

1 **PREVALENCE OF TIES TO INDUSTRY-FUNDED ORGANIZATIONS**

2 **AMONG PATIENT AND CONSUMER REPRESENTATIVES ON FDA ADVISORY**
3 **COMMITTEES**

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ABSTRACT

Introduction

FDA advisory committees are primarily composed of scientific
experts, but also include a patient representative and a
consumer representative providing public perspectives. Although
the FDA has enacted policies to curb conflicts of interest
common among its scientific members, it has paid less attention

1 to potential conflicts arising from patient and consumer
2 representatives who have ties to organizations financially
3 supported by pharmaceutical companies.

5 **Methods**

6 We analyzed the prevalence of industry funding of advocacy
7 organizations in which patient and consumer representatives were
8 actively involved in the year they attended FDA advisory
9 committee meetings between 2013 and 2022.

11 **Results**

12 Between 2013 and 2022, nearly two in five (38%) FDA advisory
13 committee meetings included either a patient or consumer
14 representative with active ties to a pharmaceutical-funded
15 advocacy organization. For several FDA committees, this share
16 was greater than 50%. More than 1 in 10 (11%) advisory committee
17 meetings included a representative affiliated with an
18 organization receiving funds from the sponsor of the drug under
19 review.

21 **Conclusion**

1 These prevalence rates show that these organizational
2 relationships extend beyond isolated cases and signal a broader
3 problem warranting FDA policy attention.

4

5 **Key Takeaways**

- 6 • The FDA has well-established conflict-of-interest policies
7 for its scientific advisory committee members but less
8 developed policies for patient and consumer
9 representatives, especially related to industry funding of
10 these members' advocacy organizations.
- 11 • Between 2013 and 2022, nearly two in five (38%) FDA
12 advisory committee meetings included a patient or consumer
13 representative with active ties to a pharmaceutical-funded
14 advocacy organization. For some committees, this share was
15 greater than 50%, and in some cases, the organization
16 received financial support from the product sponsor.
- 17 • These prevalence rates show that representatives with ties
18 to advocacy organizations funded by pharmaceutical
19 companies or product sponsors frequently participate in FDA
20 advisory committee meetings and signal a broader problem
21 warranting FDA policy attention.

1 Introduction

2 The FDA periodically convenes advisory committees consisting of
3 external experts to advise on drug approvals and related
4 technical issues. These committees are primarily composed of
5 scientific experts such as clinicians and biomedical
6 researchers, but also, by law, include a consumer representative
7 to provide the perspective of the general public.^{1,2} Since 1991,
8 the agency has also appointed a patient representative to
9 provide the perspective of patients or caregivers affected by
10 the condition under discussion.^{3,4}

11
12 Although the FDA has enacted policies to curb conflicts of
13 interest (COIs) common among its scientific members,⁵ it has paid
14 considerably less attention to potential conflicts affecting
15 patient and consumer representatives. The agency has largely
16 focused on members' direct financial ties to industry, which are
17 more prevalent among scientific members but infrequent among
18 patient and consumer representatives. Rather, among non-
19 scientific members, indirect ties to industry - especially
20 through affiliations with advocacy organizations that receive
21 industry funding - are a particular concern. Studies have
22 estimated that 68% of patient advocacy organizations⁶ and 83% of
23 the largest patient organizations⁷ receive donations from drug,

1 device, and biotechnology companies. Moreover, 12% of these
2 patient organizations reported receiving more than half of their
3 funding from industry.⁶ Thus, it is possible that a large number
4 of patient and consumer representatives on FDA advisory
5 committees have COIs related to organizational funding, and some
6 of these conflicts may involve substantial financial
7 dependencies, creating a risk of undue industry influence.

8
9 We analyzed the prevalence of industry funding of advocacy
10 organizations in which patient and consumer representatives were
11 actively involved in the year they attended FDA advisory
12 committee meetings between 2013 and 2022.

14 **Data and Methods**

15 Names and organizational affiliations of patient and consumer
16 representatives attending FDA drug advisory committee meetings
17 were extracted from meeting rosters and transcripts, which were
18 downloaded from the FDA website.⁸ Other organizational activities
19 of these representatives - i.e., organizational affiliations not
20 disclosed at FDA meetings - were obtained through online
21 searches. Organizations were included only if they were patient
22 advocacy organizations, patient support groups, patient

1 informational groups, or medical research foundations.
2 Affiliations were only included if: (1) the representative held
3 a senior leadership role with the organization, such as board
4 member, executive director, or founder ("executive leadership");
5 (2) their stated position title indicated leadership
6 responsibilities ("other leadership"); or (3) there was evidence
7 of repeated engagement and activities ("active involvement"). We
8 included affiliations even if the roles appeared to be unpaid
9 but excluded affiliations that were determined to be short-term
10 in duration (i.e., less than 3 months), such as participation in
11 annual events, awareness campaigns, training programs, and
12 competitions. Donating to an organization was not considered to
13 be an affiliation. Affiliations were included if they were
14 active in the calendar year of the representative's meeting
15 appearance.

16
17 Donors to affiliated organizations were extracted from
18 organizational annual reports and websites and filtered to
19 include only pharmaceutical companies. Pharmaceutical donors to
20 advocacy organizations were included if the representative's
21 affiliation was active in the year of the meeting and the
22 donation was made that same year. If donors to an advocacy
23 organization could not be identified for a given year, we

1 assumed that the organization had no pharmaceutical company
2 donors in that year. Sponsors of drugs under review were
3 identified from the list of pharmaceutical donors.

4
5 We calculated the share of meetings in which at least one
6 patient or consumer representative was actively involved with an
7 organization that received pharmaceutical funding, and
8 separately, sponsor funding. Shares were calculated for the full
9 10-year period, annually, and by committee.

10
11 Data collection began in 2023 and extended through 2024, with
12 data cleaning and matching finalized in 2025, and data analysis
13 completed in 2026. Methods are described in detail in Appendix
14 A1.

15 16 **Results**

17 Between 2013 and 2022, 98 patient representatives and 39
18 consumer representatives attended 234 voting meetings (Table 1,
19 Panel A). On average, each meeting included one patient
20 representative and one consumer representative. Patient
21 representatives had a median of 1 advocacy organization
22 affiliation when they attended an advisory committee meeting

(mean 0.8), while consumer representatives had a median of zero affiliations (mean 0.9) (Table 1, Panel B).

In the full sample, 58.8% of patient representatives and 48.7% of consumer representatives had an affiliation with an advocacy organization (Table 1, Panel C). Of those with affiliations, a majority of patient representatives (50.9%) and consumer representatives (73.7%) had executive leadership roles such as board member, executive director, or founder in that organization.

Over the sample period, 38.0% of advisory committee meetings included either a patient representative or a consumer representative actively involved with a pharmaceutical-funded advocacy organization (Appendix A2). Patient representatives with such ties were present at 25.8% of meetings, and consumer representatives with those ties were at 17.4% of meetings (Figure 1, Panels A and B).

More than 1 in 10 (10.7%) meetings included either a patient or a consumer representative affiliated with an organization that received funding from the sponsor of the product under review

(Appendix A3). About 7% of meetings included a patient representative, and 5% a consumer representative, affiliated with a sponsor-funded organization (Figure 1, Panels C and D).

All but one FDA advisory committee had meetings with patient representatives tied to pharmaceutical-funded advocacy organizations (Figure 2, Panel A). The committee with the greatest share of meetings involving patient representatives with such ties was the cardiovascular drugs committee (52.6%). Only the dermatologic/ophthalmic drugs committee had no meetings with patient representatives tied to pharmaceutical-funded organizations.

Seven of 12 advisory committees had meetings with consumer representatives tied to pharmaceutical-funded advocacy organizations (Figure 2, Panel B). The committees with the greatest share of meetings involving consumer representatives with such ties were the nervous system drugs committee (88.9%) and the gastrointestinal drugs committee (66.7%).

There was similar variation across committees in the share of patient and consumer representatives affiliated with

1 organizations receiving funding from drug sponsors (Figure 2,
2 Panels C and D). For patient representatives, prevalence was
3 highest in meetings of the cardiovascular drugs committee
4 (15.8%) and the cancer drugs committee (15.2%). For consumer
5 representatives, the highest share was in meetings of the
6 arthritis drugs committee (26.7%).

8 **Discussion**

9 We found that nearly two in five (38%) advisory committee
10 meetings included either a patient or consumer representative
11 affiliated with a pharmaceutical-funded advocacy organization.
12 For several committees, this share was greater than 50%.

13
14 Prior research has found that 19% of patient and consumer
15 representative appearances at FDA meetings between 2009 and 2012
16 had industry conflicts of interest of any kind, with 9%
17 attributed to a relationship between industry and a patient
18 advocacy organization.⁹ Our estimates of advocacy organization
19 industry ties are considerably higher, perhaps due to our
20 inclusion of a broader range of organizations and roles, as well
21 as our use of a range of web sources to identify active
22 involvement in these organizations.

1
2 At the same time, we found prevalence rates that are lower than
3 the reported share (68%-83%) of patient advocacy groups
4 receiving industry funding.^{6,7} These organizational-level funding
5 rates, however, include support from device and biotechnology
6 firms as well as pharmaceutical companies. In addition, the FDA
7 could be making efforts to select patient and consumer
8 representatives who are not connected to organizations known to
9 receive industry funding.

10
11 We also examined patient and consumer representative
12 affiliations to organizations that received funding from the
13 drug sponsor in the year of the meeting. We found that more than
14 1 in 10 (11%) advisory committee meetings included a
15 representative affiliated with a sponsor-funded advocacy
16 organization. For several committees, this share was 15% or
17 higher.

18
19 The ties to these sponsor-funded organizations were often not
20 disclosed at advisory committee meetings. And even if
21 representatives' organizational affiliations were to be fully
22 disclosed, there is currently no mechanism for the public to be

1 informed of relevant organizational donors – even those posing a
2 clear and direct risk of undue influence or bias, like the
3 sponsor.

4
5 It is possible that, even if the public is not aware of these
6 conflicts among patient and consumer representatives, the FDA is
7 fully informed. In its 2016 draft guidance, the FDA highlights
8 being an “active participant” in an organization that has a
9 financial relationship with the sponsor as an “appearance
10 issue.” This type of tie is not considered a conflict requiring
11 recusal under Federal ethics laws but “may create the appearance
12 that a member lacks impartiality.”¹⁰ Advisory committee members
13 are required to disclose these relationships to the agency and
14 may receive a Section 502 waiver permitting them to still
15 participate. Unlike FDA’s treatment of formal conflict-of-
16 interest waivers, the FDA has never posted Section 502 waivers,
17 which are issued at 27% of meetings.¹¹ Thus, it is possible that
18 some sponsor-funded organizational ties that we identified may
19 have been permitted through the Section 502 waiver process.

20
21 It is also possible that at least some relevant organizational
22 affiliations were not reported to the agency, since many
23 affiliations were not publicly disclosed at meetings. Prior to

1 each meeting, members are required to submit Form FDA 3410 with
2 their financial disclosures. However, the section covering
3 appearance issues could easily be overlooked, as it has a catch-
4 all title of "Other Involvements," occupies about 2% of the
5 form, and does not request itemization. The instructions also do
6 not explicitly mention organizational relationships, instead
7 focusing on relationships more pertinent to scientific members
8 such as "researcher initiated study" and "gift of research
9 materials."¹²

10
11 Pharmaceutical funding of and its influence on advocacy
12 organizations are a growing public concern. FDA COI policies
13 have not kept pace with these developments despite recent
14 efforts to reform advisory committee processes. Finalizing
15 guidance for relationships with advocacy organizations, revising
16 Form FDA 3410 to more explicitly address both formal COIs and
17 appearance issues related to these ties, and improving
18 transparency through the public posting of Section 502 waivers
19 would be important first steps in reinvigorating reform efforts.

20
21 A separate question is whether the organizational affiliations
22 of patient and consumer representatives materially influence
23 advisory committee proceedings and, further downstream, FDA

1 actions. Even though patient and consumer representatives
2 constitute only a small fraction of an advisory committee, votes
3 from these representatives may play a pivotal role in close
4 votes, and non-unanimous votes account for at least 60% of all
5 votes.¹³ In addition, even though the agency does not always
6 follow committee recommendations,^{14,15} and those recommendations
7 are only one part of what the agency considers for any action,
8 the FDA does pay close attention to the content of advisory
9 committee discussions. According to the agency, "the main impact
10 each member provides... is his or her contribution to the
11 discussion."¹⁶

12
13 This analysis was limited by the availability of online
14 information that we were able to collect on the activities and
15 affiliations of patient and consumer representatives as well as
16 the availability and granularity of donor information reported
17 by advocacy organizations. Both of these limitations in
18 ascertainment would lead to prevalence underestimates. Because
19 of data collection constraints, our analysis ends in 2022, so
20 may not reflect more recent practices. However, the prevalence
21 rates we report were either stable or increasing over the
22 preceding 10 years, so our reported rates are likely to
23 represent lower bounds for more recent years.

Conclusion

The organizational ties of patient and consumer representatives -- and the financial relationships between their advocacy organizations and pharmaceutical companies -- are an important but overlooked aspect of FDA advisory committees. The calculated prevalence rates show that these organizational relationships extend beyond isolated cases and signal a broader problem warranting FDA policy attention.

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TABLE 1

Caption: Summary Statistics

Source: Authors' analysis of FDA advisory committee meeting documents and original data collection on the organizational affiliations of patient and consumer representatives and the donors to those organizations, 2013-2022.

Notes: (a) There was one individual who participated in multiple meetings as a consumer representative and, in one meeting, as a patient representative. They are included in the counts of both patient representatives and consumer representatives in Panel A. In Panel C, they are included only in the calculations for consumer representatives, the role they served for most advisory

committee meetings. (b) We report the number of organizational affiliations attributed to the patient or consumer representative at the time of the advisory committee meeting they attended. (c) Affiliations were considered to be "executive leadership" if the representative held a senior leadership role in the organization, such as board member, executive director, or founder; "other leadership" if their stated position title indicated leadership responsibilities; and "active involvement" if there was evidence of repeated engagement and activities. If an individual held multiple roles, we coded them in their highest role. (d) "Disclosed" reports the number of representatives whose affiliations were always disclosed at meetings. "Undisclosed" reports the number of representatives who had at least one affiliation which went undisclosed at a meeting.

FIGURE 1

Caption: Share of Meetings With Representative Affiliated With Advocacy Organization Receiving Pharmaceutical or Sponsor Funding

Source: Authors' analysis of FDA advisory committee meeting documents and original data collection on the organizational

affiliations of patient and consumer representatives and the donors to those organizations, 2013-2022.

Notes: Each solid dot represents the percentage of meetings in that year with at least one representative affiliated with an organization receiving pharmaceutical (or sponsor) funding. Each open dot represents the percentage of meetings in that year with at least one representative affiliated with an organization receiving pharmaceutical (or sponsor) funding and whose organizational affiliation was not disclosed at the meeting. Lines are lowess-smoothed trend lines. The top left corner of each panel reports average annual percentages for the full 2013-2022 period.

FIGURE 2

Caption: Share of Meetings With Representative Affiliated With Advocacy Organization Receiving Pharmaceutical or Sponsor Funding, By Committee

Source: Authors' analysis of FDA advisory committee meeting documents and original data collection on the organizational affiliations of patient and consumer representatives and the donors to those organizations, 2013-2022.

1 **Notes:** Total length of each bar represents the percentage of
2 meetings with at least one representative affiliated with an
3 organization receiving pharmaceutical (or sponsor) funding. The
4 percentage of meetings with at least one representative
5 affiliated with an organization receiving pharmaceutical (or
6 sponsor) funding is reported to the right of the bar. The light
7 portion of the bar represents the percentage of meetings with at
8 least one representative affiliated with an organization
9 receiving pharmaceutical (or sponsor) funding and all such
10 organizational affiliations were disclosed. The dark portion of
11 the bar represents the percentage of meetings with at least one
12 representative affiliated with an organization receiving
13 pharmaceutical (or sponsor) funding and at least one such
14 organizational affiliation went undisclosed at the meeting. The
15 total number of meetings for each committee is reported under
16 the committee's name on the y-axis. The number of meetings with
17 disclosed and undisclosed affiliations with pharmaceutical (or
18 sponsor) funded organizations is reported within each section of
19 the bar. Committees are: AAC (Arthritis Advisory Committee),
20 AADPAC (Anesthetic and Analgesic Drug Products Advisory
21 Committee), AMDAC (Antimicrobial Drugs Advisory Committee),
22 CRDAC (Cardiovascular and Renal Drugs Advisory Committee), DODAC
23 (Dermatologic and Ophthalmic Drugs Advisory Committee), EMDAC
24 (Endocrinologic and Metabolic Drugs Advisory Committee), GIDAC

(Gastrointestinal Drugs Advisory Committee), ODAC (Oncologic Drugs Advisory Committee), ORUDAC (Obstetrics, Reproductive and Urologic Drugs Advisory Committee), PADAC (Pulmonary-Allergy Drugs Advisory Committee), PCNSDAC (Peripheral and Central Nervous System Drugs Advisory Committee), and PDAC (Psychopharmacologic Drugs Advisory Committee).

Table 1. Summary Statistics

Panel A. Study Units		N			
Number of meetings		234			
Number of meetings with patient representative		233			
Number of meetings with consumer representative		224			
Number of patient representatives		98 ^a			
Number of consumer representatives		39 ^a			
Number of committees		12			
Panel B. Distributional Statistics		Mean (SD)	Median (IQR)	Min	Max
No. of patient representatives per meeting		1.0 (0.1)	1.0 (1.0, 1.0)	0.0	2.0
No. of consumer representatives per meeting		1.0 (0.3)	1.0 (1.0, 1.0)	0.0	2.0
Total no. of voting attendees per meeting		15.9 (4.5)	15.0 (13.0, 18.0)	7.0	30.0
No. of meetings attended by patient representative		2.4 (2.1)	2.0 (1.0, 3.0)	1.0	12.0
No. of meetings attended by consumer representative		6.1 (6.1)	5.0 (2.0, 8.0)	1.0	31.0
No. of advocacy organization affiliations of patient representative ^b		0.8 (0.8)	1.0 (0.0, 1.0)	0.0	3.0
No. of advocacy organization affiliations of consumer representative ^b		0.9 (1.1)	0.0 (0.0, 2.0)	0.0	4.0
Panel C. Individuals with Organizational Affiliations		Patient Representatives		Consumer Representatives	
		N	% all reps	N	% all reps
			% affiliated reps		% affiliated reps

Total no. representatives	97 ^a			39		
Any affiliation ^c	57	58.8%	100.0%	19	48.7%	100.0%
Executive leadership	29	29.9%	50.9%	14	35.9%	73.7%
Other leadership	15	15.5%	26.3%	3	7.7%	15.8%
Active involvement	13	13.4%	22.8%	2	5.1%	10.5%
Disclosure status of affiliation ^d						
Disclosed	6	..	10.5%	7	..	36.8%
Undisclosed	51	..	89.5%	12	..	63.2%

Source: Authors' analysis of FDA advisory committee meeting documents and original data collection on the organizational affiliations of patient and consumer representatives and the donors to those organizations, 2013-2022. **Notes:** (a) There was one individual who participated in multiple meetings as a consumer representative and, in one meeting, as a patient representative. They are included in the counts of both patient representatives and consumer representatives in Panel A. In Panel C, they are included only in the calculations for consumer representatives, the role they served for most advisory committee meetings. (b) We report the number of organizational affiliations attributed to the patient or consumer representative at the time of the advisory committee meeting they attended. (c) Affiliations were considered to be "executive leadership" if the representative held a senior leadership role in the organization, such as board member, executive director, or founder; "other leadership" if their stated position title indicated leadership responsibilities; and "active involvement" if there was evidence of repeated engagement and activities. If an individual held multiple roles, we coded them in their highest role. (d) "Disclosed" reports the number of representatives whose affiliations were always disclosed at meetings. "Undisclosed" reports the number of representatives who had at least one affiliation which went undisclosed at a meeting.

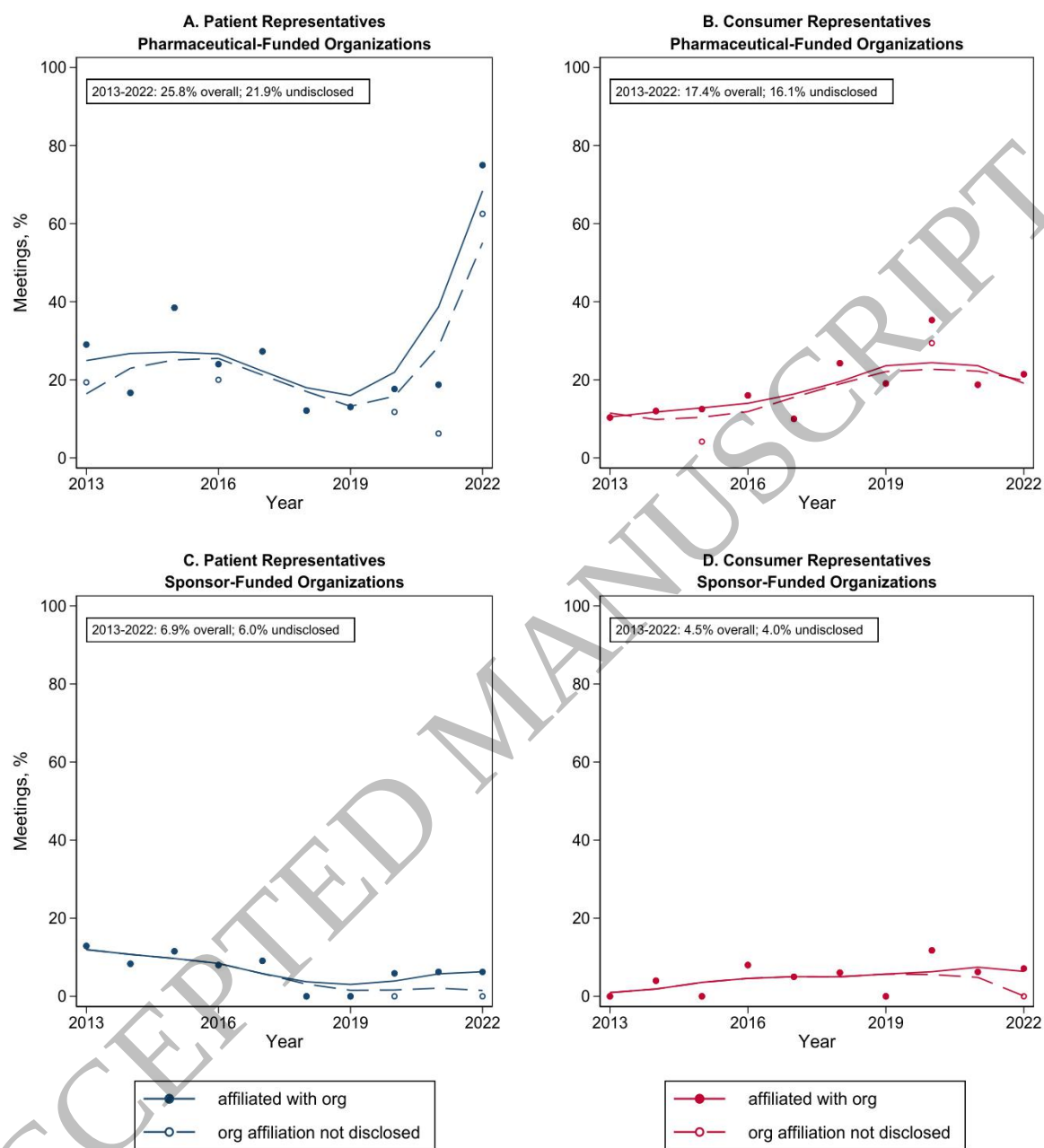


Figure 1
178x190 mm (x DPI)

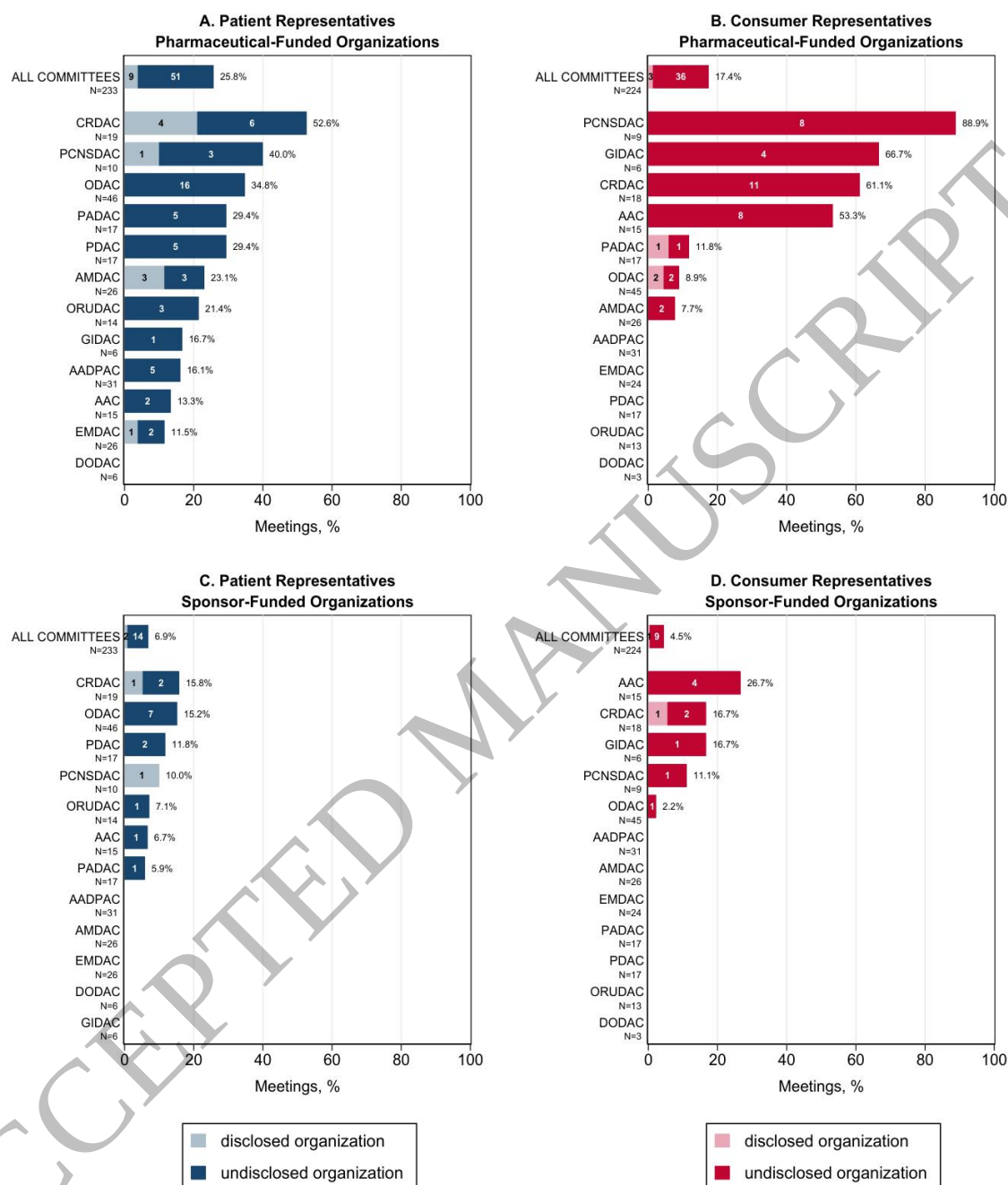


Figure 2
178x203 mm (x DPI)