Letters

RESEARCH LETTER

Conflicts of Interest in Federal Vaccine Advisory Committees

US Department of Health and Human Services (HHS) Secretary Robert F. Kennedy Jr has expressed concerns about conflicts of interest (COIs) in HHS vaccine advisory committees. He has stated that the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) is "plagued" with COIs and that "97% of the people on [ACIP] had conflicts,"[1] citing a 2000 congressional report on a single vaccine.[2]

Supplemental content

We analyzed the prevalence of reported COIs among attendees at 2000-2024 meetings of ACIP and the US Food and Drug Administration's (FDA) Vaccines and Related Biological Products Advisory Committee (VRBPAC).

Methods | Financial COIs for each ACIP voting meeting were obtained from a database of CDC disclosures created by HHS, which includes past, current, and pending relationships.[3] ACIP members are expected to recuse themselves from deliberations and votes related to any product for which they have a current COI. A list of attendees was extracted from meeting minutes or transcripts.[4]

For VRBPAC voting meetings, waivers related to 18 USC §208—allowing members with "essential expertise" to participate even with current financial COIs—were obtained from the FDA's website[5] or a Freedom of Information Act request. Attendee names were extracted from the roster and meeting minutes, with discrepancies resolved by the meeting transcript.

Conflicts of interest for both index and competitor companies were included in the analysis. For each meeting, the prevalence of reported financial COIs and recusals was calculated, and the annual prevalence of reported COIs and recusals was calculated as the unweighted mean of meeting-level COI or recusal prevalences that year. The COI prevalence was also calculated by individual conflict types, using definitions from ACIP policies and FDA waivers. Methods are described in further detail in the eAppendix in Supplement 1.

Table. ACIP and VRBPAC Meeting Sample Characteristics and Reported COI Conflict Rates, 2000-2024[a]

	ACIP				VRBPAC			
	Full sample, 2000-2024	2000-2007	2008-2015	2016-2024	Full sample, 2000-2024	2000-2007	2008-2015	2016-2024
Sample statistics								
No. of meetings	99	25	27	47	86	30	22	34
Annual No. of meetings								
Mean (SD)	4.0 (2.2)	3.1 (0.4)	3.3 (0.5)	5.2 (3.3)	3.4 (1.8)	3.3 (1.1)	2.4 (1.5)	4.9 (2.1)
Median (IQR)	3.0 (3.0-4.0)	3.0 (3.0-3.0)	3.0 (3.0-4.0)	3.0 (3.0-6.0)	3.0 (2.0-4.0)	3.0 (3.0-4.0)	2.0 (1.0-4.0)	4.0 (3.0-7.0)
No. of voting attendees per meeting								
Mean (SD)	13.5 (1.8)	12.5 (2.1)	14.4 (1.0)	13.6 (1.6)	15.1 (3.3)	15.0 (2.7)	13.7 (2.4)	16.1 (4.0)
Median (IQR)	14.0 (13.0-15.0)	12.0 (11.0-14.0)	15.0 (14.0-15.0)	14.0 (13.0-15.0)	15.0 (13.0-17.0)	15.0 (13.0-17.0)	13.5 (12.0-16.0)	15.5 (13.0-21.0)
Meeting-level COI statistics								
Reported COI prevalence rate, % (SD)								
Any conflict type	13.5 (12.5)	27.8 (12.8)	13.1 (7.6)	6.2 (6.9)	4.0 (8.0)	9.1 (11.2)	0.0 (1.9)	1.9 (2.5)
Research or investigator support	10.1 (8.5)	17.1 (8.2)	12.6 (7.6)	4.9 (5.4)	1.0 (3.5)	2.4 (5.6)	0.0 (0.0)	0.2 (1.2)
Data and safety monitoring board or end-point reviewer	1.4 (3.9)	5.4 (6.4)	0.0 (0.0)	0.1 (0.1)	1.6 (5.0)	4.5 (7.7)	0.0 (0.0)	0.0 (0.0)
Consulting	1.4 (4.0)	5.0 (6.3)	0.2 (1.3)	0.1 (1.0)	1.0 (3.4)	2.9 (5.2)	0.0 (0.0)	0.0 (0.0)
Stock, royalties, or ownership	1.4 (3.5)	4.4 (5.5)	0.0 (0.0)	0.6 (2.0)	0.3 (1.4)	0.4 (1.6)	0.4 (1.9)	0.0 (0.0)
Recusal rate, % (SD)	1.3 (3.9)	0.3 (1.3)	0.9 (2.5)	2.1 (5.2)	7.4 (9.1)[b]		5.5 (5.4)[c]	8.1 (10.1)[d]

Abbreviations: ACIP, Advisory Committee on Immunization Practices; COI, conflict of interest; VRBPAC, Vaccines and Related Biological Products Advisory Committee.

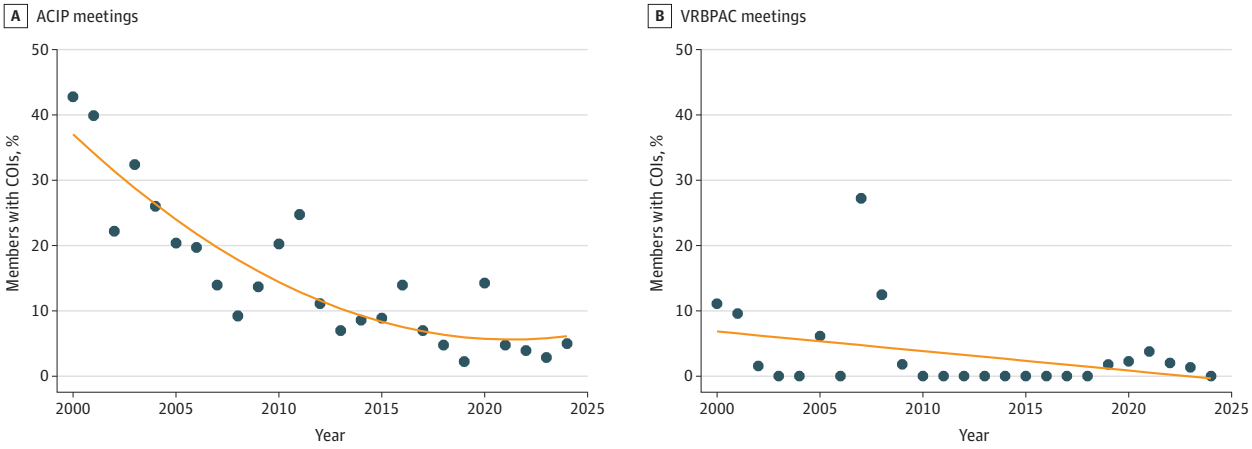
[a] Sample includes only voting meetings. Average prevalence of COIs in a given year was calculated as the unweighted mean of meeting-level COI prevalence rates for all meetings in that year (ie, prevalence was not weighted by the number of meeting attendees). Rates for 4 leading conflict types are reported. Additional conflict types include advisory board, nonresearch grant, employer relationship, paid speaking, expert witness, clinical trial participation (as a participant), and no detail reported.

[b] Includes meetings from November 2012 to June 2024.

[c] Includes meetings from November 2012 to December 2015.

[d] Includes meetings from January 2016 to June 2024.

Figure. Annual Average Reported COI Prevalence Rates in ACIP and VRBPAC Meetings, 2000-2024



Each dot is the mean of the meeting-level conflict-of-interest (COI) prevalence rates for all meetings in that year. The lines are the quadratic fitted line for the Advisory Committee on Immunization Practices (ACIP) and a fitted linear regression line for the Vaccines and Related Biological Products Advisory Committee (VRBPAC). Average prevalence of COIs in a given year was calculated as the unweighted mean of meeting-level COI prevalence rates for all meetings in that year (ie, prevalence was not weighted by the number of meeting attendees).

We estimated the quadratic least-squares model and the nested linear model of the association between time and mean reported COI prevalence. We used an F test (α = .05) to determine the better fit for each committee.

Results | Between 2000 and 2024, ACIP and VRBPAC convened an average of 4.0 and 3.4 meetings per year, respectively, with the highest annual frequency of meetings in 2016-2024 (**Table**).

The average annual reported COI prevalence for ACIP was 13.5%, declining from 42.8% to 5.0% over the study period (**Figure**, A). Reported COI prevalence for VRBPAC declined from 11.1% in 2000 and has remained less than 4% since 2010, including 10 years when it was 0% (Figure, B).

The quadratic least-squares model was a better fit than a linear model for ACIP (F = 9.20; *P* = .006) but not for VRBPAC (F = 0.33; *P* = .57). The annual rate of decline in reported COI prevalence was statistically significant for ACIP (−2.96 [95% CI, −4.1 to −1.8] percentage points; *P* < .001) but was not statistically significant for VRBPAC (−0.3 [95% CI, −0.6 to 0.4] percentage points; *P* = .08).

The most frequent conflict type was research or investigator support (10.1% of attendees for ACIP, 1.0% for VRBPAC), followed by data and safety monitoring board or blinded endpoint reviewer, consulting, and stock/royalties/ownership (Table). Average recusal rates were 1.3% for ACIP and 7.4% for VRBPAC.

Discussion | Although annual prevalence rates of reported COIs were high in the early 2000s, reaching 43% for ACIP and 27% for VRBPAC, they were considerably lower in 2016-2024 for both committees, at 6.2% for ACIP and 1.9% for VRBPAC. The most frequently reported COI was research support, reflecting members' expertise, with the prevalence of conflicts that were related to personal income (consulting, stock/royalties/ownership) less than 1% for both committees since 2016. Policy changes placing caps on FDA advisory committee COI rates in 2007[6] and greater awareness and scrutiny of COIs in agency decision-making may have spurred these large declines.

Because ACIP does not post formal waivers, members may have reported past financial relationships or those not considered COIs by the agencies. Agency definitions of COIs may have expanded over time, leading to upward bias in COI estimates in later years.

In conclusion, reported COI prevalence rates have declined for ACIP and VRBPAC over the last 25 years and were at historically low levels through 2024.

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