board Members should be invited to attend	7/17/2024 5:46 PM

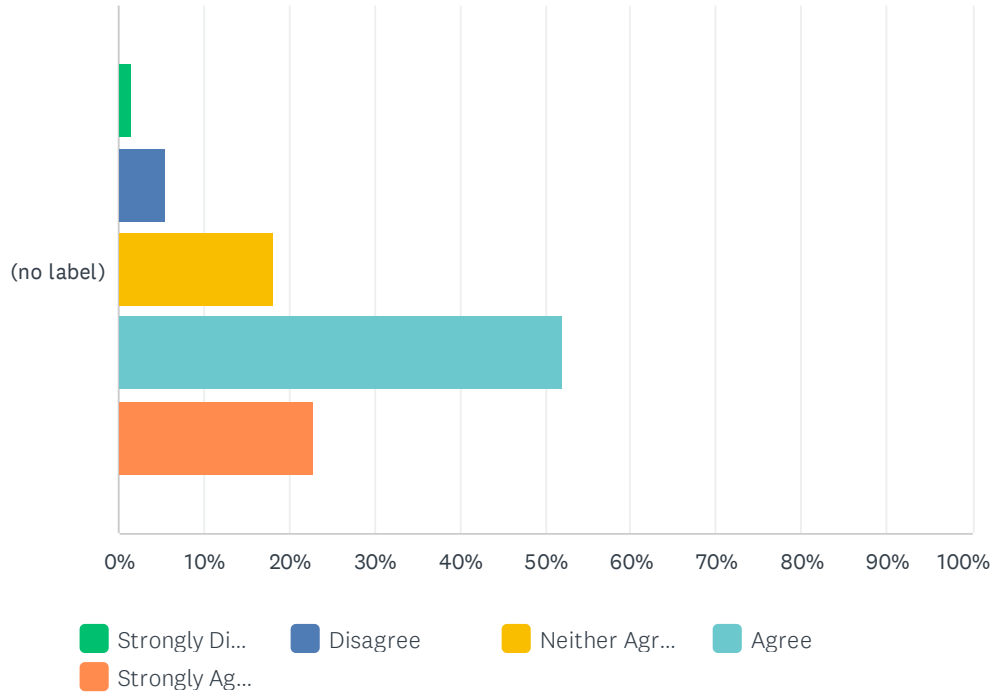
10	And also to allow for those individuals who do not have the physical or financial means to be in-person to still have a voice.	7/17/2024 4:48 PM
11	this is an equitable and inclusive practice	7/17/2024 4:45 PM
12	This makes the process more transparent and democratic.	7/17/2024 2:59 PM
13	The goal of increasing public involvement, beyond the current situation, would need to be clarified.	7/17/2024 1:40 PM
14	I would suggest that the FDA allow public comment in the form of either written or recorded video submission in lieu of personal attendance at a mtg. Live participation remotely will likely result in technical mishaps and delays so I would not allow this activity.	7/17/2024 12:12 PM
15	Virtual participants should have to meet certain IT parameters to participate as to Internet speed, et al to assure a smooth virtual meeting and prevent frozen screens et al	7/17/2024 11:59 AM
16	Videoconference is not the optimal means for achieving this objective	7/17/2024 11:48 AM
17	I think the system worked well before. I would have no objection to allow remote participation but would not favor increasing the time available for open public comment.	7/17/2024 11:24 AM
18	I have not observed such meetings so do not have a feel for how effecive or distracting having remote participation is.al	7/17/2024 11:09 AM
19	Remote broadcast could and should be allowed to ensure that people with fewer means can still participate, but in-person meetings are MUCH more effective and should be required of panelists and members.	7/17/2024 10:55 AM
20	Participation would have to limited as the meeting could definitely provide an agenda for some politically active groups	7/17/2024 10:44 AM
21	While allowing for remote participation is inclusionary, it adds to difficulty if the remote participant is doing more than listending. I do think that all AdComms should be broadcast on the internet to allow for people to hear discussion and debate.	7/17/2024 10:08 AM
22	difficult to determine but if remote participation is allowed, need to have screening of people and need to have strict time limits	7/16/2024 11:09 PM
23	in person participation is best and ideal	7/14/2024 6:00 PM
24	public comments can be emotional and even controversial. Social media has shown us that being able to hide behind a computer screen may allow for more inflammatory comments that might not otherwise be shared if in person	7/13/2024 11:43 PM
25	Those providing public comments should disclose who they are and if they are representing an organization.	7/13/2024 4:19 PM
26	It would best serve the public as distance and cost may prohibit attendance at a meeting which a person would want to attend.	7/13/2024 11:04 AM
27	This would allow people to participate whose travel has not been paid for by their drug-company-sponsored "advocacy organization"	7/13/2024 9:13 AM
28	Don’t believe this is needed. The issue is to have various issues and concerns raised. After 30 or 40 presentations for a single topics virtually all of the different concerns and opinions have been raised.	7/12/2024 6:29 PM
29	Yes, this seems entirely reasonable. I do think that FDA advisers should all be present in person. For the open public comment, speakers could be virtual.	7/12/2024 4:41 PM
30	We are able to read the posted comments in advance of the meeting. My concern is that is the open public comment part of the meeting can be very long even in person so allowing for remote comments would further extend the time. And many of the comments are redundant.	7/12/2024 3:12 PM
31	Public involvment is important, but is not the driving force for FDA approval. Testimony during the meeting is relevant and should not become a free-for-all.	7/12/2024 2:42 PM
32	Seems reasonable.	7/12/2024 1:01 PM
33	Limited number	7/12/2024 12:14 PM

34	i do not feel that it will make a difference in volume. I feel that those truly interested and invested will be present	7/12/2024 12:12 PM
35	Remove viewing of the proceedings is always helpful	7/12/2024 12:05 PM
36	I did not participate after COVID so I cannot say how well that worked.	7/12/2024 11:54 AM
37	Remote participation should always be included to assure broad representation from the public.	7/12/2024 10:34 AM
38	I don't see a problem with remote comments	7/12/2024 10:23 AM
39	In person for ODAC members, OK to have zoom for patients.	7/12/2024 9:30 AM
40	within reason	7/12/2024 9:11 AM
41	In principle it sounds like a good idea but I do not know anything about how successfulness of the COVID-19 program.	7/12/2024 8:56 AM
42	there is no reason to not allow remote public comment. the thoughts of presenters are not enhanced by in-person presentation and this clearly overcomes burden and costs of travel to present for what is only 10 minutes at most.	7/12/2024 7:37 AM
43	Because of disabilities this may be important	7/11/2024 11:19 PM
44	I have not found the virtual meeting format to be beneficial now that COVD-19 restrictions have been lifted.	7/11/2024 10:20 PM
45	In-person meetings are much more effective and efficient. One virtual meeting in particular led to one of the biggest issues in FDA history because communication was not clear (aducanumab).	7/11/2024 9:44 PM
46	This could kill a whole day. If there is a good reason for a remote entry, FDA could entertain the idea, but otherwise if all the public information is made available there weeks in advance, accepting written comments to the docket and provided to the panel members at least a week before the meeting would likely be better handled.	7/11/2024 9:25 PM
47	I have not rejoined any advisory committees because I am not willing to travel to DC. If I could participate remotely, I would volunteer to serve again.	7/11/2024 8:48 PM
48	Agree, but would have to be very organized.	7/11/2024 8:15 PM
49	consider incorporating written comments not just in person via remote	7/11/2024 8:11 PM
50	Yes, but with the foreknowledge that remote participation will not have equal impact as in-person participation.	7/11/2024 7:41 PM
51	presentation/discussion time must be carefully limited	7/11/2024 6:51 PM
52	Having attended both in person and virtual, the in person are better. But I am also local. Virtual participation should be allowed for when it is hard to travel but an expert offers valuable insight. From the perspective of a working parent who finds it hard to travel.	7/11/2024 6:41 PM
53	Concerned about authenticity and professionalisms of off-site interaction and direction of virtual interactions in future panels	7/11/2024 6:25 PM
54	Yes, I'm sure that will increase the number of comments and prolong the meeting, but I doubt that will improve the process.	7/11/2024 6:13 PM
55	the concern here is that you will open the flood gates and might get a ton of people from the public. Which i guess is a good thing but can bog things down too. Perhaps need to establish criteria for participation?	7/11/2024 6:12 PM
56	Question is unclear. Would support remote participation of public but would strongly encourage in-person participation only by committee members.	7/11/2024 5:58 PM
57	For some patients and their families, travel may be burdensome or not possible yet their voice is important.	7/11/2024 5:30 PM
58	An 'average patient' may have trouble flying to DC or taking the time off. So 100% agree.	7/11/2024 5:26 PM
59	I was not a participant in advisory meetings during the pandemic . But I imagine they might be more focused than public visual presentations	7/11/2024 5:22 PM

60	Might have to limit the number who get a speaking slot	7/11/2024 5:15 PM
61	All the meetings can appropriately be done remotely. Because this reduces cost and burden on the participants, it should lower the bar for having an advisory meeting. For example, a followup meeting could occur if additional information is to be provided based on discussion	7/11/2024 5:07 PM
62	broad participation is acceptable, if well coordinated. In person should be prioritized	7/11/2024 5:00 PM
63	Particularly in very vulnerable populations!	7/11/2024 4:48 PM
64	as well as allow for in person. Hybrid allows for more participation. Virtual should NEVER replace entirely.	7/11/2024 4:47 PM
65	Members of the public may not have the resources to travel to the DC area.	7/11/2024 4:43 PM
66	Online participation during a meeting seems useful but could be abused as there could be too many attempting to participate. Accessing on line without participation seems useful.	7/11/2024 4:42 PM
67	Yes, this improves accessibility.	7/11/2024 4:35 PM
68	the future is here. Embrace it.	7/11/2024 4:32 PM
69	They should have to show up, like everyone else.	7/11/2024 4:25 PM
70	personally, I think the conversation is much more effective when it's live, but that's not to say they can't be broadcast simultaneously and somebody monitoring the feed for Relevant questions	7/11/2024 4:16 PM
71	This is the way many communications are taking place now even after Covid and so continuing is reasonable.	7/11/2024 4:10 PM
72	Yes please make it cheap convenient and easy to participate. But keep the timeframes rigid like no more than 5 minutes each! The potential for crazy time-wasting questions is enormous particularly in our hyper-fractured political environment.	7/11/2024 3:56 PM
73	asfsafasfasf	7/10/2024 12:12 PM

Q9 The FDA currently makes advisory committee briefing documents and other materials publicly available 2 business days prior to the meeting. To increase public involvement, the FDA should make these materials available earlier so the public can decide whether to attend these events, listen online, and/or prepare their written or oral comments for the meeting.

Answered: 408 Skipped: 6



	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
(no label)	1.47% 6	5.64% 23	18.14% 74	51.96% 212	22.79% 93	408	3.89

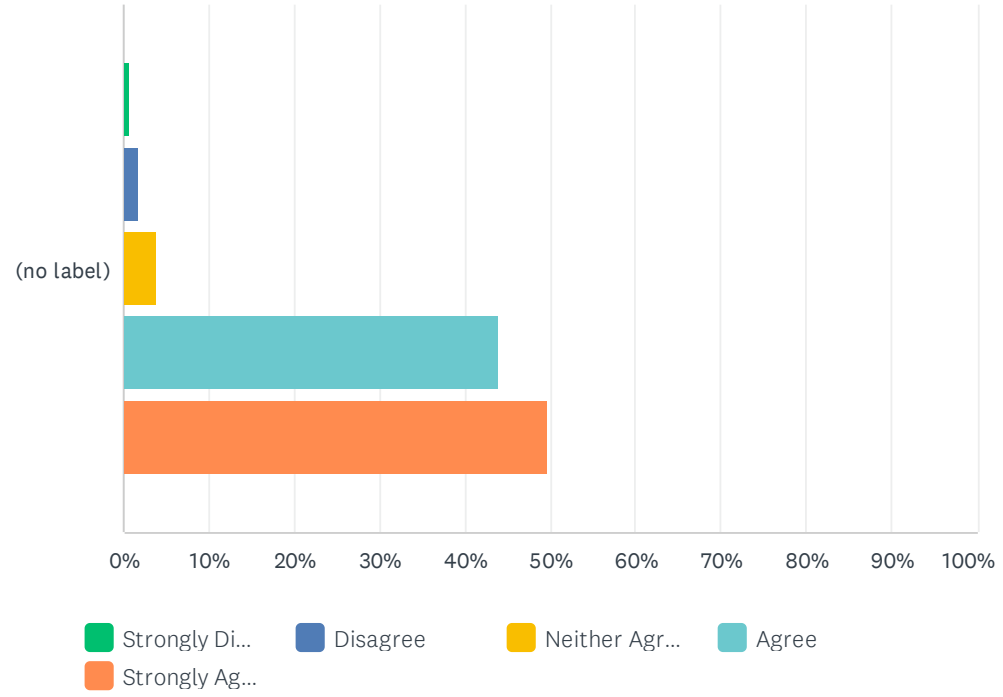
#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	No harm in this and it makes disclosure more fair...	7/20/2024 11:15 AM
2	I would suggest availability of Advisory Committee briefing documents 5 business days prior to the meeting.	7/19/2024 1:35 PM
3	somewhat earlier would be better	7/18/2024 1:54 AM
4	There may be reasons for different periods of availability depending on the nature of the treatment being considered	7/17/2024 10:59 PM
5	How are such announcements make available to the public? It might take some time for consumer and advocacy groups to prepare statements and pose questions to the OCAC. I would question whether 2 days is adequate.	7/17/2024 7:25 PM
6	depends a bit on the reasons behind the current 2 day period but if only administrative reasons, would consider extending the time period	7/17/2024 6:06 PM
7	This problem can be somewhat alleviated by allowing remote participation. Extra lead time can	7/17/2024 5:53 PM

	lead to more coordinated advocacy or opposition.	
8	Would be helpful, though, I don't see this as mandatory.	7/17/2024 4:48 PM
9	I would suggest 5-days.	7/17/2024 2:59 PM
10	Especially since the volume of briefing materials can be thousands of pages	7/17/2024 2:29 PM
11	This may be difficult to accomplish as some materials are likely being tweaked right up to the meeting	7/17/2024 1:10 PM
12	a 1 week advance notice is more reasonable.	7/17/2024 12:12 PM
13	7 working business days to permit adequate review of the data and research of data	7/17/2024 11:59 AM
14	I think the current system works well. It allows enough opportunity for public comment. I do not think ADCOM members need more detailed input from the open public hearing beyond what currently is provided.	7/17/2024 11:24 AM
15	Ha -- see above :)	7/17/2024 11:02 AM
16	perhaps one week is more reasonable ?	7/17/2024 10:55 AM
17	1-2 weeks	7/17/2024 10:41 AM
18	2 days is difficult to prepare and FDA requires these docs be submitted in advance. Should allow for adequate time to read as most Briefing Docs are in excess of 100 pages.	7/17/2024 10:08 AM
19	Not sure of the logistics of having the documents available much earlier.	7/16/2024 11:44 PM
20	Two days an enough time to allow folks to review matters.	7/15/2024 6:20 PM
21	2 days too short	7/15/2024 3:33 PM
22	Although I agree with the statement I recognize there are other consideration's such as impact on equity trading. I modest increase such as 5 days of less would limit the amount of time that individuals and or groups would seek to influence committee members.	7/15/2024 1:19 PM
23	it could be helpful to the public to allow 3-4 business days.	7/15/2024 10:10 AM
24	I would agree that earlier availability might be particularly helpful to people who might need to travel to attend a meeting.	7/15/2024 9:36 AM
25	public comment has been adequate so the current process seems appropriate. too much time may allow for more lobbying and increase the risk of influence and bias	7/13/2024 11:43 PM
26	Given the information with plenty of notice will allow participants to be better informed and prepared if wish to make comments	7/13/2024 11:04 AM
27	This would work best with time for structured pre-work as noted previously	7/13/2024 10:17 AM
28	One week advance notice would be great; two weeks advance notice would be perfect.	7/12/2024 8:11 PM
29	Two days in advance is probable adequate.	7/12/2024 6:29 PM
30	Agreed, it would be good to have them earlier, although sometimes that doesn't seem feasible. Having access to at least brief information online would seem reasonable.	7/12/2024 4:41 PM
31	I think a week is a more reasonable figure	7/12/2024 2:11 PM
32	how much will this slow down the approval process?	7/12/2024 1:40 PM
33	Maybe a little earlier, but not weeks or months in advance--that wouldn't be fair to the sponsor, who wants to put their latest and best foot forward for the meeting.	7/12/2024 12:23 PM
34	would recommend 1 week. Not too early, but a little more time would be good.	7/12/2024 11:58 AM
35	I would think a week is a better advance notice.	7/12/2024 11:54 AM
36	Post documents when available even if not complete, but indicate all that are expected.	7/12/2024 11:26 AM
37	Yes, it seems reasonable to extend this, to maybe a week before.	7/12/2024 10:23 AM
38	30 days seems like a reasonable interval	7/12/2024 9:11 AM

39	i think you could provide earlier but i doubt it would impact public involvement on the majority of topics discussed.	7/12/2024 7:37 AM
40	Not sure how that will help improve decisions	7/11/2024 11:19 PM
41	I haven't considered it to be an issue, and the short timeline helps prevent any type of influence.	7/11/2024 10:20 PM
42	There is a practical limit to how far in advance the materials can be made available.	7/11/2024 9:44 PM
43	I have covered this in my prior comments. The current process basically withholds information until it's too late to prepare. The rule should be a three week minimum before the meeting, no excuses. FDA should publish the name of the person responsible for providing the information three weeks in advance so there is accountability.	7/11/2024 9:25 PM
44	Matterials should be made available at least a week, if not more, in advance of the meeting.	7/11/2024 8:48 PM
45	along with define rules of participation and firm deadlines for comments	7/11/2024 8:11 PM
46	This decision depends on FDA resources.	7/11/2024 7:41 PM
47	5-7 days advance notice	7/11/2024 6:51 PM
48	probably a week instead of 2 days would be more sufficient	7/11/2024 6:35 PM
49	Two business days is not adequate to allow serious consideration and craft a response.	7/11/2024 6:13 PM
50	If possible, would be desirable, but documents are often changing up until the meeting.	7/11/2024 5:55 PM
51	a week ahead woudl be ok	7/11/2024 5:38 PM
52	When practical	7/11/2024 5:33 PM
53	A one week lead time should not be burdensome to the FDA but allows ample time for public review.	7/11/2024 5:30 PM
54	It's probably rare that specific comments or tone of the BB would affect public participation.	7/11/2024 5:26 PM
55	I am not sure what the ideal window of time would be. To make travel plans, you could be talking about weeks which may not be feasible for sponsors.	7/11/2024 5:22 PM
56	I suspect that 2 business days is sufficient for those public who have an interest in participation of the particular item.	7/11/2024 5:22 PM
57	FDA staff are working under tight deadlines, need adequate time to finalize documents	7/11/2024 5:15 PM
58	10 business days seems appropriate.	7/11/2024 5:02 PM
59	two days is reasonable and drives review to the final end deliberations of the day	7/11/2024 5:00 PM
60	It’s just an internal deadline for FDA and the Sponsor	7/11/2024 4:55 PM
61	Agree in principle but this is very challenging from a time and resource standpoint.	7/11/2024 4:48 PM
62	I agree that a longer lead time would benefit the public.	7/11/2024 4:43 PM
63	2 days seems too short. One week seems better.	7/11/2024 4:42 PM
64	Yes, the consumer comments will be significantly more organized with more time	7/11/2024 4:35 PM
65	Why not sooner? Pick a reasonable time frame.	7/11/2024 4:32 PM
66	Earlier OK, but not more than a week or two earlier.	7/11/2024 4:25 PM
67	Two days is reasonable. Perhaps announcing when the materials will be posted could be 7-10 days prior.	7/11/2024 4:10 PM
68	Yes make everything as transparent as possible	7/11/2024 3:56 PM
69	asfasfasfa	7/10/2024 12:12 PM

Q10 The FDA should establish clear public communication procedures in the event their actions disagree with advisory committee votes. This includes a thorough explanation of the advisors' recommendation and the FDA's reasoning for the discordant action.

Answered: 406 Skipped: 8



	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE	TOTAL	WEIGHTED AVERAGE
(no label)	0.74% 3	1.72% 7	3.94% 16	43.84% 178	49.75% 202	406	4.40

#	ADDITIONAL AND/OR CLARIFYING COMMENT(S)	DATE
1	The Advisory Committee process should be focused on obtaining reasoning/insights/recommendations, rather than votes, from the Advisory Committee. Hence, the FDA should communicate reasoning about their judgments/decisions, enlightened by their insights that include those obtained from the Advisory Committee.	7/23/2024 1:07 PM
2	The aducanumab decision certainly makes this point...	7/20/2024 11:15 AM
3	I agree in principle, but the particular approach must be designed to facilitate constructive feedback in the particular situation.	7/17/2024 9:29 PM
4	Yes - in the interest of complete disclosure. Again, assure literacy levels of such communications.	7/17/2024 7:25 PM
5	I don't know how the FDA should address this discordance. This being said, the fiasco concerning Aduhelm cannot be repeated.	7/17/2024 5:53 PM
6	This occurs currently, but no harm in reiterating.	7/17/2024 2:59 PM
7	I'm ok with disagreement but it should be explained	7/17/2024 2:45 PM

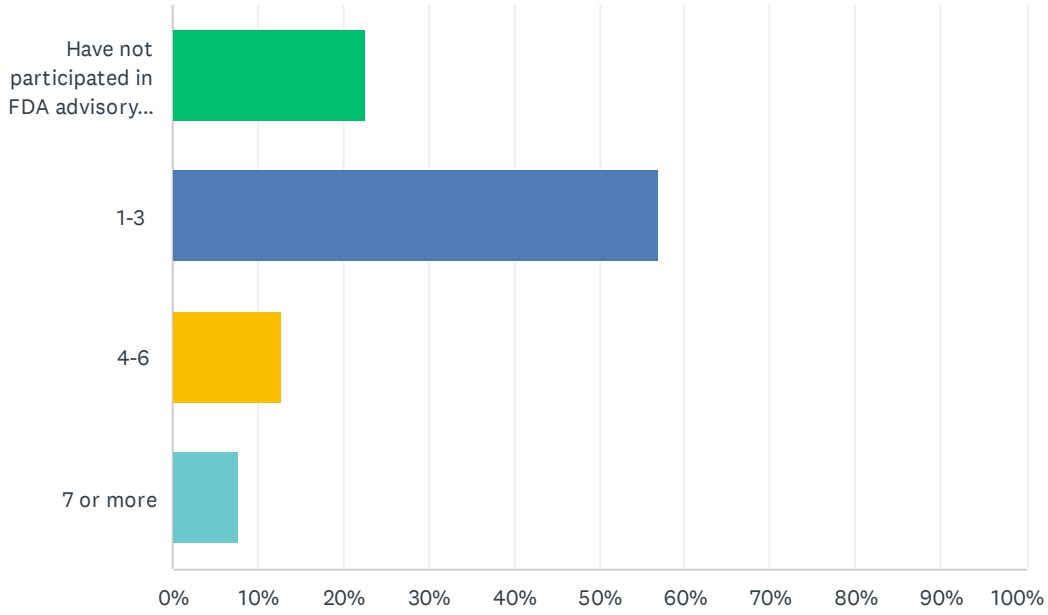
8	Feedback to the committee is helpful, perhaps at a subsequent meeting. I do not believe much time should be spent on this though, no need to litigate FDA's decisions	7/17/2024 2:29 PM
9	The importance of this kind of communication has been underscored in recent years by the approval of anti amyloid antibody treatment for alzheimer's disease. The opinions of the advisory committee, and their distress at the FDA's decision, were very public. The FDA did not adequtely justify their decision to go against the recommendation. As the data from the clinical trials were publicly available, interested parties (myself included) were able to review and evaluate the reasons for the FDA's decision. Many, including myself, did not find these convincing or compelling given the available data.	7/17/2024 2:12 PM
10	The likely negative downstream consequences of this would be greater than the upside. If the goal is to make it more difficult for the FDA to not follow AC's recommendation, that reduces regulatory autonomy with attendant risks.	7/17/2024 1:40 PM
11	this transparency is important and also helps the committee members too.	7/17/2024 12:12 PM
12	This is reasonable. ADCOM votes require an absolute yes or no, and comment from ADCOM members often reveals that they struggled to commit to this absolute choice. Thus, the vote talley can imply a clearer recommendation from the ADCOM than is the actuality. It is reasonable for the FDA to deal with this in explaining their decisions when not "apparently consistent" with the ADCOM vote. I feel strongly that ADCOM votes should not be binding on the FDA.	7/17/2024 11:24 AM
13	Clear explanations and transparency are always good attributes of a process.	7/17/2024 11:09 AM
14	Advisory Committees are advisory, not governing, but we put immense effort in getting to a consensus opinion. it should not be lightly ignored.	7/17/2024 10:47 AM
15	Believe that FDA should provide rationale for their rulings based on the data so that drug developers and patients/consumers understand b/r and rationale.	7/17/2024 10:08 AM
16	The committee is advisory. The decision making is still the action of the FDA.	7/15/2024 6:20 PM
17	Logical	7/15/2024 3:33 PM
18	This is an ongoing problem that requires repeated messaging. All AC decisions should include a statement that reinforces the advisory rather than decision-making role of the various committees	7/15/2024 1:19 PM
19	This is an important point. If the FDA takes a different course than what is recommended, it should be clearly communicated and transparent	7/15/2024 11:58 AM
20	Agree completely so all involved know what the decision hinged on.	7/15/2024 9:36 AM
21	This would require Congress approval I believe	7/15/2024 8:40 AM
22	if FDA is going to go against advisory committee recs they need to strongly and clearly clarify why this is in the patient's best interest	7/14/2024 6:00 PM
23	transparency is essential in the process that can have such tremendous implications	7/13/2024 11:43 PM
24	This provides better understanding of why a drug was or was not approved and how it could affect public health and well being.	7/13/2024 11:04 AM
25	This would allow a stronger public awareness of the process and I think strengthen public support	7/13/2024 9:13 AM
26	This is a critical issue as the advisory committee is often voting on specific issues and not all issues related to the future use of a medication. I believe the FDA should continue with the current format. What would help is greater explanations of what the advisory committee voted on and that is best done with a tailored press release within a day or two after the advisory committee meeting so that document can be used a retrospective guidepost as needed once the FDA makes a final determination for medication use and the indications for that usage.	7/12/2024 6:29 PM
27	Yes, we would like clarity on why our government agencies are disagreeing with advisory committees. That would be very helpful.	7/12/2024 4:41 PM
28	depends on circumstances that led to difference	7/12/2024 3:08 PM
29	Transparency is always the best course of action	7/12/2024 2:11 PM

30	This should be like the supreme court. Let the FDA statement say why they disagree w/ panel recomendations AND let the chair of the panel write an open response to the FDA position (concerns, consequences, need for further action or study)	7/12/2024 1:45 PM
31	I think this would be very helpful to both the scientific community and public.	7/12/2024 1:01 PM
32	I think the advisory committee members would benefit from knowing why the FDA disagreed with the vote, but that is the FDA's prerogative and their charge. The advisory committees are just that--advisory--and the FDA is very thorough in its analyses.	7/12/2024 12:23 PM
33	It is only fair that the FDA fully explain why their decision was discordant with that of the AC.	7/12/2024 11:18 AM
34	This disclosure would be welcome	7/12/2024 10:34 AM
35	Yes, they should explain why their actions disagree, but I don't think it needs to be in depth or very detailed.	7/12/2024 10:23 AM
36	i agree with clarifying why the agency would choose to not follow advisory committee recommendation in order to maintain public faith in the process. Of course the public may not be aware that the agency makes decisions on lot of potential new drugs/devices without seeking input from relevant advisory committees.	7/12/2024 7:37 AM
37	If FDA goes against a panel, it may be appropriate but providing an explanation is appropriate	7/11/2024 11:19 PM
38	I think it could go a long way to helping to understand when outcomes differ from recommendations.	7/11/2024 10:20 PM
39	Their rationale is communicated in a letter to the AC chair which is a matter of public record.	7/11/2024 9:44 PM
40	FDA only holds a panel meeting if they have to and to address questions that have not been addressed before. They do all they can to guide the panel to the answers they want and it's very entertaining when the panel starts to go in another direction. Therefore, it's critical FDA explain the scientific basis for a disagreement with the panel. I'm sure they can come up with reasons many won't buy, but make them go through the process.	7/11/2024 9:25 PM
41	This a pretty ridiculous, leading question. Operationalize "clear public communication"? What is a "thorough" explanation - who will judge? And action is "discordant" if the FDA disagrees? What if the advisors are wrong--is that discordant? You, the creators of this survey, have lost my trust. You don't seem to have the skills to pull off this survey. Will my opinion make it into the final report or will you bury it?	7/11/2024 7:41 PM
42	I think this is critical for transparency	7/11/2024 6:35 PM
43	Furthermore, the FDA should not be allowed indefinite extensions of their allowed 90 day response time.	7/11/2024 6:13 PM
44	Would be helpful in improving public trust in decisions made.	7/11/2024 5:55 PM
45	yes that is important	7/11/2024 5:38 PM
46	Transparency is key.	7/11/2024 5:30 PM
47	Super slight disagree, I can imagine having to include a rationale, not on the label, in such circumstances. I think that would be fair to the public and the panelists.	7/11/2024 5:26 PM
48	This is the only way for the public to have trust in the process. I don't think the majority of people in the country understand the responsibilities of the FDA.	7/11/2024 5:22 PM
49	This would serve the interest of better transparency and psupport the integrity of the FDA review	7/11/2024 5:22 PM
50	This is important - otherwise it is a fools errand to participate on the panel if the FDA does not follow that adcom vote	7/11/2024 5:07 PM
51	Standard procedures would be of value to increase public trust. Variable response approaches should not be seen to reflect the topic discussed.	7/11/2024 5:00 PM
52	Transparency would help.	7/11/2024 4:55 PM
53	If you are going to ask their opinion address the reason/data as to why you disagree...	7/11/2024 4:48 PM

54	As Ad Com members we never hear what happens unless we read it in the media.	7/11/2024 4:47 PM
55	Explaining the rationale for decisions leads to better decisions.	7/11/2024 4:43 PM
56	At minimum this should be explained to members of the committee. I don't have a strong opinion about whether it is communicated to the public at large.	7/11/2024 4:42 PM
57	Yes - transparency is key	7/11/2024 4:35 PM
58	OK, but the committee might not agree with the FDA's "thorough explanation of the advisors' recommendation."	7/11/2024 4:25 PM
59	My personal opinion is that it's ridiculous when the FDA goes against the panel recommendation. unless there is clear additional information around patient safety. The panel is made up of experts. why convene them if you're not going to follow the recommendations	7/11/2024 4:16 PM
60	Communications is everything and letting the public know when and why they disagree is what a public institution should do.	7/11/2024 4:10 PM
61	I'm used to the FDA ignoring some of the advisory committee's recommendations, a brief explanation for disagreement is appropriate. That would have cleared up the mess around Aduhelm, for example.	7/11/2024 3:56 PM
62	asfsaasfasfas	7/10/2024 12:12 PM

Q11 How many FDA advisory committee meetings have you participated in over the past 5 years (i.e., Jan 2019 through June 2024)?

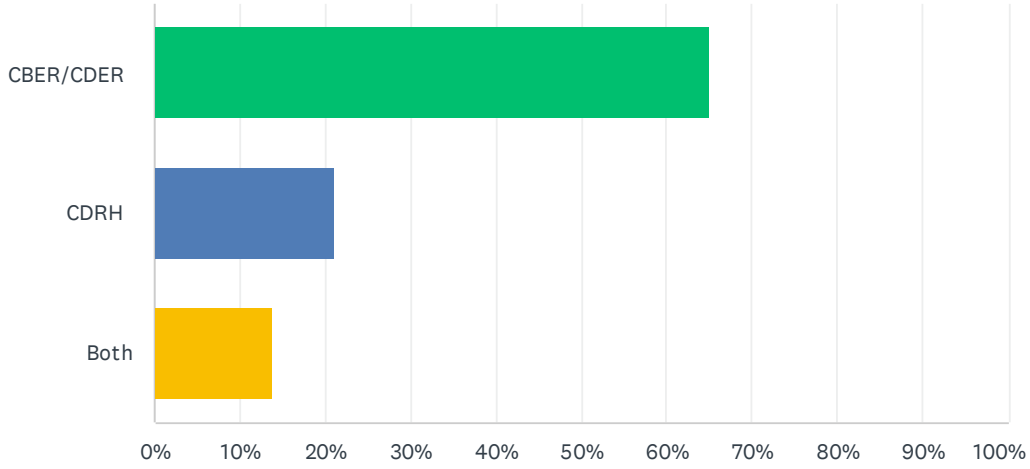
Answered: 406 Skipped: 8



ANSWER CHOICES	RESPONSES	
Have not participated in FDA advisory committee meetings in the past 5 years	22.66%	92
1-3	56.90%	231
4-6	12.81%	52
7 or more	7.64%	31
TOTAL		406

Q12 For what Centers?

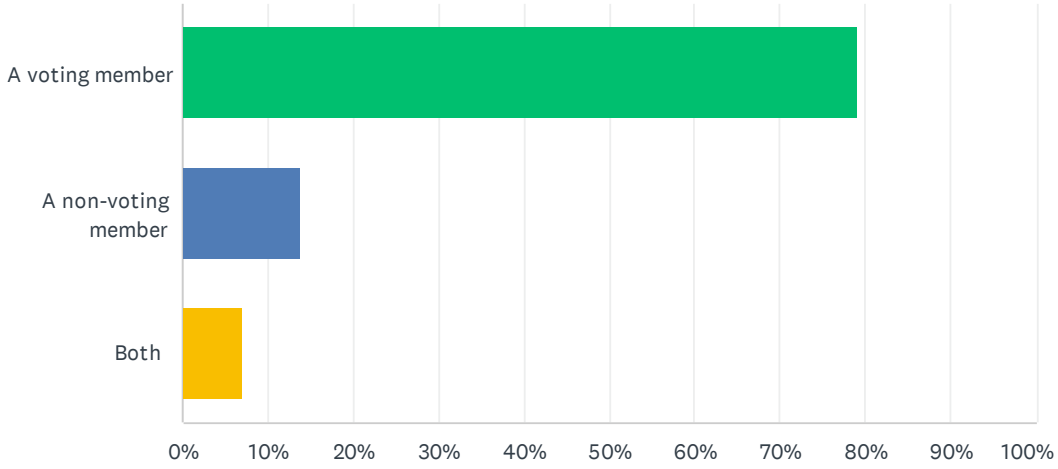
Answered: 363 Skipped: 51



ANSWER CHOICES	RESPONSES	
CBER/CDER	65.01%	236
CDRH	21.21%	77
Both	13.77%	50
TOTAL		363

Q13 Have you participated as

Answered: 374 Skipped: 40



ANSWER CHOICES	RESPONSES	
A voting member	79.14%	296
A non-voting member	13.90%	52
Both	6.95%	26
TOTAL		374