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

Genevieve P. Kanter†

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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 informational contributions. 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 discount 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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†Sol Price School of Public Policy and Leonard D Schaeffer Center for Health Policy and Economics, University of Southern California. Email: gpkanter@kanter-research.org.

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 first analyze whether the presence of members with industry financial ties reduces the variance of the informational signal sent 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 three 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 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 oversight of pharmaceutical and biological drug products.[1] Organized by therapeutic areas, these committees advise on the scientific evaluation of prescription drug products proposed 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 — in particular, the effects on 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 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 a serious safety warning, known as 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 after approval — two measures of safety-related expertise.

I find that members are significantly more likely to vote in favor of the sponsor – by 18.9 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.

At the same time, 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 did not appear to take sponsor conflictedness into account in its final actions.

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.

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, that occurred after 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.

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 leverage the fact that similar expertise exists among members with ties to sponsoring firms and members with ties to competing firms. Biases can emerge even absent deliberate intent, and agencies can preserve important expertise while mitigating 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 perfectly calibrated 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.

2.2 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 represen-

[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.

tative – 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 own 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. Members 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
- 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

[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."

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

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.

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).

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

The impact of these changes have never been directly studied, although Cooper and Golec (2019) included the FDAAA policy change as a covariate in their between-member analysis. The effects of waiver cap were likely minimal because 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.[8] Congress ultimately repealed the waiver caps in 2012.

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.

[8] The lowest level of the statutory cap was approximately 12%.

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 designs or control arms — 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.[9] 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 warnings — the highest-level safety 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

[9]Both fast track and breakthrough therapy designations evaluate applications on the basis of preliminary data — either nonclinical data or early clinical data — and were combined in the measure used.

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, 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 estimated date of FDA rejection from nonapprovable letters if the rejections were prior to 2008, and from company 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 therapeutic area 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. Data on clinical trials conducted in the US between 2000 and 2022 were obtained from Clarivate Cortellis, a commercial vendor of clinical trial data. (This period extends 2 years before the advisory committee sample because these data are incorporated into models with a lag.) Cortellis data were restricted to those trials involving small molecule or biological therapies, classified as commercially significant, and enrolling adults 18 years and older.

To identify the trials and drugs for each advisory committee area, I first used the trial indication specified in Cortellis. To match trials and drugs with missing indications, I mapped drugs to their most likely therapeutic area and advisory committee using the Anatomical Therapeutic Chemical (ATC) system. The ATC system classifies each drug according to its targeted organ system and its therapeutic, chemical, and pharmacological properties.

The first step in this process involved characterizing the ATC classes of drugs within the purview of each advisory committee. I created this mapping by identifying the ATC5 class (the 5th, or most

specific level, of the ATC system) of every drug reviewed by an advisory committee and assigning it to its primary advisory committee using RxNorm and WHO ATC/DDD.[10] Some ATC5 classes were mapped to more than one committee because their proposed indications were in therapeutic areas.

The second step required classifying the drugs that appeared in the clinical trial data by their ATC code. I used a similar protocol to that described above, assigning each trial drug to its ATC5 code if its generic name was listed in RxNorm or WHO ATC/DDD. If the drug was not found in either database, it was assigned an ATC4 code based on its mechanism of action and indication.[11]

Clinical trials were thus assigned to their putative advisory committees based on the stated trial indication, and secondarily, their ATC code. I then identified all clinical trials sponsored by the drug applicant and computed monthly counts of applicant-sponsored trials corresponding 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

[10] Specifically, I matched the generic names of drugs reviewed by each advisory committee to the drugs' ATC codes using RxNorm. RxNorm is a drug vocabulary maintained by the US National Library of Medicine that standardizes drug names and identifiers, and maps them across different drug classification systems, including the ATC classification system. Some drugs reviewed by advisory committees could not be mapped to ATC codes through RxNorm because they were not in clinical use in the US — i.e., had not been approved in the US. For these drugs, I first searched for the drug's ATC code in the ATC system maintained by the WHO Collaborating Centre for Drug Statistics Methodology (WHO ATC/DDD), which includes compounds in use outside the US. Drugs that could be matched exactly through either RxNorm or WHO ATC/DDD were assigned their ATC5 codes. For drugs that were not found in RxNorm or WHO ATC/DDD, I identified their closest pharmacological analogue, and assigned these drugs the same ATC4 code — i.e., the chemical or pharmacological subgroup code — as that of the analogue. For example, the experimental drug oxycodegol is a μ-opioid receptor agonist used to treat pain and is most pharmacologically similar to oxycodone, an approved μ-opioid receptor agonist that is part of the ATC4 class N02AA ("natural opium alkaloids").

[11] For this step in the assignment procedure, I first used the empirical mapping between mechanisms of action and known ATC codes among drugs in the clinical trial data to identify the candidate ATC4 codes for each mechanism of action. I then used the trial indication, from among trials that listed their indication, to refine the list of ATC4 codes, selecting the modal ATC4 code for that indication from among the candidate codes. About 10.5% drugs in the trial data could not be matched to an ATC code because they were not listed in RxNorm or WHO ATC/DDD, and either did not have a mechanism of action reported in the Cortellis database or had a novel mechanism of action that had not yet been matched to an ATC code.

(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 in FDA guidance.

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. Moreover, there also appear to have been waivers issued in recent years that have exceeded the $50,000 eligibility threshold.[12]

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 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 study period and sub-periods 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-

[12] Although the dollar value of the financial interest is frequently redacted, we have identified waivers with unredacted dollar amounts that exceed the waiver threshold.

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 COI 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 current-meeting COI status on their vote in the previous meeting. 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. The equation I estimated was:

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

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, was considered first-in-class, whether the application had an orphan designation, whether the application was on an accelerated approval pathway, whether the application was on a fast track or breakthrough therapy pathway, and whether the application 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 were multiple approval questions, an approval question was selected at random. If there was no approval question, the question asking if the benefits outweigh the risks was selected. If there were multiple risk-benefit comparison questions, a risk-benefit question was selected at random. 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.[13] I then calculated the residuals (= actual vote - predicted probability), transformed to normalized Pearson residuals[14] as a well-behaved measure of excess dispersion. These normalized residuals captured 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.

[13]The unweighted version of Equation (1) was used at this stage to improve prediction.

[14]The normalized Pearson residual is the square of the residual divided by an estimate of the Bernoulli variance $p(1-p)$.

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

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

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

4.2.1 Analyses of voting

For meeting-level voting analyses, the structural equation was:

$$majority_favor_sponsor_{mct} = \beta_0 + \beta_1\, share_sponsor_{mct} + \beta_2\, share_competitor_{mct} + \boldsymbol{\gamma}' \mathbf{x}_{mct}^{drug} + \mu_c + \lambda_1 t + \lambda_2 t^2 + u_{mct} \tag{3}$$

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, and $share_competitor$ is the share of members who had a tie to a competitor. Additional covariates included committee fixed effects, linear and quadratic time trends, and indicators of drug characteristics (new 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 voting outcomes of interest: (1) the share of members voting in favor of the sponsor, and (2) 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).[15] This instrument captures the applicant's intensity of research activity in committee areas that might create financial ties to the sponsor.

However, one might be concerned that clinical trial activity might capture factors that could also have affected members' probability of voting in favor of the sponsor, such as the competitive environment or innovation in "hot" areas. Although advisory committee members are specifically instructed to only take into account evidence related to the safety and efficacy of the particular drug under review – ignoring other considerations such as pipeline, costs, and reputation — it is possible that these other factors may nevertheless influence voting.

I therefore also used a refined trial instrument: the number of applicant-sponsored trials in a committee's therapeutic domain *excluding* the trials in the same ATC3 class of the drug under review. The ATC3 class would include products with the same indication but potentially different mechanisms of action, thus minimizing concerns about exclusion restriction violations through unobserved sentiment about "hot" areas. For example, semaglutide (Ozempic/Wegovy) is defined by its ATC5 code (A10BJ06). The ATC4 level (A10BJ) is the class of glucagon-like peptide-1 (GLP-1) drugs, where there may be acute concerns about violations of the exclusion restriction. The ATC3 level (A10B) is the class of blood glucose lowering drugs excluding insulins. This class includes biguanides like metformin, sulfonylureas, and sodium-glucose co-transporter 2 (SGLT2) inhibitors. The ATC2 level (A10) is the class of drugs used for diabetes.

By excluding the ATC3 class of the drug under review, the refined instrument filters out unobserved pipeline, drug development, and firm reputation influences in the relevant ATC area that might also affect members' propensity to vote in favor of the sponsor. Conditional on committee fixed effects, time trends, drug novelty, and unmet need, this instrument should isolate variation in sponsor conflicts that affected voting only through the sponsor financial relationship and not

[15] Since a COI is based on a current industry relationship, and the lookback period, when applicable, is 12 months, this 18 month gap should exclude activity that directly causes the COI.

through other channels, like the competitive landscape, domain-specific developments, or firm reputation in the index drug's therapeutic area. It would capture features directly related to the likelihood of a COI, such as the probability of an industry relationship in a therapeutic area, a previous relationship, or even friendly sentiment towards the sponsor based on a prior relationship or sponsor generosity, but not *non-COI* pathways.

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.[16] 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:

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

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 54.55 (p <0.001) for *share_sponsor* and 31.51 (p <0.001) for *share_competitor*, so the null hypothesis of no conditional relevance can be rejected. The Anderson-Rubin Wald F-statistic was 7.69 (p=0.008), so the null hypothesis of no joint relevance can be rejected as well.

4.2.2 Analyses of black box warnings

Analyses of black box warnings investigate the safety-related expertise brought to the committee by conflicted members. For these analyses, a black box warning issued at the time of approval is a measure of the prescience or additional safety-related expertise of advisory committee scientists, and the frequency of at-approval black box warnings should increase with greater expertise. In contrast, a *post*-approval black box warning reflects unanticipated safety events that emerged after drug approval and should decline with greater expertise.

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

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 the approval (or rejection) 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 that were issued as a result of a meeting.

For these analyses, I restricted the sample to meetings related to new drug approvals or expanded populations or indications (NDAs, sNDAs, BLAs, and sBLAs). To minimize selection bias, I included meetings for drugs that were approved as well as those that were not approved. Since drugs that were not approved would never have a black box warning — and could have been recommended by the committee for rejection because of serious safety concerns — estimates from this analysis might understate the expertise effect.

Unlike with voting analyses, analyses of black box warnings pose fewer endogeneity concerns. The agency, not the advisory committee, makes the decision on whether to apply a black box warning, and very frequently issues these warnings without committee input, so OLS should be sufficient. Durbin-Wu-Hausman tests also fail to reject the null hypothesis of COI exogeneity for both the at-approval black box warnings ($p = 0.283$) and the post-approval black box warnings ($p = 0.963$), supporting the use of OLS. As an additional precaution, I report estimates from an IV model that uses the total clinical trials instrument and the waiver eligibility instrument.

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 3 shows the estimates from the individual-level 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 18.9 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 either type of strategic behavior among competitors.

One might have also 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 in general. The null effect of competitor ties are evidence against the frequent claim that there is selection for pro-industry preferences among those members who have any kind of industry relationship.

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. As an additional check, I estimated a model with sample restrictions and a specification similar to that of Cooper and Golec (2019), who previously found no effect of sponsor COIs. I am able to reproduce their null result, which persists even with the addition of individual fixed effects. This result suggests that their zero finding may be specific to a subset of questions and advisory committee meetings.

5.2 Individual COI and Voting Dispersion

Table 4 shows the estimated relationship between individual financial ties and 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. There appears to be no effect of sponsor ties or competitor ties on voting dispersion when drug characteristics are included. This finding suggests that any noise reduction from a sponsor only tie (as seen in model (3)) is primarily driven by the kinds of drugs that were reviewed in meetings that had sponsor COIs.

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 a sizable and significant increase 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 9 percentage points. Similar results are reported in Table A6 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 IV 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 model accounting drug characteristics. As discussed in the methods section, endogeneity does not appear to be an important threat to identification for black box warnings, so OLS is likely capturing the true effect.

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. This behavior could also reflect strategic efforts by experts with ties to competitors to impede the marketing efforts by the sponsor. A potentially more informative analysis is underway examining adverse event rates of reviewed drugs.

Table 7 shows the OLS and instrumental variables estimates for the model analyzing post-approval black box warnings. Neither sponsor-conflicted experts nor competitor-conflicted experts appear to contribute expertise that reduces post-approval drug safety, as reflected in the frequency of post-approval black box warnings.

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 to meetings for new drug approvals and expansion of indication — cases where FDA action could be directly mapped to specific committee recommendations — and focused on actions within this 6-month 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, as expected, the agency frequently follows the advisory committee's recommendation. However, conditional on the committee's recommendation, the agency does not discount recommendations from committees with sponsor (or competitor) conflicts. I also find that there was no asymmetry in agency concordance. Regardless of whether the committee voted favorably for or unfavorably against the sponsor, the agency did not account for 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 reflected in 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 after approval. On the other hand, there is some preliminary evidence that competitor ties increase the probability of identifying pre-approval safety risks, suggesting greater informational value from these types of industry ties. Additional analyses is underway to examine the effects of conflicts on adverse event rates.

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, if needed, drawing on 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 and members with ties to competing firms. 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 imperfect. In tandem, the two strategies of leveraging expertise from competitor ties and agency internalization of committee biases show promise as ways to support sound agency decision-making.

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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***	0.225***	0.189***
	(0.056)	(0.068)	(0.068)	(0.072)	(0.067)
Competitor only tie	0.027	0.050	0.061	0.060	0.066
	(0.038)	(0.043)	(0.040)	(0.039)	(0.039)
Both sponsor and competitor ties	0.041	0.099	0.112	0.127**	0.120**
	(0.055)	(0.063)	(0.061)	(0.062)	(0.061)
Drug characteristics					
New molecular entity				0.194***	0.185***
				(0.028)	(0.028)
First-in-class				0.094***	0.089**
				(0.033)	(0.035)
Orphan designation				−0.040	−0.047
				(0.030)	(0.032)
Expedited pathway or review					
Accelerated approval					0.011
					(0.049)
Fast track or breakthrough therapy					−0.078
					(0.041)
Priority review					0.077**
					(0.031)
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	−0.053	−0.145*	−0.158**	−0.151*	−0.130
	(0.060)	(0.077)	(0.078)	(0.082)	(0.080)
Competitor only tie	−0.015	−0.044	−0.056	−0.055	−0.060
	(0.043)	(0.051)	(0.051)	(0.050)	(0.050)
Both sponsor and competitor ties	−0.052	−0.074	−0.096	−0.110	−0.105
	(0.066)	(0.071)	(0.074)	(0.075)	(0.074)
Drug characteristics					
New molecular entity				−0.175***	−0.169***
				(0.034)	(0.033)
First-in-class				−0.099**	−0.097**
				(0.043)	(0.045)
Orphan designation				0.036	0.039
				(0.036)	(0.038)
Expedited pathway or review					
Accelerated approval					0.014
					(0.057)
Fast track or breakthrough therapy					0.048
					(0.042)
Priority review					−0.053
					(0.038)
Sample mean of outcome	0.955	0.955	0.955	0.955	0.955
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 actual votes and predicted votes based on individual, drug, and meeting characteristics, normalized by the Bernoulli variance. A value of 1 indicates dispersion consistent with Bernoulli voting; values below 1 indicate less dispersion (more predictable voting). 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) OLS	(3) IV	(4) IV\ATC3
Share of attendees with sponsor tie	0.948***	0.862***	4.781***	9.156***
	(0.177)	(0.260)	(1.285)	(1.186)
Share of attendees with competitor tie	0.089	0.189	−1.765	−3.254
	(0.233)	(0.194)	(2.661)	(3.177)
Sanderson–Windmeijer F (sponsor tie)			224.75	54.55
			[p <0.001]	[p <0.001]
Sanderson–Windmeijer F (competitor tie)			25.37	31.51
			[p <0.001]	[p <0.001]
Kleibergen–Paap rank Wald F			8.48	6.86
Sample mean pro-sponsor majority voting	0.626	0.626	0.626	0.626
Drug characteristics	N	Y	Y	Y
Expedited pathway or review	N	Y	Y	Y
Quadratic time trends	Y	Y	Y	Y
Committee FE	Y	Y	Y	Y
ATC3 exclusion from trial IV	–	–	N	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 the number of applicant-sponsored clinical trials in the committee's therapeutic domain measured 18 months prior to the meeting, and the nominal dollar value of the waiver eligibility cutoff measured 6 months prior to the meeting (at the time the meeting was scheduled). Column (3) shows IV estimates from a specification that uses the the total count of sponsor trials in the committee's therapeutic domain as the first instrument; column (4) shows IV estimates from a specification that uses the the total count of sponsor trials in the committee's therapeutic domain excluding the drug's own ATC3 therapeutic class. 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) 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, A4, and A5.

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

	Prob of black box (BB) warning at approval		
	(1) OLS	(2) OLS	(3) IV
Share of attendees with sponsor tie	−0.009	0.118	6.831
	(0.312)	(0.299)	(4.534)
Share of attendees with competitor tie	0.356*	0.370**	−1.743
	(0.176)	(0.169)	(2.612)
Sample mean BB warning at approval	0.159	0.159	0.159
Drug characteristics	N	Y	Y
Expedited pathway or review	N	Y	Y
Quadratic time trends	Y	Y	Y
Committee FE	Y	Y	Y
No. observations	453	453	453
No. committee clusters	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. Sample restricted to NDA approval meetings. The IV estimates are obtained by instrumenting the sponsor- and competitor-tie shares with the number of applicant-sponsored clinical trials in the committee's therapeutic domain measured 18 months prior to the meeting, and the nominal dollar value of the waiver eligibility cutoff measured 6 months prior to the meeting (at the time the meeting was scheduled). Detailed first-stage statistics and reduced-form results are reported in Appendix Tables A3, A4, and A5.

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

	Prob black box (BB) warning within 5 years		
	(1) OLS	(2) OLS	(3) IV
Share of attendees with sponsor tie	0.289	0.262	0.919
	(0.178)	(0.191)	(2.635)
Share of attendees with competitor tie	−0.023	0.012	−0.394
	(0.095)	(0.087)	(1.533)
Sample mean BB warning within 5 years	0.088	0.088	0.088
Drug characteristics	N	Y	Y
Expedited pathway or review	N	Y	Y
Quadratic time trends	Y	Y	Y
Committee FE	Y	Y	Y
No. observations	453	453	453
No. committee clusters	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. Sample restricted to NDA approval meetings. The IV estimates are obtained by instrumenting the sponsor- and competitor-tie shares with the number of applicant-sponsored clinical trials in the committee's therapeutic domain measured 18 months prior to the meeting, and the nominal dollar value of the waiver eligibility cutoff measured 6 months prior to the meeting (at the time the meeting was scheduled). Detailed first-stage statistics and reduced-form results are reported in Appendix Tables A3, A4, and A5.

Table 8: FDA Concordance with Committee Recommendations

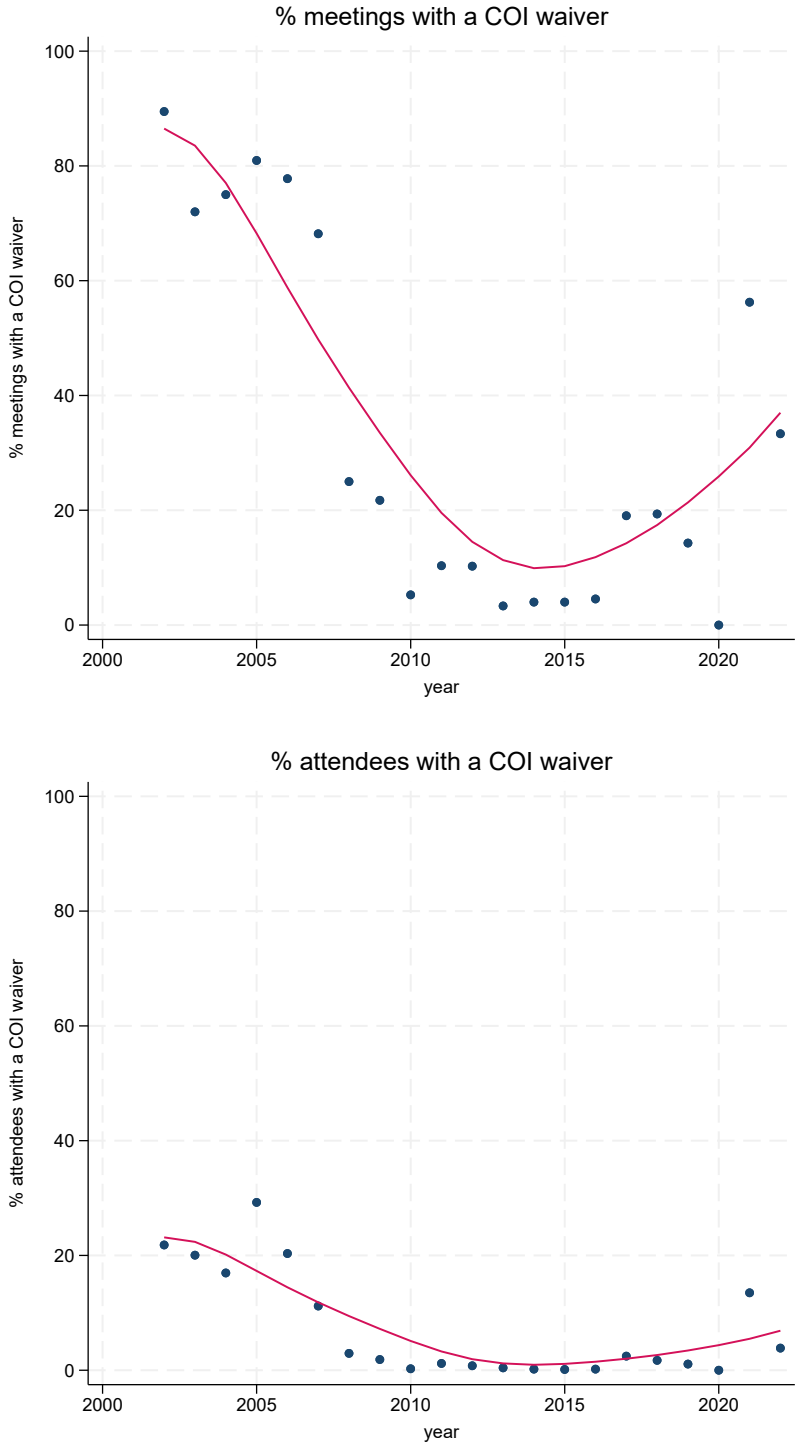
	FDA favors sponsor		
	(1) Full sample	(2) 2002–2012	(3) 2013–2022
Majority favors sponsor	0.504***	0.453***	0.519***
	(0.035)	(0.057)	(0.037)
Share of attendees with sponsor tie	1.222**	0.329	4.101***
	(0.408)	(0.414)	(0.880)
Share of attendees with competitor tie	0.344	0.305	−0.267
	(0.238)	(0.228)	(0.975)
Share of attendees with sponsor tie	−0.837	−0.105	−5.585***
× majority favors sponsor	(0.567)	(0.447)	(1.454)
Share of attendees with competitor tie	−0.091	−0.066	2.283
× majority favors sponsor	(0.277)	(0.304)	(1.377)
Sample mean FDA favors sponsor	0.534	0.508	0.569
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	453	258	195
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 (new drug approvals and expanded indications). 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

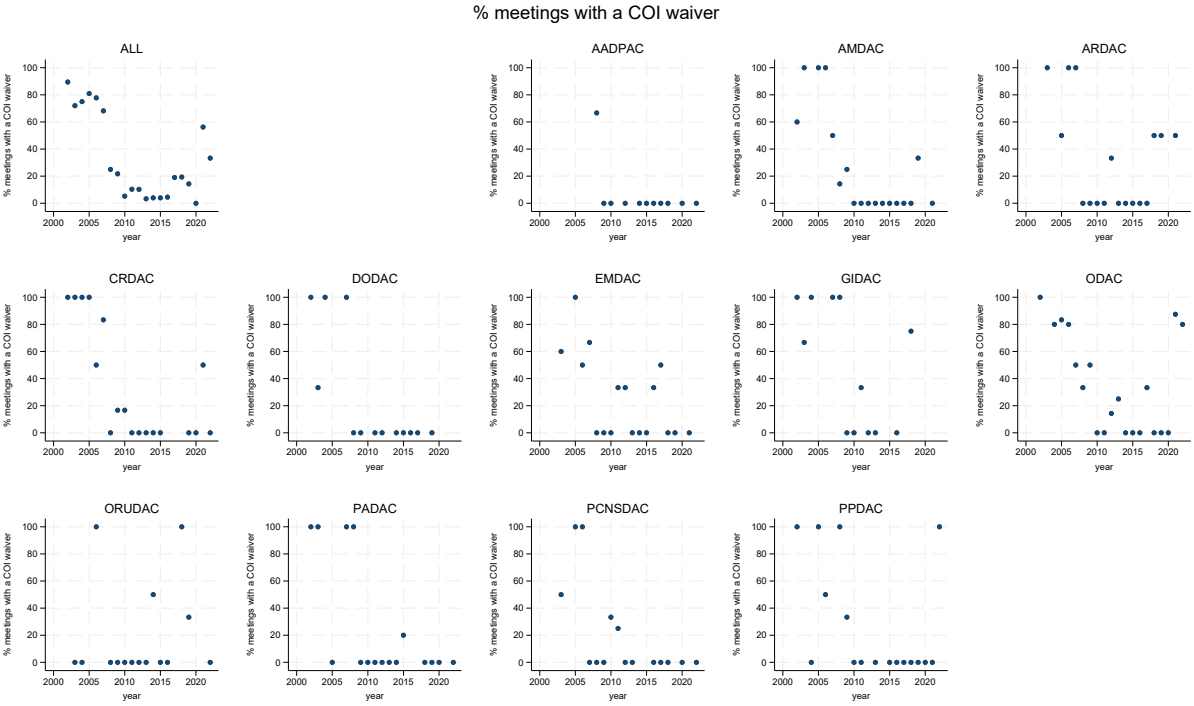
Figure 1: Share of Meetings and Share of Attendees COI Waiver, All Committees
Figure 2: Share of Meetings with One or More COI Waivers, By Committee
Figure 3: Share of Attendees with a COI Waiver, By Committee
Figure 4: Residualized Pro-Sponsor Voting vs. Residualized Sponsor and Competitor COIs

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



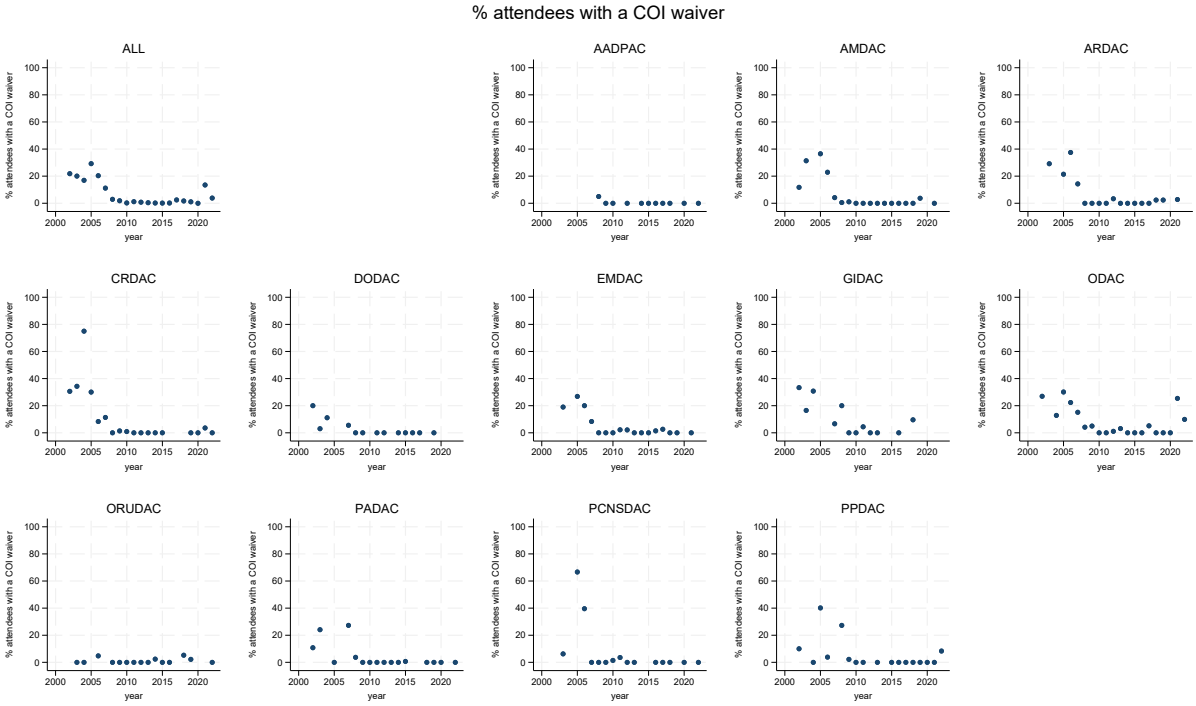
Note: Annual meeting-level averages shown.

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



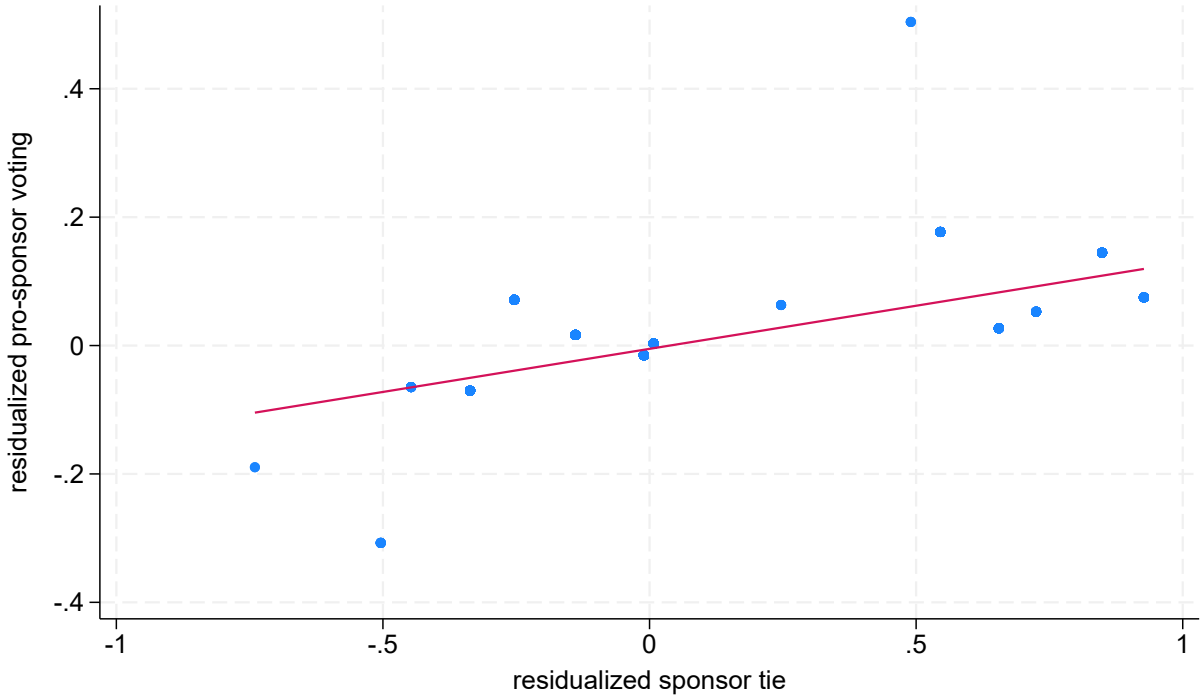
Note: Annual meeting-level averages shown. AADPAC: Anesthetic and Analgesic Drug Products Advisory Committee; AMDAC: Antimicrobial Drugs Advisory Committee;ARDAC: Arthritis Drugs Advisory Committee; CRDAC: Cardiovascular and Renal Drugs Advisory Committee; DODAC: Dermatologic and Ophthalmic Drugs Advisory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

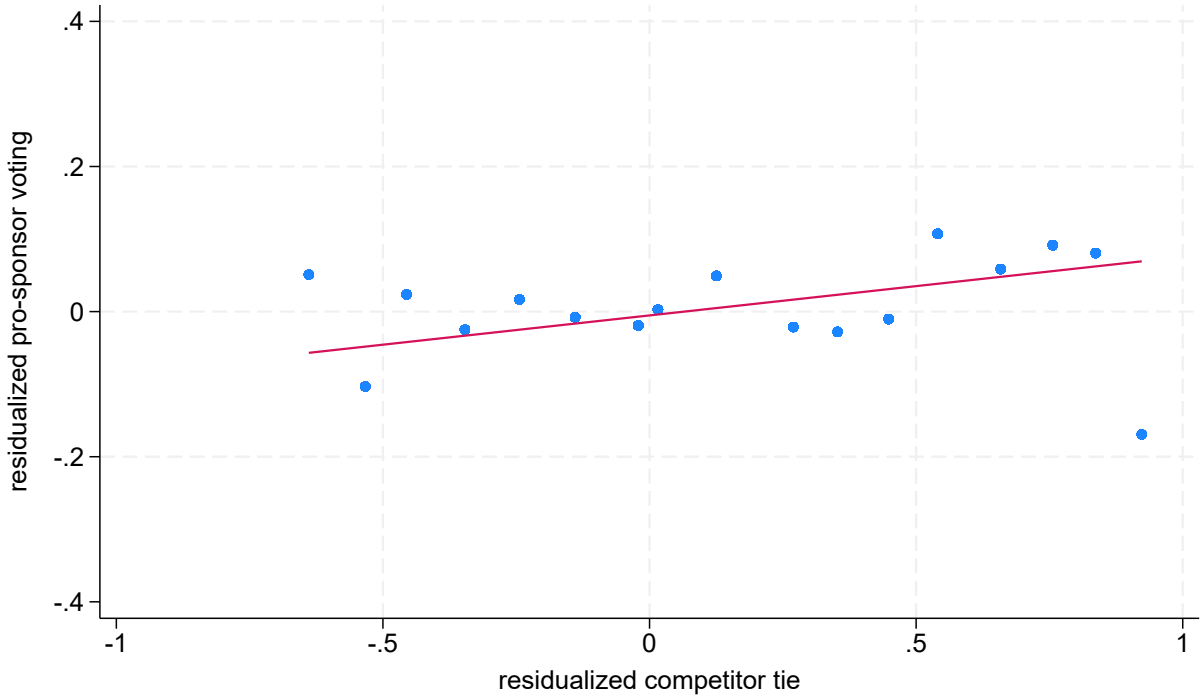
Figure 3: Share of Attendees with a COI Waiver, By Committee



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

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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

	COI in current meeting		
	(1) Sponsor only	(2) Competitor only	(3) Both
Pro-sponsor vote in previous meeting	−0.0046	0.0104	−0.0027
	(0.0049)	(0.0075)	(0.0045)
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 member's COI status in the current meeting. Independent variable is the share of the member's votes in the previous meeting that favored the sponsor. 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)	(2)	(3)
	Full sample	Single question	Cooper rep
Sponsor only tie	0.111**	0.225***	0.112
	(0.050)	(0.067)	(0.079)
Competitor only tie	0.067*	0.099**	0.020
	(0.038)	(0.049)	(0.031)
Both sponsor and competitor ties	0.163***	0.176**	0.124*
	(0.052)	(0.071)	(0.070)
Drug characteristics			
New molecular entity	0.132***	0.186***	
	(0.028)	(0.033)	
First-in-class	0.059	0.102**	
	(0.036)	(0.040)	
Orphan designation	−0.013	−0.037	
	(0.033)	(0.035)	
Expedited pathway or review			
Accelerated approval	−0.008	−0.072	
	(0.049)	(0.054)	
Fast track or breakthrough therapy	−0.064	−0.091**	
	(0.039)	(0.042)	
Priority review	0.091***	0.088**	
	(0.031)	(0.036)	
Sample mean pro-sponsor voting	0.585	0.586	
Drug characteristics	Y	Y	
Expedited pathway or review	Y	Y	
Attendee FE	Y	Y	
Year FE	Y	Y	
Committee FE	Y	Y	
No. observations	17,617	6,782	6,355
No. attendee clusters	1,508	1,125	
No. meeting clusters	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 unweighted. (1) includes all observations in the sample. (2) 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 risk-benefit questions asked at the meeting). (3) reproduces, using my data, sample restrictions and a specification similar to those used by (Cooper and Golec (2019)), including only NDA and sNDA meetings, only approval or risk-benefit questions, and no fixed effects.

Table A3: First-Stage Statistics: IV with no ATC Exclusion

	(1) Sponsor	(2) Competitor	Note
Panel A. First-stage coefficients			
No. applicant-sponsored clinical trials (thousands) in committee's therapeutic classes at $t-18$ months	0.483***	0.074	
	(0.038)	(0.057)	
Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months	0.003	0.009***	
	(0.002)	(0.002)	
Panel B. First-stage statistics			
First-stage F statistic			
Sponsor tie share	393.64 [p <0.001]		Reject H_0 of no relevance
Competitor tie share	7.77 [p=0.008]		Reject H_0 of no relevance
Sanderson–Windmeijer F statistic			
Sponsor tie share	224.75 [p <0.001]		Reject H_0 of no conditional relevance
Competitor tie share	25.37 [p <0.001]		Reject H_0 of no conditional relevance
Kleibergen–Paap rk LM statistic (χ^2_1)	4.87 [p=0.027]		Reject H_0 of underidentification
Kleibergen–Paap rk Wald F statistic	8.48		10%–15% threshold for weak identification Stock-Yogo 15% critical value = 4.58 Stock-Yogo 10% critical value = 7.03
Anderson–Rubin Wald F statistic ($F_{2,11}$)	6.31 [p=0.015]		Reject H_0; robust to weak instruments
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: First-Stage Statistics: IV with ATC3 Exclusion

	(1) Sponsor	(2) Competitor	Note
Panel A. First-stage coefficients			
No. applicant-sponsored clinical trials (thousands) in committee's therapeutic classes excluding index drug's ATC3 class at $t-18$ months	0.285*** (0.047)	0.018 (0.077)	
Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months	0.003 (0.002)	0.009*** (0.002)	
Panel B. First-stage statistics			
First-stage F statistic			
Sponsor tie share	128.34 [p <0.001]		Reject H_0 of no relevance
Competitor tie share	6.65 [p=0.013]		Reject H_0 of no relevance
Sanderson–Windmeijer F statistic			
Sponsor tie share	54.55 [p <0.001]		Reject H_0 of no conditional relevance
Competitor tie share	31.51 [p <0.001]		Reject H_0 of no conditional relevance
Kleibergen–Paap rk LM statistic (χ^2_1)	2.82 [p=0.093]		Reject H_0 of underidentification
Kleibergen–Paap rk Wald F statistic	6.86		10%–15% threshold for weak identification Stock-Yogo 15% critical value = 4.58 Stock-Yogo 10% critical value = 7.03
Anderson–Rubin Wald F statistic ($F_{2,11}$)	7.69 [p=0.008]		Reject H_0; robust to weak instruments
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 A5: Reduced-Form Estimates of Meeting-Level Outcomes

	(1) IV	(2) IV\ATC3
Pr(majority (> 50%) favoring sponsor)		
No. applicant-sponsored clinical trials (thousands) in committee's therapeutic classes at $t-18$ months	2.180*** (0.657)	2.554*** (0.681)
Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months	−0.003 (0.017)	−0.003 (0.017)
Share of attendees favoring sponsor		
No. applicant-sponsored clinical trials (thousands) in committee's therapeutic classes at $t-18$ months	2.027*** (0.313)	2.467*** (0.305)
Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months	−0.008 (0.017)	−0.008 (0.016)
Pr(black box warning at approval)		
No. applicant-sponsored clinical trials (thousands) in committee's therapeutic classes at $t-18$ months	0.918 (0.479)	
Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months	0.008 (0.009)	
Pr(black box warning within 5 years)		
No. applicant-sponsored clinical trials (thousands) in committee's therapeutic classes at $t-18$ months	0.097 (0.236)	
Waiver eligibility cutoff (tens of thousands of dollars) at $t-6$ months	−0.001 (0.009)	
Drug characteristics	Y	Y
Expedited pathway or review	Y	Y
Quadratic time trends	Y	Y
Committee FE	Y	Y
ATC3 exclusion from trial IV	N	Y
No. observations (voting sample)	519	519
No. observations (black box sample)	453	453
No. committee clusters	12	12

Notes: $^{*}p < 0.10$, $^{**}p < 0.05$, $^{***}p < 0.01$. Standard errors, reported in parentheses, are clustered at the committee level. The black box sample consists only of meetings for new drug approvals or supplemental applications related to an expansion of expansion of indication or population. Column (1) shows reduced form estimates from a specification that uses the the total count of sponsor trials in the committee's therapeutic domain as the first instrument; column (2) shows reduced form estimates from a specification that uses the the total count of sponsor trials in the committee's therapeutic classes excluding the drug's own ATC3 therapeutic domain as the first instrument. Both specifications use the waiver eligibility cutoff as the second instrument.

Table A6: Meeting-Level Estimates of Effect of COIs on Share of Attendees Voting in Favor of Sponsor

	Share voting in favor of sponsor			
	(1) OLS	(2) OLS	(3) IV	(4) IV\ATC3
Share of attendees with sponsor tie	0.832***	0.750***	4.548***	8.884***
	(0.191)	(0.243)	(0.660)	(0.833)
Share of attendees with competitor tie	0.073	0.153	−2.315	−3.791
	(0.167)	(0.151)	(2.357)	(2.707)
Sanderson–Windmeijer F (sponsor tie)			224.75	54.55
			[p <0.001]	[p <0.001]
Sanderson–Windmeijer F (competitor tie)			25.37	31.51
			[p <0.001]	[p <0.001]
Kleibergen–Paap rank Wald F			8.48	6.86
Sample mean share in favor of sponsor	0.606	0.606	0.606	0.606
Drug characteristics	N	Y	Y	Y
Expedited pathway or review	N	Y	Y	Y
Quadratic time trends	Y	Y	Y	Y
Committee FE	Y	Y	Y	Y
ATC3 exclusion from trial IV	–	–	N	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 the number of applicant-sponsored clinical trials in the committee's therapeutic domain measured 18 months prior to the meeting, and the nominal dollar value of the waiver eligibility cutoff measured 6 months prior to the meeting (at the time the meeting was scheduled). Column (3) shows IV estimates from a specification that uses the the total count of sponsor trials in the committee's therapeutic domain as the first instrument; column (4) shows IV estimates from a specification that uses the the total count of sponsor trials in the committee's therapeutic domain excluding the drug's own ATC3 therapeutic class. 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) 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, A4, and A5.

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

