# Managing Conflicts of Interest and Industry Influence in Government Advisory Committees*

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**Abstract**

Government agencies rely on advisory committees of external experts to provide guidance on policy decisions, but financial conflicts of interest may bias members' recommendations towards industry interests. In this paper, I examine the bias-expertise trade-off in appointing conflicted members on advisory committees. Using more than 20 years of data on FDA advisory committee meetings, I examine how members' industry ties affect their voting behavior and the identification of drug safety risks. Using exogenous within-person variation in the scheduling of drug reviews relative to members' industry relationships, I find that when members have ties to the drug sponsor, they are more likely to vote in favor of the sponsor, but there is no such pro-approval bias when members have ties to competitor firms. These findings are buttressed by a second analysis using two novel instrumental variables. I also find no informational or safety-related benefits of industry expertise and show that the FDA does not account for conflict-of-interest biases in its decision-making. These findings suggest that agencies can preserve the integrity of their decision-making by leveraging the expertise of committee members with competitor ties and internalizing advisory committee biases.

**Keywords:** conflicts of interest, regulatory capture, expert advice, advisory committees, FDA

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# 1 Introduction

Government agencies frequently convene advisory committees consisting of external experts to provide guidance on policy and regulatory matters. Because advisory committee members are not full-time government employees, they may, in the course of their regular work, have financial relationships with organizations that pose a conflict of interest for committee activities. For example, members may serve on the board of or receive research support from a firm that is regulated by the government and is the subject of advisory committee discussions. A concern that arises with these conflicts of interest is that members may be biased in favor of the firm with which they have a financial relationship, even absent deliberate intent.

Excluding all committee members who have relevant financial conflicts of interest (COIs) for a particular meeting could alleviate concerns about bias. However, because advisors often gain their expert knowledge from experience in precisely the industry that poses a conflict, excluding members with relevant industry financial ties could limit the knowledge and expertise available to the government. The tension between bias and the potential informational benefits of conflicted advice is a recurring concern for government advisory committees, but there has been limited empirical analysis of and guidance for how to optimally balance this trade-off.

In this paper, I examine this trade-off for government advisory committees, analyzing how financial conflicts of interest affect the bias and the informational value of committee recommendations. In addition, I evaluate the degree to which the government accounts for these COI biases in its decision-making. These three empirical features – bias, informational value, and government internalization of bias – provide guidance for optimally managing conflicts of interest in advisory committees.

This study focuses on FDA drug advisory committees, which provide detailed disclosures of members' COIs and committee meeting votes. Nearly all votes can be classified as either favorable to the drug sponsor — for example, supporting drug approval or looser labeling requirements — or not, and can be used to analyze the relationship between COIs and voting biases.

In addition, this study examines the informational value contributed by conflicted members. I analyze whether the presence of members with industry financial ties reduces the variance of the informational signal about the quality of given drug. The FDA seeks external guidance from

advisory committees when there is uncertainty about the quality or net benefit of a candidate drug. The purpose of advisory committees is to contribute expertise that reduces the informational noise of drug quality. If committees with more conflicted members provide a lower-variance set of recommendations than non-conflicted committees, conflicted members and committees can be thought to contribute more informational value to the agency.

I also examine specific informational contributions related to drug safety. Safety labeling requirements imposed by the FDA at the time of approval and unexpected safety events occurring after approval reflect, respectively, the safety issues anticipated and unanticipated by the committee. To the extent that conflicted advisors contribute relevant safety expertise, their participation should be associated with more extensive pre-approval safety safeguards and fewer unanticipated post-approval safety events.

Finally, although the advisory committee provides recommendations, it is the agency that ultimately makes the regulatory decisions. I examine the concordance between committee recommendations and FDA decisions in order to assess the degree to which the agency accounts for bias in committee recommendations. If the agency fully discounts advisory committee COI bias in its final decisions, the presence of conflicts on these committees is not a cause for concern. However, if the agency fails to fully account for COI bias and there is limited informational value from conflicted experts, optimal policy calls for tighter COI restrictions.

Drawing on these 3 threads of evidence — committee COI bias, conflicted expert information, and agency-committee concordance — I evaluate whether existing COI policies are close to an optimal policy that would account for the bias-information trade-off.

To investigate these 3 issues, I analyze 21 years (2002-2022) of data from advisory committee meetings convened by the FDA Center for Drug Evaluation and Research (CDER). I focus on the 12 CDER committees that provide advice on scientific issues related to regulatory oversight of pharmaceutical and biological drug products.[1] Organized by therapeutic areas, these committees advise on the scientific evaluation of prescription drug products for use in the US.

Because industry financial interests are not assigned randomly to committee members, I use two empirical strategies to isolate the effect of members' COIs on voting and other key outcomes.

[1] Cell and gene therapies are reviewed by a different FDA center and are excluded from the sample. I also exclude the CDER committee that reviews over-the-counter (i.e., non-prescription) drug products.

I first conduct an individual-level analysis to estimate the effect of a member's financial ties on their votes. Using exogenous within-person variation in the scheduling of drug reviews relative to members' industry relationships, I implement an individual-level fixed effects design to estimate the causal effect of members' financial ties on their voting behavior. I also use this design to estimate the relationship between members' financial ties and the estimated dispersion, or variance, of their voting behavior. This dispersion reflects the noisiness of the recommendation signal conveyed to the FDA; the smaller the dispersion, the more informative the signal.

I also use an instrumental variables (IV) approach to estimate the effects of the share of members with COIs on meeting-level voting measures, including the share of members voting in favor of the sponsor and whether a majority of members votes in favor of the sponsor. I use two novel instruments: (1) the number of clinical trials sponsored by the applicant in the committee's therapeutic area — excluding the therapeutic class of the index drug — 18 months prior to the advisory committee meeting, and (2) the dollar value threshold beyond which members are ineligible for a conflict-of-interest waiver. I use these instruments to estimate the effect of meeting-level COIs on member voting and on the probability that safety-related labeling (a black box warning) is imposed by the agency at the time of drug approval and on the probability that a black box warning is issued for a drug within 5 years after approval – two measures of safety-related expertise.

I find that members are significantly more likely to vote in favor of the sponsor – by 19.6 percentage points – when they have a financial tie to the sponsor. By contrast, having a financial tie to a competitor has no impact on pro-sponsor voting, negative or positive.

I find similar results at the meeting level: an increase in the share of committee members with a sponsor tie significantly increases both the share of members voting in favor of the sponsor and the probability of a majority (>50%) vote in favor of the sponsor. These findings suggest that pro-sponsor voting is driven by financial ties to the sponsor rather than by selection of generally pro-industry individuals into financial relationships with drug companies.

In contrast to these pro-sponsor bias findings, I find no evidence of additional informational value, or expertise, attributable to members with sponsor ties. In particular, I find no effect of sponsor ties on the dispersion of the member recommendations — i.e., the dispersion of the informational signal conveyed to the FDA. I also find no safety-related expertise attributable to members with sponsor ties. If sponsor COIs had contributed safety expertise that improved information

for the agency, there would have been more frequent early detection of serious safety risks – as measured by the FDA's imposition of a black box warning at approval – or less frequent unanticipated safety events – as measured by fewer black box warnings after approval. I find no effect of sponsor COIs on at-approval black box warnings or post-approval black box warnings. Indeed, I find that competitor COIs increased the probability of at-approval black box warnings, indicating that members with competitor relationships contributed safety expertise.

Finally, I examine whether the FDA accounted for the biased recommendations from its conflicted advisory committees. If the agency were aware of the potential for bias and discounted the biased advice, it would be less likely to follow the committee's recommendations if they came from a conflicted committee. I find no such effect. The agency followed committee recommendations to the same degree regardless of the level of sponsor conflictedness.

In summary, I find that sponsor conflicts introduced bias without detectable informational or safety-related benefits, while competitor conflicts introduced no bias but contributed safety expertise. Given that the FDA does not discount pro-sponsor bias from its advisory committees, the agency could move toward a better bias-expertise trade-off point by restricting its sponsor conflicts while permitting competitor conflicts.

The findings from this study contribute to the growing literature on the trade-off between bias and advice quality in expert committees. Li (2017) studies external reviewers of NIH research proposals and finds that the benefits from additional expertise slightly outweigh the costs of bias in NIH reviews. Chan and Dickstein (2019) similarly characterize a bias-information trade-off among members of an expert committee that advises Medicare on physician resource use, but they do not draw specific welfare conclusions.

This current study does not directly measure expertise but evaluates whether conflicted participation is associated with more precise drug quality informational signals and improved identification of drug safety risks. An earlier study of FDA advisory committees (Cooper and Golec (2019)) documents a decline in average committee expertise, as measured by publication citations, correlated with the enactment of a law imposing restrictions on FDA COIs, but they do not directly estimate the relationship between COIs and expertise.

Previous studies analyzing the relationship between COIs and FDA voting have relied on between-person identification and report conflicting findings. Lurie et al. (2006), Ackerley et al.

(2007), and Pham-Kanter (2014) find small but statistically significant associations between sponsor ties and pro-sponsor voting, while Cooper and Golec (2019) find no association. However, Cooper and Golec analyze only approval meetings, and I also find null results when I restrict my analyses to a similar sample.

In analyzing the empirical evidence related to conflicts of interest in FDA advisory committees, I also introduce two ways forward for COI policy in government advisory committees. First, agencies can and should leverage the fact that similar expertise exists among members with ties to sponsoring firms (or more generally, firms that will benefit directly from a policy being deliberated) and members with ties to competing firms (firms that will be at a disadvantage as a result of the policy). Biases can emerge even absent deliberate intent, and agencies can preserve important expertise while containing potential bias by accommodating competitor financial interests in their COI policies rather than banning industry ties altogether.

Second, even if residual bias remains in advisory committees, agencies have considerable scope for action. As long as agencies remain vigilant about, and account for, biases that can arise from conflicted advisory committees, high-quality decisions are achievable without perfection in COI policies.

# 2 Background and Institutional Setting

## 2.1 FDA advisory committees

Agencies throughout the federal government convene advisory committees consisting of external experts to provide guidance on a range of policy decisions. Among agencies within the Department of Health and Human Services, the FDA uses advisory committees intensively, relying on them to assist in the deliberation of scientific issues related to the safety and efficacy of drugs and devices.

Not all drug applications are reviewed by FDA advisory committees. Applications for which there is strong evidence, in the view of the agency, in support of or against approval are usually evaluated without external input. Instead, applications that pose complex technical issues, that require expertise beyond the knowledge available in-house, or about which there are internal differences of opinion are most likely to be presented to a committee (Moffitt, 2010).

Advisory committees are also asked to deliberate on a range of other issues beyond new drug

applications. These include, for example, supplemental drug applications for which the drug sponsor is providing evidence to expand the treatment population or indication (condition that the drug is intended to treat); review of confirmatory trial evidence for drugs that had been approved conditionally through the accelerated approval pathway; review of new safety or adverse event reports that have emerged for a currently marketed drug; and input on clinical trial designs for specific therapeutic areas.

Because the agency does not disclose the number of applications it receives, there are no statistics on the share of applications that are sent to advisory committees. However, Moffitt (2012) estimates that 24%-52% of new molecular entities (the most novel drugs for which applications could be submitted) are reviewed by advisory committees, and Daval et al. (2022) calculates that 6%-51% of *approved* drugs were reviewed by advisory committees.

The Center for Drug Evaluation and Research, or CDER, is responsible for the review of drugs marketed in the US and oversees 12 committees, among others, that have purview over different therapeutic areas. These committees include:

- AADPAC: Anesthetic and Analgesic Drug Products Advisory Committee[2]
- AMDAC: Antimicrobial Drugs Advisory Committee[3]
- ARDAC: Arthritis Drugs Advisory Committee
- CRDAC: Cardiovascular and Renal Drugs Advisory Committee
- DODAC: Dermatologic and Ophthalmic Drugs Advisory Committee
- EMDAC: Endocrine and Metabolic Drugs Advisory Committee
- GIDAC: Gastrointestinal Drugs Advisory Committee
- ODAC: Oncologic Drugs Advisory Committee
- ORUDAC: Obstetrics, Reproductive, and Urologic Drugs Advisory Committee[4]
- PADAC: Pulmonary-Allergy Drugs Advisory Committee
- PCNSDAC: Peripheral and Central Nervous System Drugs Advisory Committee
- PPDAC: Psychopharmacologic Drugs Advisory Committee.

[2]This committee was named the Anesthetic and Life Support Drugs Advisory Committee until 2012.

[3]This committee was named the Antiviral Drugs Advisory Committee until 2013. It was combined with the Anti-infective Drugs Advisory Committee in 2015.

[4]This committee was named the Reproductive Health Drugs Advisory Committee until 2013, and named the Bone, Reproductive, and Urologic Drugs Advisory Committee from 2014 to 2021.

## 2.2 FDA advisory committee meetings

Committees convene with varying frequencies throughout the year, depending on the flow of applications submitted by sponsoring firms and on emerging scientific issues. Standing committee members, also called permanent members, are typically appointed to serve for 4-year terms and include medical experts with knowledge of the targeted condition and the current standard of care, pharmacologists with knowledge of a drug's mechanism of action and pharmacologic properties, epidemiologists, biostatisticians, and a consumer representative. There is also a patient representative – someone who has (or had) the condition or the caregiver of someone with the condition – who varies meeting-to-meeting, depending on the targeted condition. In addition to these voting members, there is a non-voting industry representative who can provide pharmaceutical industry expertise.

At the meeting, which can range from a half-day to two-full days, representatives from the drug sponsor present their data and evidence, followed by agency staff, who present their scientific assessment of the data. Committee members are permitted to ask questions of the sponsor and agency staff throughout, and there is dedicated time during the meeting for discussion among committee members. Member are then asked to vote on specific questions, such as whether they would recommend the drug under review for approval, or equivalently, whether the benefits of the drug outweigh the risks.[5] Committee recommendations are non-binding, although the agency very frequently, but not always, follows the recommendations of its committees (Zhang et al. (2019); Daval et al. (2023)).

## 2.3 Conflict-of-interest determinations

At all government agencies, advisory committee members are asked to complete financial disclosure forms annually as well as prior to each meeting. Members are asked to disclose:

- current investments (e.g., stocks, bonds)
- current and future employment
- current and future consulting and advising activities

[5] According US Food and Drug Administration (2023), "benefit-risk assessment is ... integrated into FDA's regulatory review of marketing applications for new drug and biological products. Broadly speaking, benefit-risk assessment in FDA's drug regulatory context is making an informed judgment as to whether the benefits (with their uncertainties) of the drug outweigh the risks."

- current and future contracts and grants
- past,[6] current, and future expert witness work
- past,[6] current, and future speaking
- patents and royalties
- financial interests of the member's spouse and minor children.

Before each meeting, agency staff review disclosure forms to identify potential financial conflicts for the "particular matter" to be discussed at the meeting.[7] For the FDA, a "particular matter" is defined by the product and the manufacturer of that product (the drug sponsor). If a conflict is identified – based on the member's disclosed relationship with the sponsor of the product or with a firm that has a competing product – additional detailed information is collected, including contract dates and amounts. In general, financial relationships with the sponsor or a competitor that have value above a *de minimis* amount and that fall into any of the above categories are considered disqualifying financial interests.

However, federal law (18 USC §108(b)) allows agencies to issue waivers permitting individuals with COIs to participate under specified circumstances. According to FDA guidance (US Food and Drug Administration, 2008), a member may be issued a waiver allowing them to participate and vote in the meeting if the benefits of the member's expertise are thought to outweigh the risks from a conflict of interest.

Note that it is possible for advisory committee members to have many industry financial ties but never have been determined to have a conflict of interest during their tenure as a member. This is because COIs are defined meeting-by-meeting and are specific to the product and the product sponsor. Unless the member's portfolio of financial relationships includes the specific firm *and* the at-issue product or a competitor's firm and its competing product at the time of the product meeting, the member is not considered to have a financial COI. As well, past financial ties are only relevant to the extent that they relate to the specific parties and products implicated within a lookback period of 12 months. This narrow "particular matters" approach to COI is the general ethics standard for federal government agencies and, as discussed below, gives rise to useful quasi-experimental variation in conflicts of interest.

[6]The window for past financial interests is the previous 12 months.

[7]For more information on the definition of a "particular matter," see Cusick (2007).

During the study period 2002-2022, there were three documented policy changes in how the FDA managed conflicts of interest. The first two occurred in 2007, coinciding with the FDA Amendments Act (FDAAA), enacted in September of that year. That law placed a cap on the number of waivers that the FDA could issue, lowering the cap by 5% each year between 2007 to 2012. Following the passage of FDAAA, FDA also launched a review of its COI policies, culminating in a 2008 guidance that announced that the threshold for eligibility for a waiver would be lowered from $100,000 to $50,000.(US Food and Drug Administration, 2008)

Cooper and Golec (2019) include the FDAAA policy change as a covariate in their between-member analysis but did not use it as an instrument. The effects of the waiver cap have never been studied although the cap appears to have never been binding; after 2007, the FDA voluntarily reduced their use of waivers to levels well below the statutory caps, the lowest of which was 12%. In 2012, with the enactment of the FDA Safety and Innovation Act, Congress repealed the cap on waivers.

# 3 Data and Measures

## 3.1 Data sources

Data collected for this study can be grouped into 3 main categories: data on FDA advisory committee meetings; data on characteristics of and FDA actions related to the drugs reviewed by the advisory committees; and data on clinical trials, which were used to construct one of the instrumental variables.

### 3.1.1 FDA advisory committee meetings and attendees

Data on advisory committee meetings, including meeting topics and member attendance, votes, and financial conflicts (i.e., waivers issued), were collected from documents posted online by the FDA, either at the agency's current website or at archived locations. Documents from which meeting data elements were extracted included agendas, attendance rosters, minutes, and transcripts.

Data on financial conflicts of interest for each meeting were obtained from the conflict of interest waivers posted online and from meeting transcripts, which included the text of the conflict of interest oral announcement made at the beginning of every advisory committee meeting. Waivers

that were not posted publicly, usually because of incomplete document availability in the early part of the study period, were obtained through FOIA requests. Although the waivers often include information about the implicated firms, products, relationships, and dollar amounts, many details are often redacted, and the only field that could be consistently extracted was the firm type — sponsor or competitor. The type of financial relationship (e.g., consulting, research support) was frequently but not always publicly available. The dollar value of members' conflicts was not systematically disclosed.

Documents were collected for the meetings of the 12 CDER advisory committees, described and enumerated in Section 2.1, with purview over therapeutic areas . Data were collected from all voting meetings, which comprised the majority of advisory committee meetings, convened between 2002 and 2022. Voting questions asked at each meeting were obtained from transcripts, minutes, and when available, briefing documents listing meeting questions. Members' votes were extracted from transcripts, and the total number of votes for each answer choice was cross-checked with meeting minutes summarizing the vote count. Votes were also coded according to whether the selected option favored the sponsor. In general, votes recommending approval, concluding that the benefits of the drug outweighed its risks, or easing sponsor requirements — for example, opposing restrictive labeling or supporting less stringent research design criteria — were considered favorable to the sponsor.

### 3.1.2 Drug characteristics and FDA actions

Characteristics of approved drugs discussed at advisory committee meetings were obtained from the Drugs@FDA database, FDA CDER annual reports of novel drug approvals, and the FDA website. Measures of drug novelty included whether the drug was considered a new molecular entity or first-in-class at the time of the original approval. Measures of whether the drug addressed an unmet medical included indicators for orphan drug, accelerated approval, and fast track or breakthrough therapy designation.[8] The priority review status of the application was also recorded.

Data on key agency actions relating to approved drugs were also obtained from the FDA. Approval dates were collected from the Drugs@FDA database. Black box safety warnings — the

[8]Both fast track and breakthrough therapy designations evaluate applications on the basis of preliminary data (e.g., nonclinical or early clinical data) and were combined in the measure used.

highest-level warning that can be issued by the FDA to highlight serious risks associated with a drug — were identified by compiling labels from all original drug applications, as well as all supplemental drug applications associated with labeling changes, and applying automated text- and image-based detection methods to identify labels with black box warnings. If a black box warning for a drug appeared on a label within 6 months after an advisory committee meeting for that drug, that warning was considered to have been required by the agency based on meeting-related or other pre-approval information. If a black box warning appeared more than one year after the meeting for that drug, that warning was considered to have been required by the agency in response to unanticipated post-approval safety events. For this study, I restricted the measure to black box warnings issued within 5 years of the meeting date.

Prior to 2008, the FDA publicly disclosed their responses to applicant firms, indicating whether the agency viewed the application as "approvable" or "not approvable." Beginning in 2008, however, the agency began treating these responses, known as complete response letters (CRLs) as confidential. Consequently, data on drugs that were not approved after advisory committee meetings are not available from the FDA. For these non-approved drugs, I obtained data on application designations and the date of FDA rejection from nonapprovable letters if the rejections were prior to 2008, and from press releases and news reporting if the rejections were 2008 or after.

Drugs that were approved but subsequently withdrawn are also not in the current Drugs@FDA database. For this set of drugs, I relied on news items to identify application characteristics, approximate dates of approval, and dates and reasons for withdrawal.

### 3.1.3 Clinical trial data and ATC classifications

I used the number of clinical trials conducted in the therapeutic area covered by each advisory committee to construct one of the instrumental variables. (Note that the number of clinical trials alone would not satisfy the exclusion restriction. I describe the construction of the instrumental variable in more detail in the Empirical Strategies section. In this section, I provide a high-level overview of the clinical trial data and the trial count measure.) Data on clinical trials conducted in the US between 2000 and 2022 were obtained from Cortellis Clarivate, a commercial vendor of clinical trial data.

To identify the trials and drugs for each advisory committee area, I first matched the generic

names of drugs reviewed by each advisory committee in 2000-2022 to the drugs' Anatomical Therapeutic Chemical (ATC) codes.[9] The ATC system classifies each drug according to its targeted organ system and its therapeutic, chemical, and pharmacological properties. These groupings of ATC codes define the set of drug classes that would be routed to the different advisory committees for review, with some ATC codes included in multiple committee groupings.

Drugs appearing in the clinical trial data were also classified by ATC code. Clinical trials were then assigned to advisory committees based on the ATC classification of the drug under study, using the ATC-based committee groupings described above. I then identified all clinical trials sponsored by the drug applicant and computed monthly counts of applicant-sponsored trials and total clinical trials matched to each advisory committee.

### 3.2 Sample Statistics

Summary statistics of the sample are reported in Table 1. Between 2002 and 2022, 1,903 unique individuals voted in 519 meetings. The median number of voting attendees per meeting was 14.0 (mean 14.7), and the median number of voting questions per meeting was 2.0 (mean 2.4).

The share of meetings with at least one conflicted member has varied considerably over time (Figure 1, top panel), as has the share of attendees attending a meeting with a conflict of interest (Figure 1, bottom panel). Between 2002 and 2007, about 77% of meetings included one or more individuals with a COI waiver. There was a steep decline beginning in 2007, likely spurred by the FDA Amendments Act enacted that year. As discussed above, the law imposed a cap on the number of waivers the FDA could issue, and the following year, the agency began to apply a lower dollar threshold for waiver eligibility. Although the waiver cap was repealed in 2012, the tightened eligibility threshold has remained and appears to have been strictly enforced until recently. Since COVID, there has been a resurgence in both the share of meetings with a COI waiver and the share of attendees with COI waivers. There also appear to have been waivers issued in recent years that have exceeded the $50,000 eligibility threshold.[10]

There is also considerable variation in COI levels across committees (Figure 2 and Figure 3). For example, the average share of meetings with a waiver during the study period was 19% for

[9] I thank Pragya Kakani for sharing her data on the ATC codes for new molecular entities.

[10] A more systematic investigation into these trends is not possible because the dollar value of the financial interest is frequently redacted.

ORUDAC (the Obstetrics, Reproductive, and Urologic Drugs Advisory Committee) but 36% for ODAC (the Oncologic Drugs Advisory Committee). Time trends in COI levels have varied across committees as well. For instance, the share of attendees with waivers in meetings of AMDAC (the Antimicrobial Drugs Advisory Committee) has followed the overall COI waiver trend (high, then low), while attendee COI prevalence in AADPAC (the Anesthetic and Analgesic Drug Products Advisory Committee) has remained consistently low throughout the sample period. Overall, all committees have been exposed to a range of different COI levels, as measured by the share of meetings with a waiver and the share of attendees with waivers. The summary statistics for COI levels for the full sample are reported in Table 2.

# 4 Empirical Strategies

## 4.1 Individual-Level Analyses

Advisory committee members are generally appointed for 4-year terms and likely do not have precise knowledge of the drug applications that they will be asked to review during their term. Some of the applications may involve products and firms that conflict with pre-existing financial relationships, while many may not. Thus, the occurrence of a financial COI is arguably quasi-random with respect to the products under review.

Strategic forward-looking firms could of course anticipate submitting a drug application and attempt to secure a position for their favored expert on an advisory committee in the hopes that they will secure a COI waiver. Although this long-term strategy cannot be ruled out, the data show evidence of exogeneity meeting-to-meeting.

Figure A1 shows the distribution of the share of members' pro-sponsor votes in the meeting *prior* to the meeting in which they had a conflict. These figures show no systematic pattern in pre-meeting voting behavior of those who had a conflict in the current meeting. In addition, the pre-meeting voting behavior of those who had conflicts in the current meeting does not appear to be different from the pre-meeting voting behavior of those without conflicts. This holds true regardless of whether the conflict is a sponsor-only tie, a competitor-only tie, or a tie to both the sponsor and competitors.

This relationship can be formally evaluated by regressing each member's vote in the previous

meeting on that member's current-meeting COI status. Table A1 shows no relationship between prior voting behavior and any current-meeting COI.

Given this plausible exogeneity, I was able to estimate the causal effect of a conflict of interest — a member's sponsor-only tie, competitor-only tie, or tie to both sponsor and competitor — using a fixed-effects (FE) linear probability model (LPM). The equation I estimated was:

$$favor_sponsor_{iqmct} = \beta_0 + \beta_1 \mathbf{1}\{sponsor_only\}_{imct} + \beta_2 \mathbf{1}\{competitor_only\}_{imct} + \beta_3 \mathbf{1}\{both\}_{imct} + \boldsymbol{\gamma}' \mathbf{x}_{mct}^{drug} + \alpha_i + \mu_c + \lambda_t + \varepsilon_{iqmct} \tag{1}$$

where $i$ indexes the member, $q$ indexes the question, $m$ indexes the meeting, $c$ indexes the committee, and $t$ indexes the year. The dependent variable $favor_sponsor$ is a binary indicator of whether the member voted in a way favorable to the sponsor for question $q$. Additional covariates include individual, year, and committee fixed effects, as well as $\mathbf{x}^{drug}$, a vector of drug-specific characteristics that included indicators of whether the drug under review was a new molecular entity or was considered first-in-class, whether the application had an orphan designation, and whether the application was on an accelerated approval pathway, fast track or breakthrough therapy pathway, or had a priority review designation. Standard errors were clustered at the attendee-meeting-level.

I estimated this model using a sample that included all questions asked in a meeting, with some meetings contributing multiple questions. Each observation (attendee-question) was weighted by the inverse of the number of voting questions in the meeting to ensure that meetings with more questions did not contribute more to the estimation than meetings with fewer questions. As robustness checks, I also estimated this model without weights and, in a separate specification, restricted the sample to one question per meeting. For the single-question sample, if an approval question was asked during a meeting, that question was selected. If there was no approval question, the question asking if the benefits outweigh the risks was selected. If neither type of question was asked, I selected a question from the meeting at random.

I also used the individual-level model specified in Equation (1) to estimate the relationship between conflicts of interest and voting dispersion, a member-level measure of the informational content of each member's recommendations. This measure is intended to capture the "excess dispersion" in each member's vote, after accounting for member FEs, drug characteristics, and

meeting characteristics. To create this measure, I first calculated the probability of member $i$ voting in favor of the sponsor for question $q$ in meeting $m$ in committee $c$ in year $t$ by estimating Equation (1) and computing each member's predicted probability of voting in favor of the sponsor.[11] I then calculated the residuals (= actual vote - predicted probability) and used the normalized (Pearson) residuals as the measure of excess dispersion. These normalized residuals capture the degree to which a member's actual votes had lower or greater variance than their predicted votes based on member, drug, and meeting characteristics. A more precise informational signal about drug quality is conveyed to the agency when a member's votes have less dispersion.

To determine the relationship between COIs and voting dispersion, I estimated:

$$\begin{aligned} vote_dispersion_{iqmct} = \beta_0 + \beta_1 \mathbf{1}\{sponsor_only\}_{imct} + \beta_2 \mathbf{1}\{competitor_only\}_{imct} + \beta_3 \mathbf{1}\{both\}_{imct} \\ + \boldsymbol{\gamma}' \mathbf{x}_{mct}^{drug} + \alpha_i + \mu_c + \lambda_t + \varepsilon_{iqmct} \end{aligned} \tag{2}$$

If a member's sponsor tie conferred expertise that led to a more informative signal to the agency, we would expect those votes to have lower dispersion, i.e., $\beta_1 < 0$. Similar reasoning applies for competitor ties ($\beta_2 < 0$) and ties to both sponsor and competitor ($\beta_3 < 0$).

### 4.2 Meeting-Level Analyses

For meeting-level analyses, the structural equation was:

$$\begin{aligned} majority_favor_sponsor_{mct} = \beta_0 + \beta_1\, share_sponsor_{mct} + \beta_2\, share_competitor_{mct} \\ + \theta\, total_trials_{c,t-18} + \boldsymbol{\gamma}' \mathbf{x}_{mct}^{drug} + \mu_c + \lambda_1 t + \lambda_2 t^2 + u_{mct} \end{aligned} \tag{3}$$

where $m$ indexes the meeting, $c$ indexes the committee, and $t$ indexes the year. The dependent variable $majority_favor_sponsor$ is a binary indicator of whether a majority of members voted in favor of the sponsor for a key meeting question. The variable $share_sponsor$ is the share of members who had a tie to the sponsor, $share_competitor$ is the share of members who had a tie to a competitor, and $total_trials$ is the total number of trials in the committee's therapeutic domain measured 18 months prior to the committee meeting (more below). Additional covariates included committee fixed effects, linear and quadratic time trends, and indicators of drug characteristics (new

[11] The unweighted version of Equation (1) was used to improve prediction.

molecular entity, first-in-class, orphan designation) and expedited pathway or review (accelerated approval, fast track or breakthrough therapy, priority review) for the given application. Given the small number of committees ($n$=12), I used a parsimonious time-trend specification in place of year fixed effects. I clustered standard errors at the committee level to account for within-committee correlations.

Because there may be concerns about unobserved meeting-level and drug-level factors that could affect both the likelihood of higher (or lower) shares of individuals with a sponsor conflict and their probability of voting in favor of the sponsor, I used an instrumental variables strategy to identify the causal effect of the share of individuals with a sponsor COI and the share of individuals with a competitor COI on the share of members voting in favor of the sponsor and on the probability of a majority of members voting in favor of the sponsor.

To instrument for the share of members with a sponsor COI, I used the number of clinical trials sponsored by the applicant in the committee's therapeutic domain conducted 18 months prior to the advisory committee meeting (i.e., the number of trials occurring in the month of the meeting lagged by 18 months), but *excluding the clinical trials in the ATC6 class of the drug under review.* This instrument captures the applicant's intensity of research activity in committee areas that might create financial ties to the sponsor – but by excluding the ATC6 class of the drug under review, it filters out unobserved pipeline and drug development features in the relevant ATC area that might also affect members' propensity to vote in favor of the sponsor. Note that advisory committee members, in reviewing drug applications, are specifically instructed to only take into account evidence related to the safety and efficacy of the particular drug under review. Other factors, such as pipeline, costs, and reputation, are not to be included in committee deliberations.

To control for industry research activity that could also have affected members' probability of voting in favor of the sponsor (such as the competitive environment or innovation in "hot" areas), I also included, as a covariate, the total number of trials in the committee's therapeutic domains, also lagged by 18 months. Conditional on committee fixed effects, time trends, drug novelty, unmet need, and this proxy of the drug development environment in the committee's therapeutic areas, this instrument should isolate variation in sponsor conflicts that affected voting only through the sponsor financial relationship and not through other channels, like the competitive landscape or domain-specific developments.

The second instrument I used was the dollar value of the threshold for COI waiver eligibility. As discussed above, the FDA lowered the threshold for waiver eligibility from $100,000 to $50,000 in 2008.[12] According to FDA guidance, members with relevant financial interests above this amount would not be issued a waiver regardless of their level of expertise. The specific instrument was the level of the threshold 6 months prior to the meeting since that is approximately the time that COI waiver eligibility would have been determined.

The first-stage equation for *share_sponsor* was therefore:

$$\begin{aligned} share_sponsor_{mct} = \pi_0 + \pi_1\, sponsor_trials_{c,t-18} + \pi_2\, waiver_threshold_{mc,t-6} \\ + \pi_3\, total_trials_{c,t-18} + \boldsymbol{\gamma}'\mathbf{x}_{mct}^{drug} + \mu_c + \lambda_1 t + \lambda_2 t^2 + \nu_{mct}. \end{aligned} \tag{4}$$

A similar first-stage equation was estimated for *share_competitor*. As shown in Table A3, the two instruments were strongly individually relevant and conditionally relevant. The Sanderson-Windmeijier F-statistic was 127.08 ($p$ <0.001) for *share_sponsor* and 21.30 ($p$ <0.001) for *share_sponsor*, so the null hypothesis of no conditional relevance can be rejected. The Anderson-Rubin Wald F-statistic was 75.84 ($p$ <0.001), so the null hypothesis of no joint relevance can be rejected as well.

I used the same instrumental variables strategy to estimate the effect of COIs on the probability of a black box safety warning at approval and post-approval. The at-approval black box warning is a measure of the prescience or additional safety-related expertise of committee scientists, and should increase with greater expertise. The post-approval black box warning reflects unanticipated safety events and should decline with greater expertise.

For the at-approval measure, I identified black box warnings issued within 6 months of the meeting date, or approximately the time from the advisory committee meeting to approval or launch. For the post-approval measure, I identified black box warnings issued more than 1 year after the meeting date extending through 5 years. Advisory committee meetings can be convened to decide whether to impose a black box warning, so the 1-year lower bound was used to exclude warnings issued as a result of a meeting.

[12] US Food and Drug Administration (2008) states that the lower threshold was applicable beginning with the December 3, 2008 advisory committee meeting.

# 5 Results

## 5.1 Individual COI and Voting

Figure 4 shows the graphical relationship between the (residualized) financial ties and (residualized) pro-sponsor voting. These figures show a clear positive relationship between the sponsor tie and pro-sponsor voting and a rather weak relationship between the competitor tie and pro-sponsor voting.

Table 2 shows the individual-level estimates from the fixed-effects models. In all of these models, there is a highly statistically significant relationship between a member's tie with the sponsor and their probability of voting in favor of the sponsor. In the preferred specification (4), which includes drug characteristics and accounts for expedited pathways and priority review, an exclusive tie to the sponsor increases the probability of a pro-sponsor vote by 19.6 percentage points, from a baseline of 58.4%.

In contrast, there is no comparable effect of an exclusive tie to a competitor. On the one hand, members with ties to competitors might be less likely to vote in favor of the sponsor in order to gain a competitive advantage. On the other hand, a pro-sponsor (pro-approval) vote might pave the way for easier approval of a subsequent drug or less scrutiny of a currently marketed drug produced by a competitor. My findings do not provide evidence of the dominance of either type of strategic behavior among competitors.

In addition, having ties to both the sponsor and a competitor does not lead a member to favor the sponsor. One might have expected that members with *any* ties to industry, whether sponsor or competitor, might have had a pro-industry bias and have been more likely to vote in favor of more approvals. The null effect of competitor ties and the null effect of ties to both the sponsor and a competitor are evidence against the frequent claim that there is selection for pro-industry preferences among those members who have industry relationships.

Notably, the pro-sponsor voting effect of having a sponsor COI is absent when the sample is restricted to drug approval questions (Table A2). Rather, the pro-sponsor bias appears to be concentrated among non-approval questions, which typically focus on one aspect of the evidence presented in isolation, such as (solely) safety or (solely) efficacy; recommended clinical endpoint

measures; sufficiency of evidence; and features of trial design. There may be scope for additional discretion and subjectivity with these types of questions.

The results reported in Table 3 are for a weighted sample that included multiple questions for each meeting. The results for the unweighted sample and for the single-question sample (i.e., one question per meeting) are reported in Table A2. I find similar results for these models, with a statistically significant effect of the sponsor-only tie. One difference is that these unweighted models also show a positive effect of multiple ties (i.e., having a tie to both the sponsor and a competitor) on the probability of voting in favor of the sponsor. This difference between the weighted and unweighted models suggest that the bias from multiple ties is concentrated in meetings with multiple voting questions. These meetings may have more complex issues and as noted above, may involve questions that leave more scope for subjectivity and bias.

### 5.2 Individual COI and Voting Dispersion

Table 4 shows the estimated relationship between individual financial ties and voting dispersion. There appears to be no effect of sponsor ties or competitor ties on voting dispersion. Recall that less dispersion reflects a more precise signal of drug quality, as conveyed through member votes. These results show that financial ties do not result in a less noisy signal of drug quality.

### 5.3 Meeting-level COI and Majority Voting

Table 5 reports the OLS and instrumental variables estimates for the relationship between the share of members with a sponsor tie or a competitor tie and the probability of a majority of members voting in favor of the sponsor. I find that increases in the share of members with a sponsor tie leads to significant and large increases in the probability that more than 50% of members vote in favor of the sponsor for a key meeting question. In particular, in the preferred specification (4), a 1 percentage point increase in the share of members with a sponsor tie increases the probability of a majority voting in favor of the sponsor by 12 percentage points. Similar results are reported in Table A5 for the relationship between financial ties and the share of members voting in favor of the sponsor.

### 5.4 Meeting-level COI and Black Box Warnings

Table 6 shows the OLS and instrumental variables estimates for the relationship between the share of members with a sponsor tie or a competitor tie and the probability of a black box safety warning at approval. This unconditional analysis shows that there is no effect of a sponsor tie on the probability of a black box warning at approval.

There is, however, an effect of a competitor tie on these early black box warnings in the OLS models. Since the coefficients of the OLS and IV models are similar, there does not appear to be a COI endogeneity problem with this outcome measure, so the OLS estimates likely reflect a real effect. Indeed, the IV coefficient for the competitor tie appears to not reach significance because of the larger standard errors characteristic of IV.

These results show the presence of sponsor-conflicted experts does not translate into greater contemporaneous identification of serious safety risks. By contrast, competitor-conflicted experts appear to be contributing additional safety expertise.

Table 7 shows the OLS and instrumental variables estimates for the model analyzing post-approval black box warnings. The IV coefficients appear to be 5 times larger than the OLS coefficients, but the standard errors are about 10 times larger. The coefficients suggest that an increase in the share of members with sponsor ties *increases* the probability of a black box warning in 5 years, but the estimates are not very precise and are statistically indistinguishable from zero.

### 5.5 Concordance Between Committee Recommendation and Agency Decisions

An important policy feature of advisory committees is that their recommendations are not binding. Although many agencies, including the FDA, take their committees' advice seriously, their final decisions may well deviate from committee recommendations. It is therefore possible that agencies take into account the bias introduced by conflicted members in their final decisions. If agencies fully discount the bias from conflicted advice, conflicts of interest on advisory committees are far less worrisome.

To examine this possibility, I analyzed relevant FDA actions six months after each advisory committee meeting. I restricted the analysis of actions to this window to avoid capturing post-meeting applicant responses to concerns raised by the committee. For example, a committee could

vote against approval given the evidence presented but specify conditions – for example, additional information or analyses – under which approval should be granted. If the agency had followed committee recommendations in requesting additional information, and the firm conducted the additional analyses ultimately leading to agency approval, one would mistakenly consider FDA action non-concordant if the follow-up period were not restricted (since the FDA ultimately approved the drug even though the committee did not recommend approval). A shorter window would more accurately capture the true concordance state.

In this concordance analysis, I examined whether the agency was less likely to follow committee recommendations when the committee was conflicted. If the agency discounted bias from conflicted members, they would be less likely to follow recommendations when faced with higher levels of conflictedness.

As Table 8 shows, I find that, conditional on the committee's recommendation, the agency does not account for conflictedness at all in its final decisions. In other words, the agency does not discount the recommendations from committees with sponsor (or competitor) conflicts.

I also find that there is no asymmetry in agency concordance. Regardless of whether the committee votes favorably for or unfavorably against the sponsor, the agency does not discount conflictedness bias.

# 6 Discussion

In this analysis of conflicts of interest among FDA advisory committees, I examined the bias-expertise trade-off that is believed to be present when conflicted members participate in deliberations. I find that when members have financial ties to the sponsor of the drug under review, they are more likely to vote in favor of the sponsor. In contrast, when members have financial ties to competitors, they show no voting bias. This bias finding is also reproduced in meeting-level analyses.

However, I find no evidence of additional expertise from the participation of members with sponsor ties. Financial ties to the sponsor do not improve the precision of the informational signal of drug quality, as conveyed by member vote dispersion. They also do not improve the probability of identifying serious safety risks prior to approval or reduce the probability of serious safety risks

post-approval. There is some evidence that competitor ties increase the probability of identifying pre-approval safety risks, suggesting greater informational value from these types of ties.

These findings suggest that the FDA has scope for improving its conflict of interest policies and practices. Sponsor ties generate bias but do not contribute detectable informational or safety-related expertise. Competitor ties do not generate bias but do contribute additional safety expertise. The FDA could move toward a more optimal policy — reducing bias while retaining expertise — by reducing its reliance on members with sponsor ties and lean towards members with competitor ties.

In addition, the FDA, in its drug approval decisions, has historically failed to account for the biases of its conflicted committees. Even if the agency does not change its COI policies, it could improve the quality of its decision-making by accounting for the biases of recommendations emerging from more conflicted committees.

Extending beyond the FDA, the findings of this study suggest that government agencies need not prohibit all industry ties to preserve the integrity of advisory committee deliberations. Similar expertise exists among members with ties to sponsoring firms (or more generally, firms that will benefit directly from a policy being deliberated) and members with ties to competing firms (firms that will be at a disadvantage as a result of the policy). Indeed, members who have ties to a sponsoring firm in one meeting are likely to be same individuals who have ties to a competing firm in another meeting. The use of members with ties to competing firms could confer expertise benefits while minimizing distortions and harms from bias.

Most importantly, agencies should be vigilant of biases from conflicted advice and account for these biases. If they can sufficiently internalize the biases of their advisory committees, agencies can maintain high quality decision-making even if their COI policies and member selection practices are not perfect. In tandem, the two strategies of leveraging expertise from competitor ties and agency internalization of committee biases show promise as ways to preserve the integrity of agency decision-making.

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## Tables

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**Table 1:** Summary Statistics

| **Panel A: Sample Units** | |
|---|---|
| No. committees | 12 |
| No. meetings | 519 |
| No. voting attendees | 1,903 |
| No. voting questions | 1,240 |
| No. votes (attendee-questions) | 18,012 |

| **Panel B: Distributional Statistics** | | | | |
|---|---|---|---|---|
| | Mean (SD) | Median (IQR) | Min | Max |
| Meetings per committee | 43.3 (24.2) | 33.0 (26.5,58.5) | 22.0 | 104.0 |
| Voting attendees per meeting | 14.7 (4.7) | 14.0 (11.0,17.0) | 3.0 | 35.0 |
| Voting questions per meeting | 2.4 (2.0) | 2.0 (1.0,3.0) | 1.0 | 17.0 |

*Notes:* Summary statistics are reported for the full sample. Approximately 2% of observations in the sample are excluded from attendee fixed-effects specifications because they are singletons.

**Table 2:** Conflict of Interest Statistics

| | Meeting-level shares of attendees with specified financial tie | | | |
|---|---|---|---|---|
| | Mean | SD | Min | Max |
| **Panel A: Full Sample (n=519 meetings)** | | | | |
| Sponsor only | 0.010 | 0.044 | 0.000 | 0.385 |
| Competitor only | 0.039 | 0.097 | 0.000 | 0.677 |
| Both sponsor and competitor | 0.009 | 0.036 | 0.000 | 0.333 |
| **Panel B: By Period** | | | | |
| 2002–2007 (n=117) | | | | |
| Sponsor only | 0.027 | 0.069 | 0.000 | 0.385 |
| Competitor only | 0.136 | 0.160 | 0.000 | 0.677 |
| Both sponsor and competitor | 0.036 | 0.065 | 0.000 | 0.333 |
| 2008–2012 (n=180) | | | | |
| Sponsor only | 0.003 | 0.015 | 0.000 | 0.100 |
| Competitor only | 0.010 | 0.035 | 0.000 | 0.268 |
| Both sponsor and competitor | 0.000 | 0.005 | 0.000 | 0.063 |
| 2013–2017 (n=123) | | | | |
| Sponsor only | 0.000 | 0.000 | 0.000 | 0.000 |
| Competitor only | 0.006 | 0.027 | 0.000 | 0.235 |
| Both sponsor and competitor | 0.001 | 0.008 | 0.000 | 0.083 |
| 2018–2022 (n=99) | | | | |
| Sponsor only | 0.014 | 0.058 | 0.000 | 0.375 |
| Competitor only | 0.017 | 0.043 | 0.000 | 0.222 |
| Both sponsor and competitor | 0.004 | 0.024 | 0.000 | 0.200 |

*Notes:* Statistics are reported at the meeting level and reflect the share of voting attendees with financial ties to the sponsor only, competitors only, or both.

**Table 3:** Individual-Level Estimates of Effect of COIs on Voting in Favor of Sponsor

| | Voting in favor of sponsor | | | | |
|---|---|---|---|---|---|
| | (1) | (2) | (3) | (4) | (5) |
| Sponsor only tie | 0.111** | 0.209*** | 0.231*** | 0.243*** | 0.196*** |
| | (0.056) | (0.068) | (0.068) | (0.075) | (0.069) |
| Competitor only tie | 0.027 | 0.050 | 0.061 | 0.047 | 0.046 |
| | (0.038) | (0.043) | (0.040) | (0.037) | (0.037) |
| Both sponsor and competitor ties | 0.041 | 0.099 | 0.112* | 0.106* | 0.094 |
| | (0.055) | (0.063) | (0.061) | (0.061) | (0.060) |
| *Drug characteristics* | | | | | |
| New molecular entity | | | | 0.217*** | 0.199*** |
| | | | | (0.029) | (0.029) |
| First-in-class | | | | 0.031 | 0.003 |
| | | | | (0.033) | (0.035) |
| Orphan designation | | | | 0.018 | -0.047 |
| | | | | (0.032) | (0.037) |
| *Expedited pathway or review* | | | | | |
| Accelerated approval | | | | | 0.034 |
| | | | | | (0.057) |
| Fast track or breakthrough therapy | | | | | 0.046 |
| | | | | | (0.051) |
| Priority review | | | | | 0.108*** |
| | | | | | (0.033) |
| Sample mean pro-sponsor voting | 0.589 | 0.584 | 0.584 | 0.584 | 0.584 |
| Attendee FE | N | Y | Y | Y | Y |
| Year FE | N | N | Y | Y | Y |
| Committee FE | Y | Y | Y | Y | Y |
| No. observations | 18,012 | 17,617 | 17,617 | 17,617 | 17,617 |
| No. attendee clusters | 1,903 | 1,508 | 1,508 | 1,508 | 1,508 |
| No. meeting clusters | 519 | 519 | 519 | 519 | 519 |

*Notes:* $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. COI: conflict of interest. Standard errors, reported in parentheses, are clustered at the attendee–meeting level. Regressions are weighted by the inverse of the number of questions in a meeting.

**Table 4:** Individual-Level Estimates of Effect of COIs on Voting Dispersion

| | Voting Dispersion (lower dispersion = greater signal precision/information) | | | | |
|---|---|---|---|---|---|
| | (1) | (2) | (3) | (4) | (5) |
| Sponsor only tie | -0.033 | -0.124 | -0.136 | -0.147 | -0.110 |
| | (0.063) | (0.084) | (0.083) | (0.090) | (0.087) |
| Competitor only tie | -0.005 | -0.029 | -0.040 | -0.028 | -0.027 |
| | (0.045) | (0.052) | (0.051) | (0.049) | (0.049) |
| Both sponsor and competitor ties | -0.054 | -0.076 | -0.097 | -0.091 | -0.080 |
| | (0.066) | (0.072) | (0.075) | (0.074) | (0.073) |
| *Drug characteristics* | | | | | |
| New molecular entity | | | | -0.209*** | -0.195*** |
| | | | | (0.036) | (0.035) |
| First-in-class | | | | -0.035 | -0.013 |
| | | | | (0.043) | (0.045) |
| Orphan designation | | | | -0.007 | 0.044 |
| | | | | (0.042) | (0.047) |
| *Expedited pathway or review* | | | | | |
| Accelerated approval | | | | | -0.022 |
| | | | | | (0.068) |
| Fast track or breakthrough therapy | | | | | -0.028 |
| | | | | | (0.064) |
| Priority review | | | | | -0.090** |
| | | | | | (0.042) |
| Sample mean of outcome | 0.954 | 0.954 | 0.954 | 0.954 | 0.954 |
| Attendee FE | N | Y | Y | Y | Y |
| Year FE | N | N | Y | Y | Y |
| Committee FE | Y | Y | Y | Y | Y |
| No. observations | 17,617 | 17,617 | 17,617 | 17,617 | 17,617 |
| No. attendee clusters | 1,508 | 1,508 | 1,508 | 1,508 | 1,508 |
| No. meeting clusters | 519 | 519 | 519 | 519 | 519 |

*Notes:* $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. COI: conflict of interest. Voting dispersion is measured as the square of the difference between the variance of actual votes and predicted votes based on individual, drug, and meeting characteristics. Standard errors, reported in parentheses, are clustered at the attendee–meeting level. Regressions are weighted by the inverse of the number of questions in a meeting.

**Table 5:** Meeting-Level Estimates of Effect of COIs on Voting in Favor of Sponsor

| | Probability of majority (> 50%) voting in favor of sponsor | | | |
|---|---|---|---|---|
| | (1) OLS | (2) IV | (3) OLS | (4) IV |
| Share of attendees with sponsor tie | 0.969*** | 12.625*** | 0.886*** | 12.361*** |
| | (0.220) | (2.230) | (0.215) | (2.297) |
| Share of attendees with competitor tie | 0.074 | -3.903 | 0.099 | -3.698 |
| | (0.187) | (4.333) | (0.183) | (4.354) |
| Sanderson-Windmeijer F (sponsor tie) | | 128.36 | | 127.08 |
| | | [$p$ <0.001] | | [$p$ <0.001] |
| Sanderson-Windmeijer F (competitor tie) | | 24.45 | | 21.30 |
| | | [$p$ <0.001] | | [$p$ <0.001] |
| Kleibergen-Paap rank Wald F | | 6.98 | | 5.68 |
| Sample mean pro-sponsor majority voting | 0.626 | 0.626 | 0.626 | 0.626 |
| Total no. clinical trials in committee's ATC therapeutic classes at $t-18$ months | N | N | Y | Y |
| Drug characteristics | Y | Y | Y | Y |
| Expedited pathway or review | Y | Y | Y | Y |
| Quadratic time trends | Y | Y | Y | Y |
| Committee FE | Y | Y | Y | Y |
| No. observations | 519 | 519 | 519 | 519 |
| No. committee clusters | 12 | 12 | 12 | 12 |

*Notes:* $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. COI: conflict of interest. Standard errors, reported in parentheses, are clustered at the committee level. The IV estimates are obtained by instrumenting the sponsor- and competitor-tie shares with: (1) the number of applicant-sponsored clinical trials in the committee's ATC class, excluding the drug's ATC class, measured 18 months prior to the meeting, and (2) the nominal dollar value of the waiver eligibility cutoff measured 6 months prior to the meeting (at the time the meeting was scheduled). The Sanderson–Windmeijer F-statistic tests the conditional relevance of the excluded instruments for each endogenous regressor, conditional on the other endogenous regressor being instrumented. $H_0$ is that the instruments are irrelevant for the given endogenous regressor; associated $p$-values are reported in brackets. The Kleibergen-Paap rank Wald F statistic tests for weak identification in the presence of heteroskedasticity and clustering. For reference, the Stock-Yogo (2005) the critical value for $K_1$=2 endogenous regressors and $L_1$=2 excluded instruments is 7.03 for 10% maximal IV size and 4.58 for 15% maximal IV size. Detailed first-stage statistics and reduced form results are reported in Appendix Tables A3 and A4.

**Table 6:** Meeting-Level Estimates of Effect of COIs on Black Box Warning at Approval

| | Probability of black box (BB) warning at approval | | | |
|---|---|---|---|---|
| | (1) OLS | (2) IV | (3) OLS | (4) IV |
| Share of attendees with sponsor tie | -0.097 | -0.041 | -0.096 | -0.050 |
| | (0.216) | (1.316) | (0.227) | (1.404) |
| Share of attendees with competitor tie | 0.379** | 0.191 | 0.378** | 0.198 |
| | (0.146) | (0.881) | (0.150) | (0.948) |
| Sample mean BB warning at approval | 0.148 | 0.148 | 0.148 | 0.148 |
| Total no. clinical trials in committee's ATC classes at $t-18$ months | N | N | Y | Y |
| Drug characteristics | Y | Y | Y | Y |
| Expedited pathway or review | Y | Y | Y | Y |
| Quadratic time trends | Y | Y | Y | Y |
| Committee FE | Y | Y | Y | Y |
| No. observations | 519 | 519 | 519 | 519 |
| No. committee clusters | 12 | 12 | 12 | 12 |

*Notes:* $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. COI: conflict of interest. BB: black box. Standard errors, reported in parentheses, are clustered at the committee level. The IV estimates are obtained by instrumenting the sponsor- and competitor-tie shares with: (1) the number of applicant-sponsored clinical trials in the committee's ATC class, excluding the drug's ATC class, measured 18 months prior to the meeting, and (2) the nominal dollar value of the waiver eligibility cutoff measured 6 months prior to the meeting (at the time the meeting was scheduled). First-stage statistics are as previously reported. Detailed first-stage statistics and reduced form results are reported in Appendix Tables A3 and A4.

**Table 7:** Meeting-Level Estimates of Effect of COIs on Black Box Warning Within 5 Years

| | Probability of black box (BB) warning within 5 years | | | |
|---|---|---|---|---|
| | (1) OLS | (2) IV | (3) OLS | (4) IV |
| Share of attendees with sponsor tie | 0.281 | 1.332 | 0.271 | 1.319 |
| | (0.182) | (1.285) | (0.175) | (1.381) |
| Share of attendees with competitor tie | -0.011 | -0.537 | -0.008 | -0.527 |
| | (0.095) | (1.249) | (0.095) | (1.327) |
| Sample mean BB warning within 5 years | 0.079 | 0.079 | 0.079 | 0.079 |
| Total no. clinical trials in committee's ATC classes at $t-18$ months | N | N | Y | Y |
| Drug characteristics | Y | Y | Y | Y |
| Expedited pathway or review | Y | Y | Y | Y |
| Time trends | Y | Y | Y | Y |
| Committee FE | Y | Y | Y | Y |
| No. observations | 519 | 519 | 519 | 519 |
| No. committee clusters | 12 | 12 | 12 | 12 |

*Notes:* COI: conflict of interest. BB: black box. Standard errors, reported in parentheses, are clustered at the committee level. The IV estimates are obtained by instrumenting the sponsor- and competitor-tie shares with: (1) the number of applicant-sponsored clinical trials in the committee's ATC class, excluding the drug's ATC class, measured 18 months prior to the meeting, and (2) the nominal dollar value of the waiver eligibility cutoff measured 6 months prior to the meeting (at the time the meeting was scheduled). First-stage statistics are as previously reported. Detailed first-stage statistics and reduced form results are reported in Appendix Tables A3 and A4.

**Table 8:** FDA Concordance with Committee Recommendations

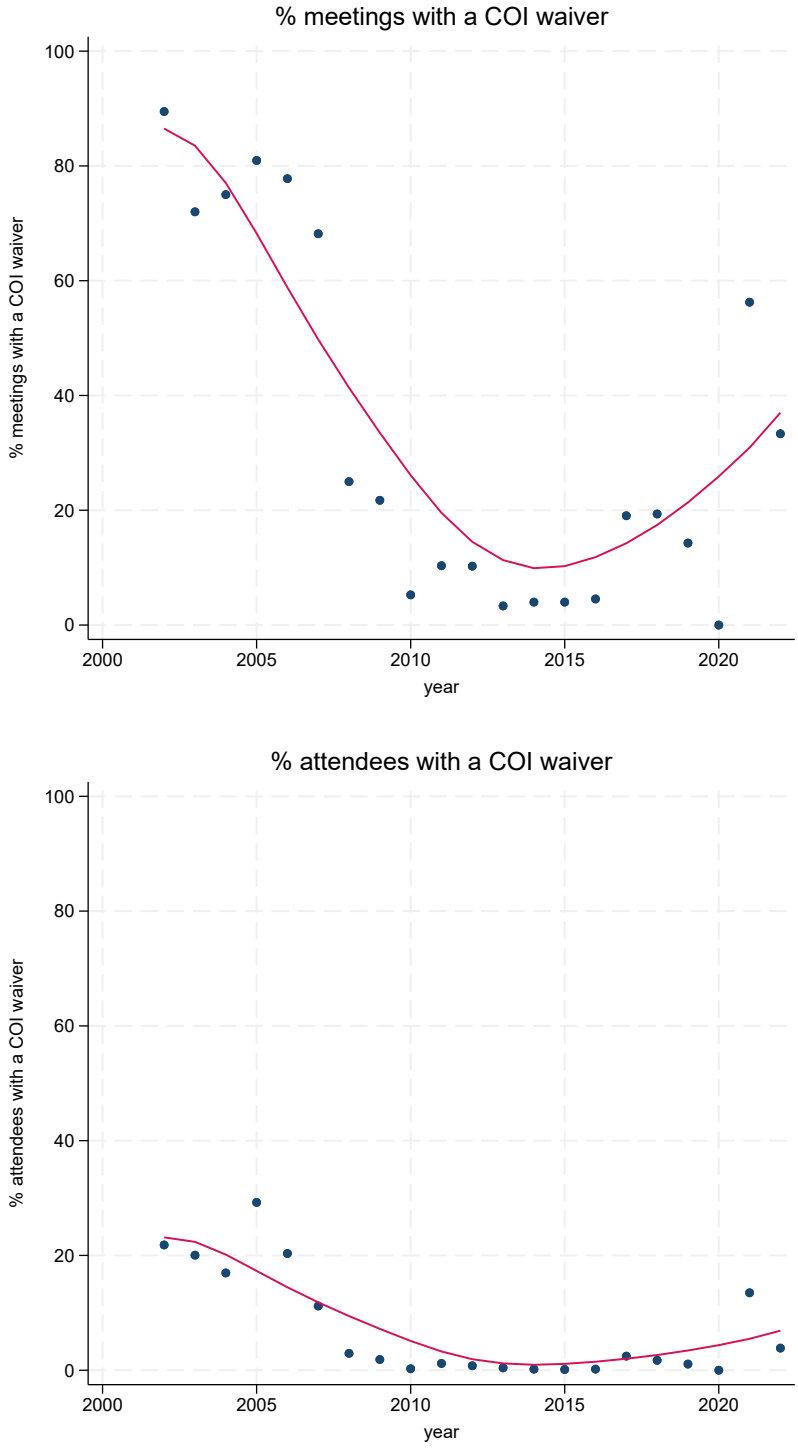
| | FDA favors sponsor | | |
|---|---|---|---|
| | (1) Full sample | (2) Majority favors sponsor | (3) Minority favors sponsor |
| Majority favors sponsor | 0.502*** | | |
| | (0.038) | | |
| Share of attendees with sponsor tie | 0.895* | 0.331 | 0.863 |
| | (0.443) | (0.296) | (0.941) |
| Share of attendees with competitor tie | 0.319 | 0.297 | 0.156 |
| | (0.223) | (0.232) | (0.197) |
| Share of attendees with sponsor tie × majority favors sponsor | −0.707 | | |
| | (0.547) | | |
| Share of attendees with competitor tie × majority favors sponsor | −0.071 | | |
| | (0.259) | | |
| Sample mean FDA favors sponsor | 0.533 | 0.737 | 0.161 |
| Drug characteristics | Y | Y | Y |
| Expedited pathway or review | Y | Y | Y |
| Quadratic time trends | Y | Y | Y |
| Committee FE | Y | Y | Y |
| No. observations | 454 | 293 | 161 |
| No. committee clusters | 12 | 12 | 12 |

*Notes:* $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. Sample is restricted to new or supplemental applications to which FDA actions can be precisely matched (e.g., approvals). Only FDA actions occurring within 6 months of the meeting are considered, to avoid capturing post-meeting applicant responses. Standard errors, reported in parentheses, are clustered at the committee level.

## Figures

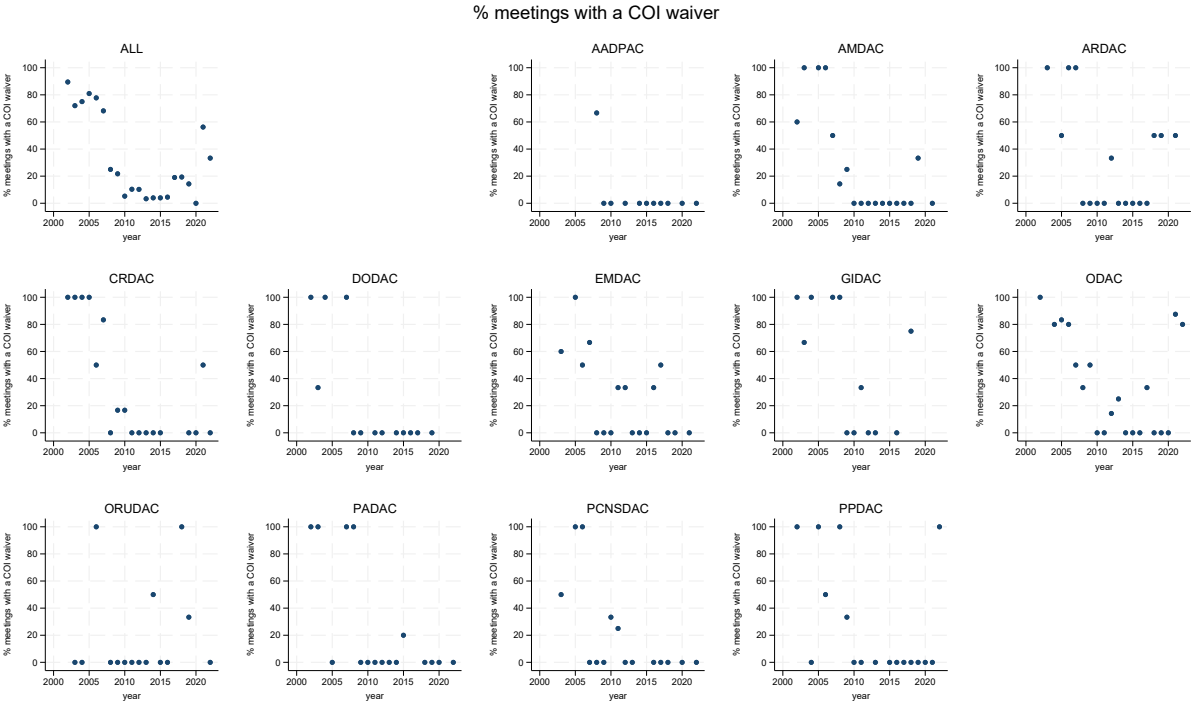
Figure 1: Share of Meetings and Share of Attendees COI Waiver, All Committees
Figure 2: Share of Meetings with One or More COI Waivers, By Committee
Figure 3: Share of Attendees with a COI Waiver, By Committee
Figure 4: Residualized Pro-Sponsor Voting vs. Residualized Sponsor and Competitor COIs

**Figure 1:** Share of Meetings and Share of Attendees with COI Waiver, All Committees



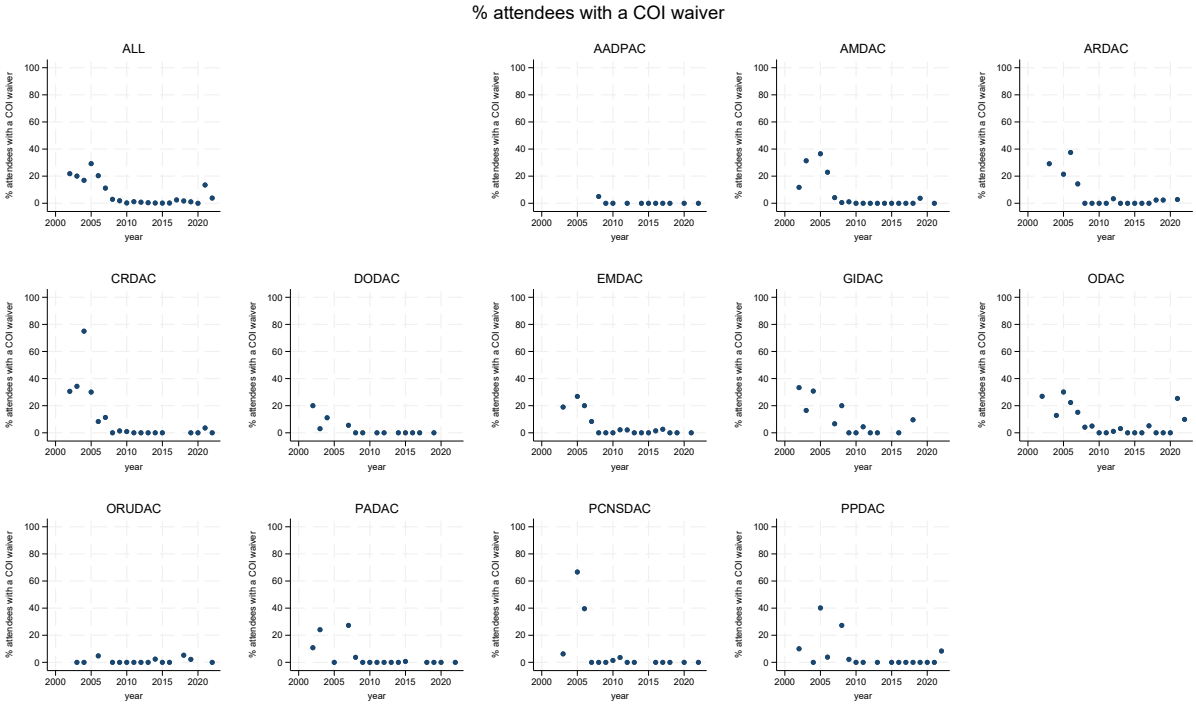

*Note:* Annual meeting-level averages shown.

**Figure 2:** Share of Meetings with One or More COI Waivers, By Committee



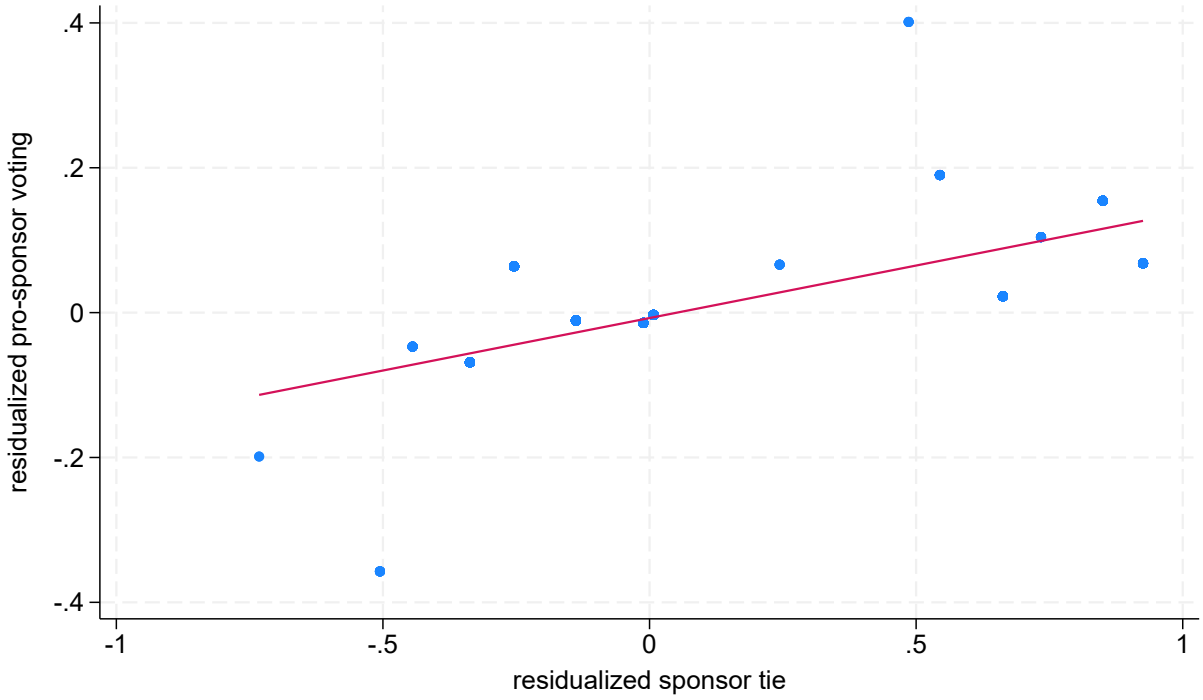

*Note:* Annual meeting-level averages shown. AADPAC: Anesthetic and Analgesic Drug Products Advisory Committee; AMDAC: Antimicrobial Drugs Advisory Committee;ARDAC: Arthritis Drugs Advisory Committee; CRDAC: Cardiovascular and Renal Drugs Advisory Committee; DODAC: Dermatologic and Ophthalmic Drugs Advisory Committee; EMDAC: Endocrine 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; PPDAC: Psychopharmacologic Drugs Advisory Committee

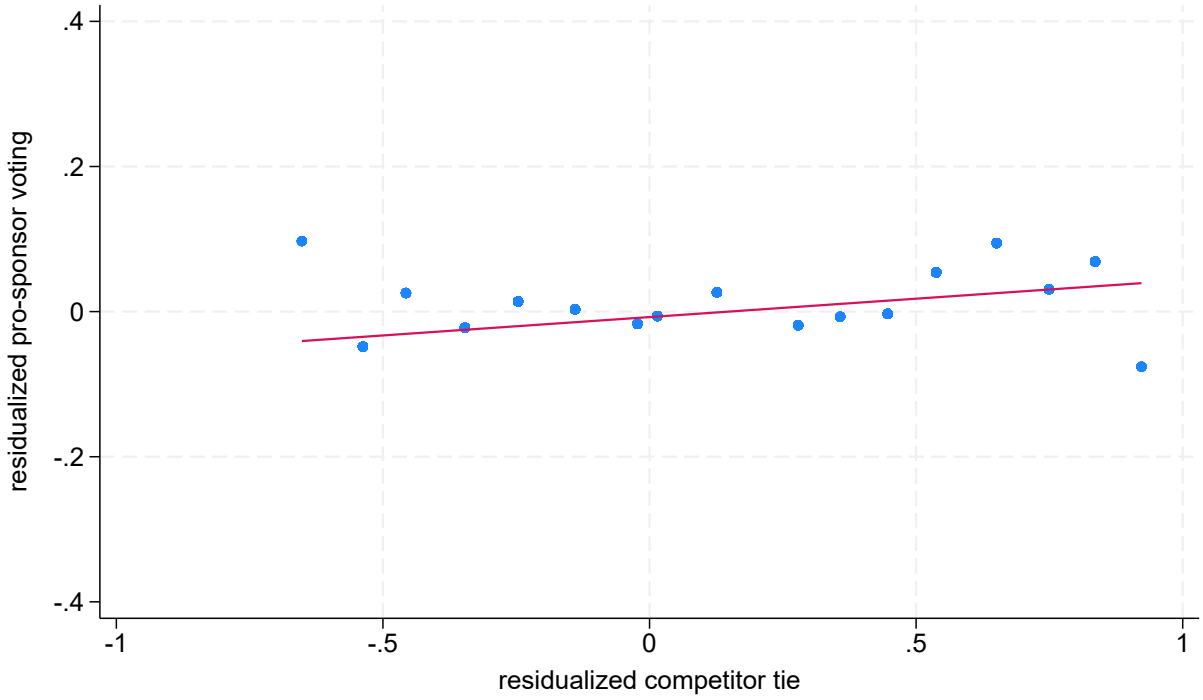
**Figure 3:** Share of Attendees with a COI Waiver, By Committee




*Note:* Annual meeting-level averages shown. AADPAC: Anesthetic and Analgesic Drug Products Advisory Committee; AMDAC: Antimicrobial Drugs Advisory Committee;ARDAC: Arthritis Drugs Advisory Committee; CRDAC: Cardiovascular and Renal Drugs Advisory Committee; DODAC: Dermatologic and Ophthalmic Drugs Advisory Committee; EMDAC: Endocrine 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; PPDAC: Psychopharmacologic Drugs Advisory Committee

**Figure 4:** Residualized Pro-Sponsor Voting vs. Residualized Sponsor and Competitor COIs




*Notes:* The x-axis bins the range of residual values from a regression of an indicator of a sponsor only tie (top panel) or a competitor only tie (bottom panel) on an indicator of tie to both sponsor and competitor, committee fixed effects, year fixed effects, and indicator of drug characteristics (new molecular entity, first-in-class), and special FDA designations (orphan drug, accelerated approval, fast track, priority review) into equal-width bins. The y-axis shows the range of residual values from a regression of an indicator of pro-sponsor voting on an indicator of a sponsor only tie (top panel) or a competitor only tie (bottom panel) and the same controls as above. Each point represents the mean within each bin. The line shown is the fitted line for the points.

## Appendices

Appendix Tables
Table A1: Association Between Member's Current Meeting COI and Their Pro-Sponsor Voting in Previous Meeting
Table A2: Unweighted Individual-Level Estimates of Effect of COIs on Voting in Favor of Sponsor
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Figure A2: First-Stage Relationship Between Instruments and Endogenous Variables

**Table A1:** Association Between Member's Current Meeting COI and Their Pro-Sponsor Voting in Previous Meeting

| | Financial COI in current meeting | | |
|---|---|---|---|
| | (1) Sponsor only | (2) Competitor only | (3) Both |
| Pro-sponsor vote in previous meeting | -0.0046 | 0.0104 | -0.0027 |
| | (0.0053) | (0.0079) | (0.0039) |
| Attendee FE | Y | Y | Y |
| Year FE | Y | Y | Y |
| N | 2,660 | 2,660 | 2,660 |

*Note:* *p<0.10, **p<0.05, ***p<0.01. COI: conflict of interest. Dependent variable is the share of the member's votes in the previous meeting that favored sponsor. All regressions also include constant. Standard errors, reported in parentheses, are clustered at the attendee level.

**Table A2:** Unweighted Individual-Level Estimates of Effect of COIs on Voting in Favor of Sponsor

| | Voting in favor of sponsor | | | |
|---|---|---|---|---|
| | (1) Full | (2) Approval | (3) Non-Approval | (4) Single-Question |
| Sponsor only tie | 0.127** | 0.061 | 0.144** | 0.235*** |
| | (0.055) | (0.064) | (0.065) | (0.070) |
| Competitor only tie | 0.045 | 0.125* | 0.024 | 0.076 |
| | (0.038) | (0.067) | (0.042) | (0.047) |
| Both sponsor and competitor ties | 0.153*** | 0.238* | 0.140*** | 0.149** |
| | (0.051) | (0.121) | (0.051) | (0.070) |
| *Drug characteristics* | | | | |
| New molecular entity | 0.154*** | 0.236*** | 0.135*** | 0.229*** |
| | (0.029) | (0.045) | (0.032) | (0.035) |
| First-in-class | -0.017 | 0.074 | -0.047 | 0.008 |
| | (0.036) | (0.049) | (0.042) | (0.040) |
| Orphan designation | -0.008 | -0.053 | 0.011 | -0.052 |
| | (0.037) | (0.045) | (0.045) | (0.041) |
| *Expedited pathway or review* | | | | |
| Accelerated approval | -0.038 | -0.175 | -0.045 | -0.039 |
| | (0.057) | (0.107) | (0.063) | (0.066) |
| Fast track or breakthrough therapy | 0.088* | 0.120* | 0.067 | -0.003 |
| | (0.045) | (0.067) | (0.054) | (0.054) |
| Priority review | 0.092*** | 0.178*** | 0.070* | 0.135*** |
| | (0.033) | (0.053) | (0.037) | (0.040) |
| Sample mean pro-sponsor voting | 0.585 | 0.606 | 0.579 | 0.586 |
| Attendee FE | Y | Y | Y | Y |
| Year FE | Y | Y | Y | Y |
| Committee FE | Y | Y | Y | Y |
| No. observations | 17,617 | 3,470 | 13,726 | 6,782 |
| No. attendee clusters | 1,508 | 695 | 1,348 | 1,125 |
| No. meeting clusters | 519 | 239 | 388 | 519 |

*Notes:* $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. COI: conflict of interest. Standard errors, reported in parentheses, are clustered at the attendee–meeting level. (1) includes all observations in the sample. (2) includes only approval questions. (3) includes only questions that are not approval questions. (4) includes only one question per meeting (the approval question if there was one asked in the meeting; a randomly selected approval question if there were multiple approval questions asked in the meeting; a question comparing drug benefits to risks if there were no approval questions; and a randomly selected question if there were neither approval questions nor benefit-risk questions asked at the meeting.

**Table A3:** First-Stage Statistics

| | (1) | (2) | Note |
|---|---|---|---|
| *Panel A. First-stage coefficients* | | | |
| Share of attendees with sponsor tie | | | |
| No. applicant-sponsored clinical trials (thousands) in committee's ATC classes excluding index drug's ATC at $t-18$ months | 0.0014*** (0.0001) | 0.0013*** (0.0001) | |
| Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months | 0.0021 (0.0017) | 0.0023 (0.0017) | |
| Share of attendees with competitor share | | | |
| No. applicant-sponsored clinical trials (thousands) in committee's ATC classes excluding index drug's ATC at $t-18$ months | 0.0009*** (0.0002) | 0.0009*** (0.0002) | |
| Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months | 0.0085*** (0.0022) | 0.0084*** (0.0022) | |
| *Panel B. First-stage statistics* | | | |
| First-stage F statistic | | | |
| Sponsor tie share | 66.85 [$p$ <0.001] | 64.74 [$p$ <0.001] | Reject $H_0$ of no relevance |
| Competitor tie share | 15.54 [$p$ <0.001] | 16.77 [$p$ <0.001] | Reject $H_0$ of no relevance |
| Sanderson–Windmeijer F statistic | | | |
| Sponsor tie share | 128.36 [$p$ <0.001] | 127.08 [$p$ <0.001] | Reject $H_0$ of no conditional relevance |
| Competitor tie share | 24.45 [$p$ <0.001] | 21.30 [$p$ <0.001] | Reject $H_0$ of no conditional relevance |
| Kleibergen–Paap rk LM statistic ($\chi^2_1$) | 4.50 [$p$=0.034] | 4.33 [$p$=0.038] | Reject $H_0$ of underidentification |
| Kleibergen–Paap rk Wald F statistic | 6.98 | 5.68 | 10%-15% threshold for weak identification<br>Stock-Yogo 15% critical value = 4.58<br>Stock-Yogo 10% critical value = 7.03 |
| Anderson–Rubin Wald F statistic ($F_{2,11}$) | 89.57 [$p$ <0.001] | 75.84 [$p$ <0.001] | Reject $H_0$ of no joint relevance |
| Total no. clinical trials in committee's ATC therapeutic classes at $t-18$ months | N | Y | |
| Drug characteristics | Y | Y | |
| Expedited pathway or review | Y | Y | |
| Quadratic time trends | Y | Y | |
| Committee FE | Y | Y | |
| No. observations | 519 | 519 | |
| No. committee clusters | 12 | 12 | |

*Notes:* $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. Panel A reports first-stage coefficients (cluster-robust SEs in parentheses). First-stage F-statistics are cluster-robust. Kleibergen-Paap statistics and Anderson-Rubin Wald F are applicable under clustering.

**Table A4:** Reduced-Form Estimates of Meeting-Level Outcomes

| | (1) | (2) |
|---|---|---|
| **Pr(majority (> 50%) favoring sponsor)** | | |
| No. applicant-sponsored clinical trials (thousands) in committee's ATC classes excluding index drug's ATC at $t-18$ months | 0.0136*** | 0.0129*** |
| | (0.0011) | (0.0011) |
| Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months | −0.0072 | −0.0025 |
| | (0.0182) | (0.0196) |
| **Share of attendees favoring sponsor** | | |
| No. applicant-sponsored clinical trials (thousands) in committee's ATC classes excluding index drug's ATC at $t-18$ months | 0.0089*** | 0.0085*** |
| | (0.0012) | (0.0012) |
| Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months | −0.0107 | −0.0078 |
| | (0.0163) | (0.0177) |
| **Pr(black box warning at approval)** | | |
| No. applicant-sponsored clinical trials (thousands) in committee's ATC classes excluding index drug's ATC at $t-18$ months | 0.0001 | 0.0001 |
| | (0.0014) | (0.0014) |
| Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months | 0.0015 | 0.0015 |
| | (0.0063) | (0.0064) |
| **Pr(black box warning within 5 years)** | | |
| No. applicant-sponsored clinical trials (thousands) in committee's ATC classes excluding index drug's ATC at $t-18$ months | 0.0013 | 0.0013 |
| | (0.0008) | (0.0007) |
| Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months | −0.0018 | −0.0014 |
| | (0.0091) | (0.0091) |
| Total no. clinical trials in committee's ATC therapeutic classes at $t-18$ months | N | Y |
| Drug characteristics | Y | Y |
| Expedited pathway or review | Y | Y |
| Quadratic time trends | Y | Y |
| Committee FE | Y | Y |
| No. observations | 519 | 519 |
| No. committee clusters | 12 | 12 |

*Notes:* $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. Standard errors, reported on parentheses, are clustered at the committee level.

**Table A5:** Meeting-Level Estimates of Effect of COIs on Share of Attendees Voting in Favor of Sponsor

| | Share in favor of sponsor | | | |
|---|---|---|---|---|
| | (1) OLS | (2) IV | (3) OLS | (4) IV |
| Share of attendees with sponsor tie | 0.787*** | 8.826*** | 0.735*** | 8.749*** |
| | (0.216) | (1.367) | (0.210) | (1.491) |
| Share of attendees with competitor tie | 0.071 | -3.403 | 0.087 | -3.343 |
| | (0.152) | (3.082) | (0.153) | (3.195) |
| Sanderson–Windmeijer F (sponsor tie) | | 128.36 | | 127.08 |
| | | [$p$ <0.001] | | [$p$ <0.001] |
| Sanderson–Windmeijer F (competitor tie) | | 24.45 | | 21.30 |
| | | [$p$ <0.001] | | [$p$ <0.001] |
| Kleibergen–Paap rank Wald F | | 6.98 | | 5.68 |
| Sample mean share in favor of sponsor | 0.606 | 0.606 | 0.606 | 0.606 |
| Total no. clinical trials in committee's ATC therapeutic classes at $t-18$ months | N | N | Y | Y |
| Drug characteristics | Y | Y | Y | Y |
| Expedited pathway or review | Y | Y | Y | Y |
| Quadratic time trends | Y | Y | Y | Y |
| Committee FE | Y | Y | Y | Y |
| No. observations | 519 | 519 | 519 | 519 |
| No. committee clusters | 12 | 12 | 12 | 12 |

*Notes:* $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. COI: conflict of interest. Standard errors (in parentheses) are clustered at the committee level. The dependent variable is the share of voting committee members favoring the sponsor. IV estimates instrument the sponsor- and competitor-tie shares with: (1) the number of applicant-sponsored clinical trials in the committee's ATC class, excluding the drug's ATC class, measured 18 months prior to the meeting, and (2) the nominal dollar value of the waiver eligibility cutoff measured 6 months prior to the meeting. The Sanderson–Windmeijer F-statistic tests the conditional relevance of the excluded instruments. The Kleibergen–Paap rank Wald F statistic tests for weak identification under clustering. Detailed first-stage statistics and reduced-form results are reported in Appendix Tables A3 and A4.

**Figure A1:** Distribution of Member's Pro-Sponsor Votes in Previous Meeting if Member Has COI in Current Meeting vs. Member Has No COI in Current Meeting, By COI Type

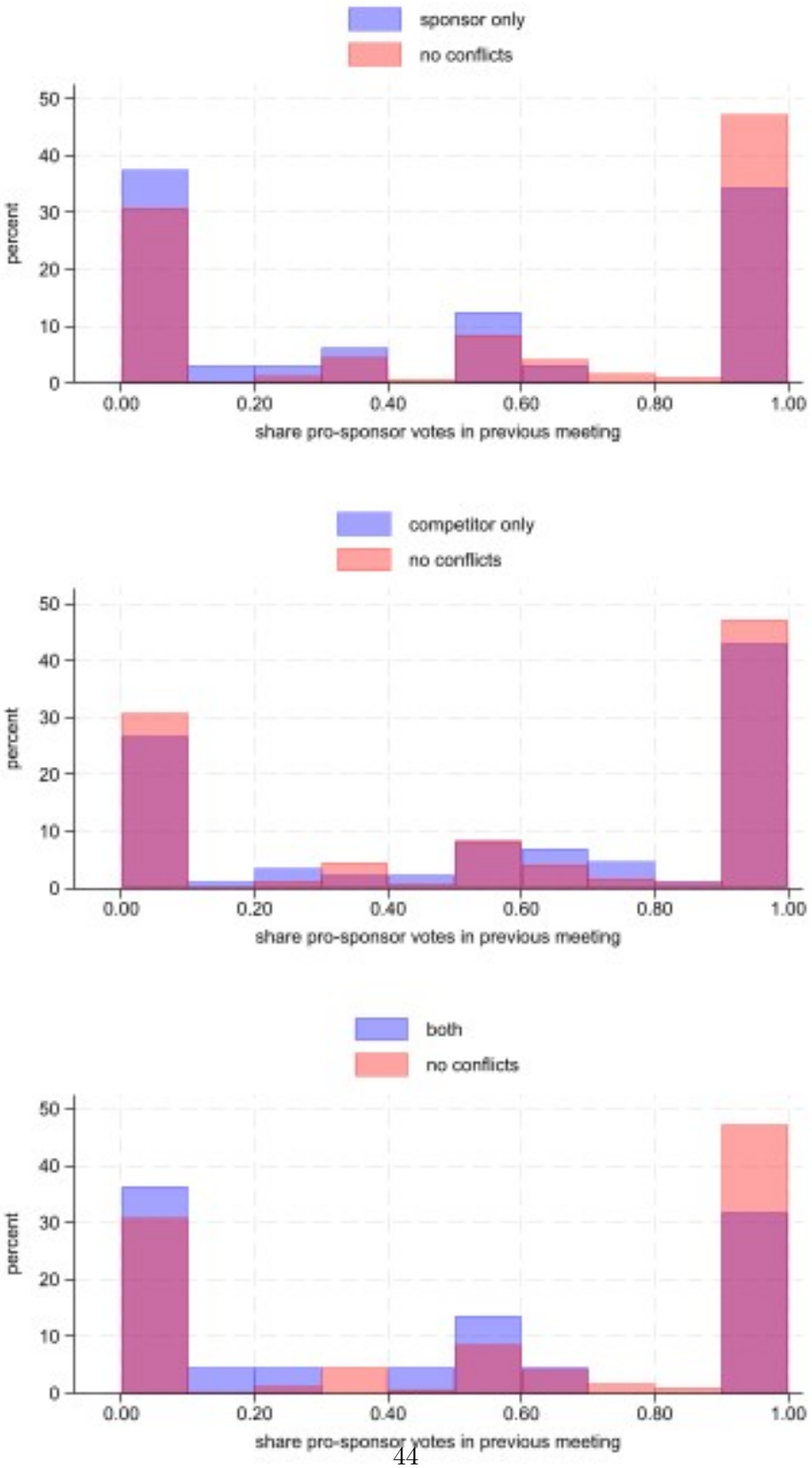
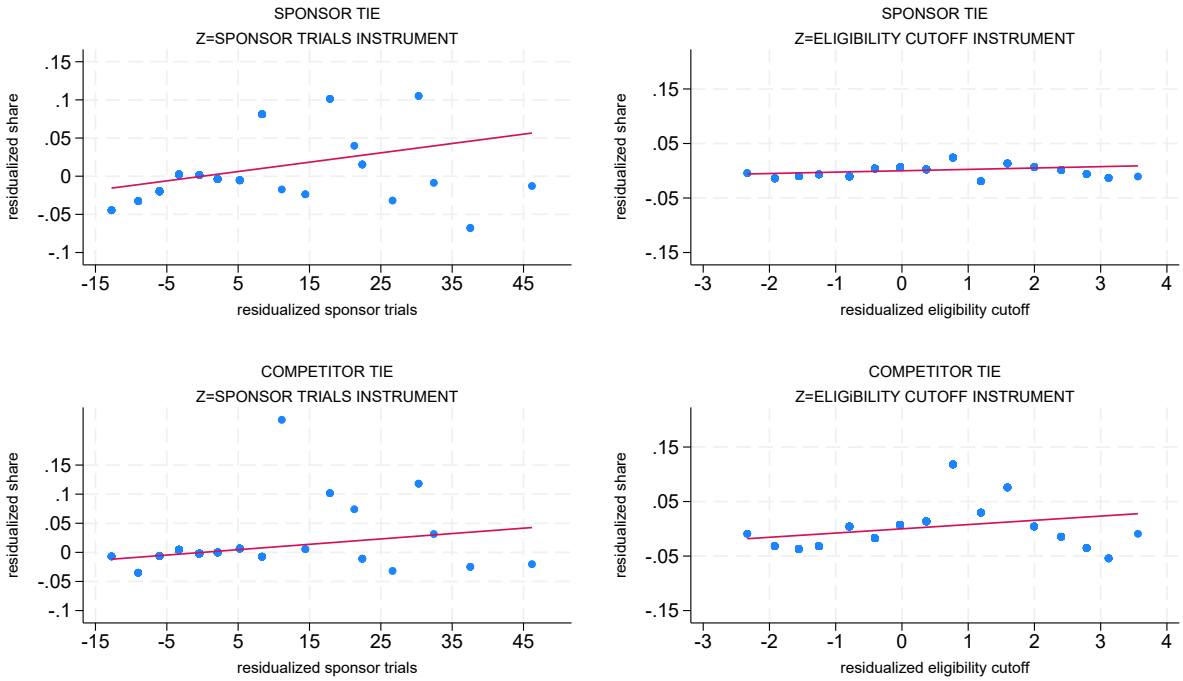


**Figure A2:** First-Stage Relationship Between Instruments and Endogenous Variables




*Notes:* Each panel plots binned means of a residualized endogenous variable (share of members with a sponsor tie or share of members with a competitor tie) against a residualized instrument (number of trials sponsored by the applicant or waiver eligibility cutoff). The x-axis bins the range of residual values from a regression of the number of clinical trials sponsored by the applicant (left panels) or the cutoff for eligibility for a waiver (right panels) on committee fixed effects, quadratic time trends, indicators of drug characteristics (new molecular entity, first-in-class, orphan designation), and indicators of expedited pathway or review (accelerated approval, fast track or breakthrough therapy, priority review) into equal-width bins. The y-axis shows the range of residual values from a regression of the share of attendees with a sponsor tie (top panels) or the share of attendees with a competitor tie (bottom panels) on the same controls as above. Each point represents the mean within each bin. The line shown is the fitted line for the points.