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EVALUATING DECISION-MAKING IN THE FDA

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ABSTRACT

The FDA is responsible for the approval of new drugs, biological products and medical devices in the United States. As part of the approval process, the FDA relies on advisory committees, which provide independent advice from outside experts. We combine a structural approach with newly collected data from meetings' transcripts to study the process of collective learning and policy recommendation in advisory committees. We quantify the effectiveness of advisory panels, and evaluate changes to its institutional framework. We find that deliberation significantly increases the accuracy of decision-making. Changes in deliberation rules or committee membership do not uniformly improve outcomes.

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1 Introduction

The Food and Drug Administration (FDA) is responsible for the approval of new drugs, biological products, and medical devices in the United States. These decisions carry substantial public health and economic implications. Successful approvals can lead to significant advancements in treating complex medical conditions, and result in products with annual revenues exceeding billions of dollars. On the other hand, post-approval complications have occasionally required market withdrawals and comprehensive safety reviews (e.g., Vioxx, Fen-Phen, Rezulin). The major issues at stake highlight the delicate balance between innovation, economic interests, and public safety in the pharmaceutical sector.

To address these tradeoffs effectively, the FDA gradually reshaped its review process to incorporate feedback from private sector experts, through the use of specialized advisory committees (ACs). This institutional innovation is now used by FDA’s sister agencies across the world,¹ and across other policy domains within the US government.²

In this paper, we study the process of *collective learning* and policy recommendations in FDA advisory committees, with a structural approach. We address two main questions: Does the current institutional setting lead to effective policy recommendations? Can alternative arrangements improve policy outcomes?

To answer these questions, we exploit data extracted from the transcripts and rosters of all FDA advisory committee meetings held between 2007 and 2020. In a typical committee meeting, representatives from the FDA and the industry sponsor answer committee members’ questions about the safety and efficacy of the product, based on data obtained from clinical and preclinical studies.

¹Prominent examples include the European Medicines Agency Committees, Health Canada Expert Advisory Committees, Japan’s Pharmaceuticals and Medical Devices Agency Expert Panels, UK’s Medicines and Healthcare Products Regulatory Agency Expert Advisory Groups, and Brazil’s Health Regulatory Agency Technical Advisory Committees.

²Advisory committees are used extensively throughout the US government, including the departments of Health and Human Services (HHS), Defense (DoD), Energy (DoE), Education (ED), Agriculture (USDA), Commerce (DoC), Transportation (DoT), the Environmental Protection Agency (EPA), and the National Aeronautics and Space Administration (NASA). For a complete list of advisory committees, see the Federal Advisory Committee Act (FACA) database, maintained by the US General Services Administration.

Following deliberation, members vote on an up-or-down recommendation on each matter before the committee, and offer a rationale for their vote. The committee’s recommendation is then presented to the FDA for final approval.³

From each meeting’s materials, we obtain information about the issues under consideration, member characteristics, and their individual voting records. We also extract presenters’ speeches from their presentations and responses in the question-and-answer period (Q&A). We use a supervised machine learning algorithm to transform the presenters’ speech data into signals about whether the product should or should not be approved, using members’ vote justifications.

We use these data to estimate a dynamic model that captures the key tradeoffs that individual agents face when *learning in a committee*. A single decision-maker faces a tradeoff between learning from continued deliberations and incurring additional delay. Instead, a committee member must also balance learning with the possibility that other members can use the new information differently than she would, potentially overturning her preferred outcome in the future.

Our model builds on Chan, Lizzeri, Suen, and Yariv (2018), which we adapt to fit the application. We assume that committee members are uncertain about whether the product is safe and effective, and have possibly different payoffs for incorrectly approving or rejecting the product. Presenters’ answers to members’ questions provide public signals to the committee. At each point in time before a deadline, members can either obtain more information from presenters, or stop deliberations via some k -majority rule, and take a vote to approve or reject the product. In equilibrium, the committee stops deliberating and rejects (approves) if the posterior belief that the product is safe and effective is sufficiently low (high). For intermediate beliefs, the committee continues deliberation for an additional period. As we show, this *deliberation region* expands with a stricter deliberation rule, or more dispersed preferences.

We show that the parameters of the model are identified within each committee. The state-contingent means and variance of the information process can be

³Advisory committees’ recommendations are non-binding, but the FDA fully follows committee recommendations 84% of the time, and partially implements the committee recommendations 10% of the time (Federal Advisory Committee Act (FACA) database).

recovered from the realization of observed signals, as the information process is represented as a mixture model. Given the information process parameters and realized signals, we can identify the evolution of posterior beliefs for each question under consideration. Members’ preferences are identified from individual voting data, given posterior beliefs at the time of voting. Finally, the discount factor and deliberation rule are identified by stopping decisions in deliberation. For estimation, we rely on individual-level and case-level covariates to pool information across members and cases within each committee.

Our estimates uncover substantial variation in the quality of information and distribution of preferences across committees. All else equal, this leads to variation in the speed of learning and stopping times. Within committees, we find substantial heterogeneity in preferences across cases, but relatively minor differences in preferences in a given case. This indicates that most of the heterogeneity in preferences within committees is due to changes in the characteristics of the cases under consideration, as opposed to markedly different views among its members. Consistent with the informal mandates of the FDA, we find that all committees implicitly operate under a high threshold rule to stop deliberation (most commonly unanimity). This implies that it is difficult or impossible to silence a dissenter in the deliberation process. In all but one committee, we estimate a large discount factor, suggesting that extending deliberations is not very costly for committee members *per se*.

With the parameter estimates at hand, we quantify the probability that each committee provides a *correct* recommendation – i.e., that it approves the product when it is safe and effective, and rejects it when it is not – both *ex-ante*, and conditional on whether the product should or not be approved. To take into consideration that in any given period the committee can choose to not take any policy decision, we compute this measure recursively. Thus, our measure captures the probability that the committee eventually provides a correct recommendation, starting from any given initial belief.

Overall, we estimate that the expected probability of a correct recommendation (across all initial beliefs and deliberation outcomes) is above 80% for seven of the fifteen committees in the sample, and below 50% for four committees. The

ex-ante probability of reaching a correct recommendation, however, is only a partial measure, as decision-makers can weigh errors in different states differently. We show that the seven “high-performing” committees differ markedly in the probability of correctly approving good products or correctly rejecting bad products. Moreover, the four committees with the lowest ex-ante probability of making a correct recommendation do exceptionally well in one state (say correctly approving good products), but poorly on the other.

To quantify how preferences and information contribute to variation in outcomes across committees, we carry out a decomposition exercise. We find that the low ex-ante probability of a correct recommendation in the “under-performing” committees is almost entirely due to differences in preferences, and not in the quality of information. Differences between the top performing committees, instead, are driven by both preferences and quality of information.

We conduct three classes of institutional counterfactuals. In a first set of counterfactuals, we consider the effect of reducing the time allotted to deliberation (cutting it by half, and shutting down deliberation altogether). Second, we consider the effect of relaxing the deliberation rule to a simple majority and a 2/3-supermajority. Third, we consider changes in the composition of advisory committees, replacing the current membership with government scientists (FDA, NIH, CDC), or with members drawn from top research institutions.

Across different committees and case-specific conditions, we find that curtailing the time allotted to deliberation is generally very costly in terms of the effectiveness of the ACs’ recommendations. Thus, the ability of committee members to engage with both FDA specialists and the sponsors’ representatives adds significant value to merely having access to the research materials presented before the meeting. The effects of changes in membership or changes in the deliberation rules, on the other hand, are sensitive to the institutional details and interact in complex ways. The general lesson is that any institutional change should be tailored to existing conditions, accounting for the information process and committee members’ preference profiles.

2 Literature Review

Our model builds on Chan, Lizzeri, Suen, and Yariv (2018), which we adapt to our application. First, we adapt the model to a finite-horizon, discrete-time framework. The finite horizon is consistent with the data, the discrete time is chosen for convenience in estimation. Second, as in the extension in the Chan et al paper, we allow the deliberation and voting rules to differ. In particular, we assume that the voting rule is simple majority, and allow for an arbitrary deliberation rule, which we estimate. This allows us to be agnostic about the (informal) rules guiding deliberation. Third, we allow members to have heterogeneous priors, and assume a common discount factor. Allowing heterogeneous priors allows us to disentangle heterogeneity in preferences and information. The equal discount factor assumption is chosen for identification purposes.

In our model, there is no private information, and public information changes the likelihood of correctly adopting or rejecting a new product. This contrasts with models of collective experimentation (e.g., Strulovici (2010), Anesi and Bowen (2021)), where members learn about the effect of the risky alternative on their payoffs. Our setup also contrasts with models of collective sequential search (see Compte and Jehiel (2010) and Albrecht, Anderson, and Vroman (2010)), in which new alternatives arrive over time, and the committee decision is whether to accept the current alternative or continue searching. We believe that the model we set up and estimate is a closer approximation of the environment in our application.

On the empirical front, our work contributes to the literature on the role of information in committees. Iaryczower and Shum (2012), Iaryczower, Lewis, and Shum (2013), Iaryczower, Katz, and Saiegh (2013) and Hansen, McMahon, and Rivera (2014) consider models of strategic voting with interdependent values. López-Moctezuma (2016), Newham and Midjord (2022) and López-Moctezuma and Johnson (2020) extend this framework to consider sequential voting, while Goeree and Yariv (2011) and Iaryczower, Shi, and Shum (2018) study pre-vote deliberation among committee members. Differently to these papers, in our model there is no asymmetric information, but instead committee members

learn publicly throughout time, and jointly determine when to stop learning and vote on a policy recommendation. To the best of our knowledge, the only other paper to study this problem empirically is Reshidi, Lizzeri, Yariv, Chan, and Suen (2021), who test Chan et al in a lab experiment. Their main focus is to contrast static and dynamic information collection. Instead, we focus on collective learning in the FDA, and how institutional innovations affect the probability of correct recommendations in this setting.

Our paper also contributes to the literature studying the functioning of the FDA. Carpenter (2014) presents an in-depth overview of the historical context and institutional evolution of the FDA. Moffitt (2010) and Urfalino and Costa (2015) consider the problem of secrecy versus transparency in the FDA. Newham and Midjord (2022) study the effect of the change from sequential to simultaneous voting in FDA advisory committees. They use this variation to identify possible herding behavior in sequential voting. Cooper and Golec (2017) focus on industry ties and voting behavior, finding mixed results.

3 The Model

There is a committee with $n = 2m - 1$ members. The committee chooses whether to approve or reject a new product (e.g., a drug), $y \in \{a, b\}$. There is an unobservable state of the world $\omega \in \{A, B\}$, reflecting whether the drug is safe and effective. All agents prefer to approve the drug if it is safe and effective and reject otherwise, but agents differ in the intensity of their preferences. In state A , i 's payoff from approving the drug is 1, and her payoff from rejecting is 0. In state B , i 's payoff from approving the drug is zero, and her payoff if the committee rejects the drug is e^{v_i} . Thus v_i is a measure of the intensity of i 's preferences for the status quo.⁴

Time is discrete, and meetings have a known deadline T . Let $\tau = 0, \dots, T$ denote the number of periods remaining to the deadline. Denote the probability that i assigns to $\omega = A$ given the information received up to τ as $p_{i\tau}$, and let $\theta_{i\tau} \equiv$

⁴The particular normalization of payoffs is irrelevant. Suppose the state-contingent payoff function is $u(y, \omega)$, with $u(a, A) = w$, $u(b, A) = x$, $u(a, B) = y$, $u(b, B) = z$. Given information \mathcal{I} , the decision-maker wants to adopt iff $\Pr(\omega = A | \mathcal{I}) \geq \ln((z - y)/(w - x)) \equiv v$.

$\log(p_{i\tau}/(1 - p_{i\tau}))$. Note that the immediate net expected payoff from adoption for i is positive if and only if $\theta_{i\tau} > v_i$. We allow agents to have heterogeneous priors. We refer to \bar{p} as the *core* prior belief, with $\bar{\theta}_\tau \equiv \log(\bar{p}/(1 - \bar{p}))$, and let $\kappa_i \equiv \bar{\theta}_i - \bar{\theta}$ denote deviations from this core belief.⁵ We let $\tilde{v}_i \equiv v_i - \kappa_i$, and label agents so that $\tilde{v}_1 < \tilde{v}_2 < \dots$. The median is then member m , with preference parameter \tilde{v}_m . With this notation, member i prefers to adopt than to reject at any time τ if and only if

$$\theta_{i\tau} \geq v_i \Leftrightarrow \theta_\tau \geq v_i - \kappa_i \equiv \tilde{v}_i. \quad (3.1)$$

In each period of deliberation, presenters' responses to questions provide information about the product. We denote the new information transmitted by the presenter at time τ by s_τ , and assume that in state ω , $s_\tau \sim \mathcal{N}(\mu_\omega, \rho^2)$, where $\mu_A > \mu_B$. At any point $\tau > 0$, each committee member can raise her hand to ask a question to the presenter. Deliberation is stopped and a vote taken if at least $k \in \{m, \dots, 2m - 1\}$ members want to stop. Two salient cases are unanimity ($k = n$) and simple majority ($k = m$) in deliberation. Members discount payoffs at rate δ . We solve for subgame perfect equilibria of the game in undominated strategies.

3.1 Beliefs

We begin our analysis by characterizing the evolution of beliefs. Note that, by Bayes' rule,

$$\theta_{i\tau} = \log \left(\frac{\Pr(s_\tau | \omega = A)}{\Pr(s_\tau | \omega = B)} \right) + \theta_{i,\tau+1}$$

And since $s_\tau | \omega \sim \mathcal{N}(\mu_\omega, \rho^2)$,

$$s'_\tau \equiv \log \left(\frac{\Pr(s_\tau | \omega = A)}{\Pr(s_\tau | \omega = B)} \right) = \left(\frac{\mu_A - \mu_B}{\rho^2} \right) \left[s_\tau - \left(\frac{\mu_A + \mu_B}{2} \right) \right]. \quad (3.2)$$

Letting $a \equiv \frac{\mu_A - \mu_B}{\rho^2}$ and $b \equiv a \left(\frac{\mu_A + \mu_B}{2} \right)$, we can write $s'_\tau = as_\tau - b$, and

⁵The core belief can be arbitrary. In the empirics, we let the core belief be the belief consistent with the distribution of the signals. With common priors, $\kappa_i = 0$ for all i .

$$\theta_{i,\tau} = s'_\tau + \theta_{i,\tau+1} = \sum_{r=\tau}^T s'_r + \bar{\theta} + \kappa_i = \theta_\tau + \kappa_i. \quad (3.3)$$

Note that conditional on $\omega = A, B$, s'_τ is normally distributed with standard deviation $\rho' \equiv \frac{\mu_A - \mu_B}{\rho}$ and mean $\mu'_A = (\rho')^2/2$ and $\mu'_B = -(\rho')^2/2$. Thus, conditional on $\theta_{i,\tau}$ and ω , the log odds belief $\theta_{i,\tau-1}$ is normally distributed with mean $\theta_{i,\tau} + \mu'_\omega$, and standard deviation ρ' .

3.2 Equilibrium

We solve the model by backwards induction. Suppose we reach the deadline T with core belief θ_0 . From (3.1), the committee adopts the product if $\theta_0 \geq \tilde{v}_m$ and rejects if $\theta_0 < \tilde{v}_m$. Agent i gets a payoff

$$p_{i0} = \frac{e^{\theta_0 + \kappa_i}}{1 + e^{\theta_0 + \kappa_i}} \quad \text{if } \theta_0 \geq \tilde{v}_m \quad \text{and} \quad (1 - p_{i0})e^{v_i} = \frac{e^{\tilde{v}_m + \kappa_i}}{1 + e^{\theta_0 + \kappa_i}} \quad \text{if } \theta_0 < \tilde{v}_m. \quad (3.4)$$

Consider next the problem at $\tau = 1$, with core belief θ_1 . If the committee chooses to end deliberations, it adopts the product if $\theta_1 \geq \tilde{v}_m$ and rejects if $\theta_1 < \tilde{v}_m$, leading to similar payoffs as in (3.4), replacing θ_0 for θ_1 . If instead the committee decides to extend deliberations, the probability that it rejects the proposal at $\tau = 0$ (i.e., that $\theta_0 \leq \tilde{v}_m$) when the true state is ω is

$$\Pr(\theta_0 \leq \tilde{v}_m | \omega, \theta_1) = \Phi\left(\frac{\tilde{v}_m - \theta_1 - \mu'_\omega}{\rho'}\right).$$

Thus, given belief $\theta_{i1} = \theta_1 + \kappa_i$, extending deliberations gives member i an expected payoff of $\delta \bar{W}_i^0(\theta_1)$, where

$$\bar{W}_i^0(\theta_1) = \frac{e^{\theta_1 + \kappa_i}}{1 + e^{\theta_1 + \kappa_i}} \left[1 - \Phi\left(\frac{\tilde{v}_m - \theta_1}{\rho'} - \frac{\rho'}{2}\right) \right] + \frac{e^{v_i}}{1 + e^{\theta_1 + \kappa_i}} \Phi\left(\frac{\tilde{v}_m - \theta_1}{\rho'} + \frac{\rho'}{2}\right), \quad (3.5)$$

using the fact that $\mu'_A = -\mu'_B = (\rho')^2/2$. It follows that if $\theta_1 \geq \tilde{v}_m$, i prefers taking a vote now to extending deliberations if and only if

$$\bar{y}_i(\theta_1|1) \equiv \frac{e^{\theta_1 + \kappa_i}}{1 + e^{\theta_1 + \kappa_i}} - \delta \bar{W}_i^0(\theta_1) > 0, \quad (3.6)$$

and if $\theta_1 < \tilde{v}_m$, i prefers taking a vote now to extending deliberations if and only if

$$\underline{y}_i(\theta_1|1) \equiv \frac{e^{v_i}}{1 + e^{\theta_1 + \kappa_i}} - \delta \bar{W}_i^0(\theta_1) > 0. \quad (3.7)$$

Remark 3.1. *At this point, it is useful to pause briefly to examine the trade-offs in (3.6) and (3.7). Consider the latter to fix ideas. From (3.7), when i anticipates sure rejection if deliberations are halted ($\theta_1 < \tilde{v}_m$), she wants to stop deliberations and reject if and only if*

$$\begin{aligned} \delta \frac{e^{\theta_1 + \kappa_i}}{1 + e^{\theta_1 + \kappa_i}} \left[1 - \Phi \left(\frac{\tilde{v}_m - \theta_1}{\rho'} - \frac{\rho'}{2} \right) \right] &< \frac{e^{v_i}}{1 + e^{\theta_1 + \kappa_i}} \left[1 - \delta \Phi \left(\frac{\tilde{v}_m - \theta_1}{\rho'} + \frac{\rho'}{2} \right) \right] \\ \Leftrightarrow \tilde{v}_i > \theta_1 - \ln \left(\frac{1 - \delta \Phi \left(\frac{\tilde{v}_m - \theta_1}{\rho'} + \frac{\rho'}{2} \right)}{\delta - \delta \Phi \left(\frac{\tilde{v}_m - \theta_1}{\rho'} - \frac{\rho'}{2} \right)} \right) &\equiv \Upsilon_1(\theta_1). \end{aligned} \quad (3.8)$$

Note from the second expression that if $\tilde{v}_j > \tilde{v}_i$, if i wants to stop deliberations, then so does j . Thus, the decision of whether to stop or continue deliberating is monotonic in v_i . Expression (3.8) clarifies the tradeoffs. The left hand side is the wait gain given immediate rejection. This is i 's belief that the product should be adopted given core belief θ_1 , times the increase in the probability that the median correctly adopts, from 0 to $\left[1 - \Phi \left(\frac{\tilde{v}_m - \theta_1}{\rho'} - \frac{\rho'}{2} \right) \right]$, times the discounted payoff of correctly adopting, $\delta \times 1$. The right hand side is the wait loss given immediate rejection. The probability that i gives to the product not being safe and effective is $[1 + \exp(\theta_1 + \kappa_i)]^{-1}$. In this event, stopping gives i a payoff e^{v_i} , but waiting generates costly delay and reduces the probability of correctly rejecting from 1 to $\Phi \left(\frac{\tilde{v}_m - \theta_1}{\rho'} + \frac{\rho'}{2} \right)$. \square

Intuitively, the net wait loss given immediate rejection is positive (negative) when it is very likely that the product should be rejected (approved). This follows immediately from (3.8) taking limits. Thus, provided this function crosses zero once, there exists a lower threshold $\underline{\theta}_i(1) \in \mathbb{R}$, such that i votes to stop deliberations if and only if $\theta_1 \leq \underline{\theta}_i(1)$, where $\underline{y}_i(\underline{\theta}_i(1)|1) \equiv 0$. In Figure 1 we show that this is indeed the case, since the function $\Upsilon_1(\cdot)$ is strictly increasing for all parameter values. As a result, if stopping leads to rejection, i wants to

stop deliberations if and only if $\theta_1 \leq \underline{\theta}_i(1) \equiv \Upsilon_1^{-1}(\tilde{v}_i)$. Similarly, if we keep the committee's decision fixed at approval if deliberations are stopped at $\tau = 1$, there exists $\bar{\theta}_i(1) \in \mathbb{R}$ such that i votes to stop deliberations if and only if $\theta_1 \geq \bar{\theta}_i(1)$, given by $\bar{y}_i(\bar{\theta}_i(1)|1) \equiv 0$

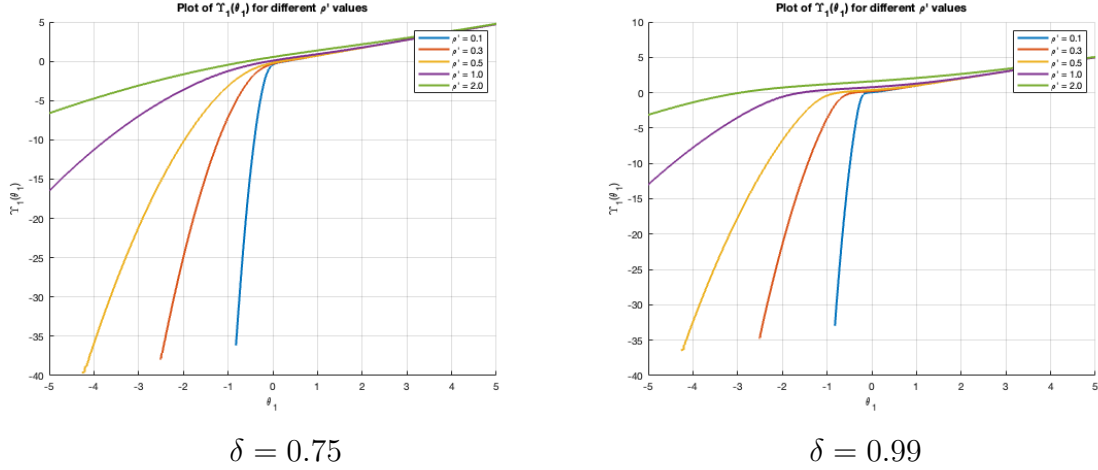


Figure 1: Figure plots the function $\Upsilon_1(\cdot)$ for $\delta = 0.75$ (LHS) and $\delta = 0.99$ (RHS), and different values of ρ' , fixing $\tilde{v}_m = 0$ (without loss).

Implicitly in the definition of $\underline{\theta}_i(1)$, we are fixing the current stopping decision at rejection, which is only true provided that $\theta_1 < \tilde{v}_m$. Similarly, in the definition of $\bar{\theta}_i(1)$, we are fixing the current stopping decision at approval, which is only true provided $\theta_1 \geq \tilde{v}_m$. Thus, letting $\gamma_i(1) = \min\{\tilde{v}_m, \underline{\theta}_i(1)\}$ and $\Gamma_i(1) = \max\{\tilde{v}_m, \bar{\theta}_i(1)\}$, the unique best response in weakly dominant strategies for $i \in N$ is:

$$\sigma_i^1(\theta_1) = \begin{cases} 0 & \text{if } \theta_1 \leq \gamma_i(1) \text{ or } \theta_1 \geq \Gamma_i(1) \\ 1 & \text{if } \theta_1 \in (\gamma_i(1), \Gamma_i(1)) \end{cases} \quad (3.9)$$

where $\sigma_i^1(\theta_1) = 1$ denotes that i wants to extend deliberation at $(\theta, \tau) = (\theta_1, 1)$ and $\sigma_i^1(\theta_1) = 0$ denotes that i stays silent at $(\theta_1, 1)$.

Now, consider equilibrium *outcomes*. Recall that deliberation ends if at least k members want to stop. Define $\gamma(1)$ to be the k th largest element in $\{\gamma_i(1)\}_{i=1}^n$ (i.e., member $2m - k$), and $\Gamma(1)$ to be the k th smallest element in $\{\Gamma_i(1)\}_{i=1}^n$

(i.e., member k). Equilibrium outcomes at $(\theta_1, 1)$ are then given by

$$x_1(\theta_1) = \begin{cases} \text{reject} & \text{if } \theta_1 \leq \gamma(1) \\ \text{continue} & \text{if } \theta_1 \in (\gamma(1), \Gamma(1)) \\ \text{adopt} & \text{if } \theta_1 \geq \Gamma(1). \end{cases}$$

Note that equilibrium outcomes at $\tau = 1$ are effectively determined by the preferences of three committee members: the median, \tilde{v}_m , and the two k -pivots, $(\tilde{v}_{2m-k}, \tilde{v}_k)$. The two pivots are not pivotal for voting outcomes, but are decisive about whether they would rather have the median decide now, with belief θ_1 , or after receiving one additional signal.⁶

In the appendix, we prove two additional results. In Proposition B.1, we show that for the committee to deliberate with positive probability, signals have to be sufficiently informative, and that the threshold of informativeness is decreasing in the level of disagreement between the most extreme pivot and the median committee member. This result has two parts. First, we show that if the deliberation region in $\tau = 1$ is empty, the committee never starts deliberating.⁷ Second, we show that for the deliberation region in $\tau = 1$ to be non-empty, signals have to be sufficiently informative relative to preference heterogeneity. This result has two relevant implications. Consider two preference profiles v' and v'' , such that v'' has a larger dispersion about the median. If the committee extends deliberations with positive probability at $\tau = 1$ with preferences \tilde{v}' , it also does so with preferences \tilde{v}'' . Similarly, if the committee extends deliberations with positive probability at $\tau = 1$ with deliberation rule k , it also does so with all stricter rules $k' > k$.

In Proposition B.2, we provide two comparative static results. First, we show

⁶Note that, in $\tau = 1$, $\underline{\theta}_i(1)$ and $\bar{\theta}_i(1)$ are strategically independent from each other. In each case, the relevant preference comparison is between \tilde{v}_{2m-k} and \tilde{v}_m and between \tilde{v}_k and \tilde{v}_m , respectively; i.e., the preferences of the left pivot do not matter in the determination of the right's pivot decision rule, and vice versa. As we will see, this is unique to $\tau = 1$, the final period in which committee members can extend deliberations.

⁷When the committee never extends deliberations at $\tau = 1$, the period $\tau = 2$ problem is strategically equivalent as to that of $\tau = 1$, and therefore the committee never extends deliberations at $\tau = 2$. The logic extends recursively to the initial period of deliberations.

that if the distribution of preferences is more dispersed around the median, the deliberation region expands. Equivalently, if $\tilde{v}_i \neq \tilde{v}_j$ for any two members i, j , increasing the strictness of the deliberation rule k expands the deliberation region. Second, we show that all else constant, as the median becomes less predisposed to approve, the committee stops to approve less often, and stops to reject more often. These results highlight the key interactions between preferences, priors, information and strategic interactions in information gathering.

Backwards Induction for $\tau \geq 2$. Having characterized equilibrium behavior in $\tau = 1$, we extend the same logic for all $\tau \geq 2$ recursively. We show that under the single-crossing condition for $\tau \geq 2$, there exists a unique $(\gamma(\tau), \Gamma(\tau))$ such that the committee decision is to halt deliberations and vote to reject the proposal whenever $\theta_\tau < \gamma(\tau)$, to halt deliberations and vote to approve the proposal whenever $\theta_\tau > \Gamma(\tau)$, and to continue deliberations whenever $\theta_\tau \in (\gamma(\tau), \Gamma(\tau))$.⁸ The derivation – which we relegate to Appendix C – is analogous to that of $\tau = 1$, with one fundamental difference. In $\tau = 1$, if the committee extends deliberations, committee members know that in $\tau = 0$ the committee will vote for a decision, either to approve or reject the product. Thus waiting means fully delegating the decision to the median voter, \tilde{v}_m . If the committee extends deliberations in $\tau \geq 2$, instead, next period’s decision can be to stop and reject, stop and approve, or *extend deliberations once more*. This means that the preferences of the median and both pivots enter the decision rules of both the left and the right pivot; i.e., $\gamma(\tau)$ and $\Gamma(\tau)$ depend on both $\gamma(\tau')$ and $\Gamma(\tau')$ for all $\tau' < \tau$. Due to the finite horizon, these thresholds are non-stationary; i.e., for the same belief θ , the committee’s behavior may differ depending on the period at play, since that changes the probability of receiving actionable information and future decision-making.

⁸In the estimation, we extensively verify that the single-crossing condition holds across individuals and deliberation periods. See Figures A.4 and A.5 in the Appendix for examples.

4 Context and Data

4.1 Institutional Background

Currently, there are thirty one advisory committees operating in the FDA, each responsible for a specific area of expertise. Advisory committees are typically conformed of nine permanent (core) members, including a chair, who are recognized experts in the advisory committee’s field. The core members of the advisory committee are appointed by the Commissioner based on their scientific or technical expertise and serve for the duration of the committee, or until their terms of appointment expire, with terms between one to four years. In addition to the core members, other individuals may be called to participate in a given meeting on an ad-hoc basis. These can include a consumer representative, a patient representative, or an industry representative who is affiliated with the industry affected by the advisory committee. In addition, committees can be supplemented at each meeting with “temporary voting members,” who provide additional guidance on specific subjects.⁹

Advisory committees typically meet a few times every year. In each meeting, the committee considers clearly specified questions, which can address the efficacy, safety, or risk/benefit of the proposed product, as well as other considerations.¹⁰ Meetings begin with presentations by FDA researchers and industry sponsors. These presentations are typically followed by free-flowing questions from members of the committee. The Chair and DFO (“Designated Federal Officer”) of an advisory committee are encouraged to generate a robust discussion about the issue under consideration before any voting takes place, “so that any comment, insight, or concern that could influence a voter’s conclusions on the matter at issue is heard and considered before a vote related to that matter occurs”.¹¹ These questions and answers are what we call deliberation, while the

⁹By law, the group of voting members in any given meeting should reflect a balanced composition of scientific expertise through members with diverse professional education, training, and experience. Core members of an advisory committee are voting members, provided that there are no conflict of interests. Ad-hoc committee members are voting members provided they have the requisite technical expertise, and no conflicts of interests.

¹⁰These questions are the objective of the meetings, not to be confused with questions asked by committee members during Q&A.

¹¹*Guidance for FDA Advisory Committee Members and Staff*, HSS.

presentations are part of the information available to committee members.

Following deliberation, these questions are put to a vote by members of the committee. Prior to 2007, the FDA advisory committees practiced sequential voting. After 2007, the advisory committees moved to a simultaneous, non-secret electronic vote, where all committee members vote at the same time and discuss their reasoning afterwards (see Newham and Midjord, 2022). To avoid institutional changes that can affect the data generating process, we limit ourselves to meetings conducted after the reform.

4.2 Data

Advisory committee data consists of (i) issues and voting data, (ii) committee member data, and (iii) deliberation data. The source for the voting and deliberation data are the transcripts and minutes of the advisory committee meetings, which the FDA makes available online. The basic source for the data about individual members are the transcripts and rosters of the meetings. We supplemented these data with additional information for employment and publication records. In this section we describe the data, and present key facts about FDA advisory committees (ACs).

4.2.1 Issues & Voting Data

We collected all available information for all meetings conducted between January of 2007 and March 2020 in which an official vote was taken. From this universe, we restricted to questions with a formal binary vote related to approval of a new product, and recoded voting outcomes so that a yes vote aligns with the sponsor’s interest (in favor of approval).¹² One hundred and eighty four questions in our sample (18%) are FDA proposals that are broader than the approval of a given product. We code votes in these questions as “in favor of approval” if the vote agrees with the FDA’s proposal. Our final data consists of

¹²We excluded 23 questions that used non-binary (multiple option) votes, 26 questions in which the direction of the vote was unclear, and 195 questions in which the FDA asked ACs for advice that was not related to the approval of a new product or an FDA proposal. We also excluded from the sample 79 questions addressed in joint committee meetings where the membership overlap with any committee was below 50%.

803 questions in 361 meetings, with decisions by 1,647 unique individual committee members. Across all meetings in our sample, there are 10,875 individual voting instances, with 218 instances of non-voting (2.0%), and 267 abstentions (2.5%). We exclude both, retaining 10,390 Yea or Nay individual votes (6.3 per member on average).

Table 1 presents the number of meetings and questions per committee, alongside the approval rate (Appr. %), size of the winning coalition (Win Size), and unanimity rate (% Unan). Across all committees, about three fourths of all motions receive the support of a majority of the committee (pass, for short). This is consistent with a positive selection effect for products that reach the AC stage on average. There is, however, substantial heterogeneity across committees, with the approval rate being as low as 41% in the Obstetrics, Reproductive and Urologic Drugs committee, and as high as 96% for the Blood products committee. Within each case, committee members often disagree about the merits of the proposals. Overall, only about 40% of the questions are decided unanimously, although votes are generally lopsided, with 86% of the voting members voting with the winning coalition across all cases on average.

Table 1: Voting Outcomes by Committee

Committee	# Meetings	# Questions	Appr. %	Win Size	% Unan.
Medical Devices	75	189	0.849	0.857	0.413
Pediatric	12	79	0.899	0.962	0.759
Antimicrobial Drugs	35	65	0.703	0.845	0.277
Endocrinologic and Metabolic Drugs	42	64	0.710	0.815	0.297
Oncologic Drugs	57	64	0.492	0.854	0.281
Pharmacy Compounding	17	59	0.915	0.896	0.492
Psychopharmacologic Drugs	13	52	0.843	0.840	0.212
Cardiovascular and Renal Drugs	32	44	0.545	0.837	0.295
Dermatologic and Ophthalmic Drugs	11	37	0.730	0.897	0.514
Gastrointestinal Drugs	9	34	0.636	0.843	0.235
Other	16	31	0.581	0.797	0.226
Obst., Reproductive & Urol. Drugs	12	30	0.414	0.822	0.233
Blood Products	12	24	0.958	0.890	0.417
Antiviral Drugs	10	16	0.750	0.900	0.500
Vaccines and Biological Products	8	15	0.933	0.935	0.533
Grand Total	361	803	0.753	0.864	0.390

Note: Cardiovascular includes 3 meetings joint with Drug Safety. Oncologic includes one meeting joint with Cellular, Tissue, and Gene Therapies, and one meeting joint with Medical Imaging Drugs. “Other” includes Allergenic Products (2), Drug Safety and Risk Management (4), Medical Imaging Drugs (4), Non-Prescription Drugs (7), and Pharmaceutical Science and Clinical Pharmacology (4).

We complement the voting data with additional information about each issue. From the text of the question, we extract details about the specifics of the motion. We created categorical variables for whether the question relates to the effectiveness (20%) or the safety (24%) of the product, or the risk/benefit assessment of approving the product (19%). We also created categorical variables for the disease being treated by the product (see Table A.2). Finally, we distinguish between questions that require the approval of a new product introduced by a firm, or a technical proposal introduced by the FDA staff (FDA policy). In addition, we use Compustat/Compustat Global to obtain the revenue of all public companies in our data.¹³ With the raw revenue data, we create four categorical variables, reflecting whether the company sponsoring the product is in the top 10%, top 10-25%, top 25-75% of revenue distribution, and other, including bottom quartile of public companies and private companies (see Table A.4). Descriptive statistics for case-level covariates are available in Table A.3 in the Appendix.

4.2.2 Committee Members' Data

In our sample, there are 1,647 unique voting members across all meetings and years, including 159 patient/consumer representatives (9.7%). Female members comprise approximately one-third (32.8%) of all voting members.

Employment. We collected information about committee members' workplace from the meetings' rosters and transcripts. Two thirds (67%) of all voting members are university professors and/or doctors serving at hospitals.¹⁴ About 14% of members are medical researchers working for a government organization, 11% of them affiliated with the FDA, NIH, or CDC (we label these organizations as *GovScience*), and 3% are affiliated with other government bodies (e.g., a state health agency, or military medical center). We collected additional information on the ranking of hospitals and universities from US News Best Hospitals

¹³We convert international currency to US dollars using FRED exchange rates, and adjust revenues for inflation expressing all revenues in 2020 US dollars.

¹⁴It is common for medical researchers in our sample to be affiliated with both a university and a hospital. When members have multiple appointments, we observe one of these, according to self identification. In our records, 55% of voting members are recorded as university professors and 12% are recorded as employed in a hospital.

for 2021-22. From the rankings for best research medical schools, we created the following categorical variables: *top 10 research institution* (20%), *top 10-20 research institution* (12%), *top 20-50 research institution* (24%), and *other research institutions* (44%).

Publication Record. We collected the publication record of all committee members in our sample from PubMed, a comprehensive record of biomedical literature.¹⁵ We obtained biomedical journal rankings from Scimago, including Medicine (7118 journals) and related fields (see Table A.1). We then constructed a member-specific research score by subfield using the sum of each member’s publications in journals listed in PubMed, weighted by the inverse of the journal ranking in that subfield. We also constructed a general research score weighting publications by the inverse of the top ranking across fields.

Education. We collected information about members’ education from the meetings’ rosters and transcripts. Approximately 70% of committee members have an M.D. degree, with 24% having a Ph.D. degree, 8% an MPH (Master in Public Health), and 3% a Pharm.D (Doctor of Pharmacy).

Experience. Using the rosters and transcripts, we computed the FDA advisory committee experience for each member. For each question j , our *experience* variable counts the number of questions (i.e., issues) the member has participated on, prior to the consideration of question j . The median number of cases per individual is 3, with an average of 6.6, and a standard deviation of 8.7.

Descriptive statistics for all individual level covariates are available in Table A.1 in the Appendix.

4.2.3 Deliberation

The deliberation stage consists of two parts: presentations by experts (industry sponsors, FDA, and invited experts) and a Q&A period, in which committee members ask questions to the presenters. We use the deliberation data to construct a measure of the information provided by experts in each meeting, in

¹⁵Of the 1,648 individuals in our sample, we were able to match 1,517 names to PubMed, leaving 131 members with no biomedical publication record. Out of these, seventy one are patient representatives (45% of all patient reps), and twenty two work in private practice/other. We treat all unmatched individuals as having zero biomedical publications.

both presentations and Q&A. To do this, we implement a supervised machine learning approach, relying on members’ vote justifications, which are required by the FDA, and part of the transcript available to us. The general idea is to use committee members’ justifications speech *across all meetings* to identify the phrases associated with positive and negative information for approval.

We begin by extracting speech text from the transcript with standard pre-processing. For presenters, we distinguish whether their speech is part of a presentation or an answer to a question.¹⁶ We then separate presenters’ speech into 300 terms batches (messages), capturing information transmitted in subsequent time intervals, $t = 1, 2, \dots$, in both presentations and Q&A. The number of messages provides a measure of the effective length of the meeting. Relying on the fact that we observe meetings running out of time, we set the meeting deadline T^c in each committee c as the maximum number of batches within that committee (see Figure A.3).

For voting members, we identify whether the speech is an intervention prior to the vote, or a vote justification. In the justification corpus, we observe a set of “phrase” frequencies that justify the individual vote of each member in each question addressed by the committee. Phrases are composed by unigrams and bigrams; i.e., one or two word phrases. As the first component of our supervised machine learning approach, we use a LASSO estimator to regress committee members’ votes on the phrases in the justification corpus, pooling information across meetings and committees.¹⁷ We then use these estimates to obtain the predicted value of the LASSO model for each message put out by a presenter during the deliberation phase. We interpret the predicted value for each message as the probability that the message conveys favorable information for a “Yea” vote. To obtain the final measure of informativeness of each message, we apply the inverse standard normal CDF on the predicted value for each message, transforming our measure from the $[0, 1]$ space of probability of approval, to an information measure on the real line. Hence, a message that predicts “Yea”

¹⁶Figure A.1 plots the distribution of length (number of words) in FDA and industry representatives’ speeches’ per meeting, across meetings, for both presentations and Q&A.

¹⁷This has the added advantages of increasing data (more justifications and words used), more power, and that our output will not be mechanical: we are using words that are often used to explain votes across meetings.

(“Nay”) votes well holds a large positive (negative) value. A measure at 0 does not convey information in favor or against approval (see Appendix D for additional details).

Validation of the Information Measure. In Section 5.1 below, we show that given signal realizations in each meeting are observed to the analyst, the information process parameters $\psi = (\mu_A, \mu_B, \rho, \bar{p})$ are identified. Given ψ , and signal realizations for each question j , we can then identify the sequence of realized core posterior beliefs $\{\theta_j(\tau)\}$. Provided our signal measure captures the information contained in presenters’ speeches, we should observe that once we control for preferences, higher posterior beliefs *at the time of voting* are correlated with a higher probability of voting in favor of adoption. To assess whether this is the case, we run a battery of regressions explaining individual vote outcomes as a function of individual and question level covariates, including the posterior belief at the time of voting in each question (see Table 2 for the main result, and Table D.2 in the Appendix for the full specification). In all specifications, the coefficient of the posterior belief is positive and precisely estimated, providing support for our measure of the informational content in presenters’ speech.¹⁸

5 Identification & Estimation

We observe data for a set of committees C . For each committee $c \in C$, we observe deliberation and voting outcomes for a set of questions \mathcal{J}_c , with $\mathcal{J} \equiv \cup_{c \in C} \mathcal{J}_c$. For each question $j \in \mathcal{J}_c$, the deliberation data consists of a stopping time $\tau_j^* \leq T_c$, and a vector of signals $\mathbf{s}_j = \{s_{j,\tau}\}_{\tau=\tau_j^*}^{\tau_j^*}$, where $s_{j,\tau}$ denotes the signal observed by members of the committee τ periods before the deadline, and T_c denotes the meeting horizon in committee $c \in C$. The voting data

¹⁸In Table D.1 in the Appendix, we explore whether the information disclosed in a meeting varies systematically between presentation and Q&A stages, or according to whether the speaker is a sponsor or an FDA representative. We find that responses during the Q&A stage tend to be more informative, and convey more negative information for approval, than during the presentation stage. This is intuitive, as the presenter has less control over the agenda. Moreover, we find that FDA speakers tend to provide more relevant information to the committee than the sponsor’s speakers.

Table 2: Posterior Beliefs and Voting Decisions (Summary)

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Posterior Belief (θ_j^*)	0.0035 (0.0004)	0.0039 (0.0004)	0.0035 (0.0004)	0.0046 (0.0019)	0.0044 (0.0019)	0.0046 (0.0019)	0.0048 (0.0006)
Individual Covs.	YES	YES	YES	YES	YES	YES	NO
Case Covs.	YES	YES	YES	YES	YES	YES	YES
Field Pub record	NO	NO	YES	NO	YES	YES	NO
Question FE	NO	NO	NO	NO	NO	NO	NO
Committee FE	NO	NO	NO	YES	YES	YES	NO
Disease FE	NO	NO	NO	NO	NO	YES	YES
Individual FE	NO	NO	NO	NO	NO	NO	YES
# observations	10326	8471	8471	10326	10326	8471	8472
# clusters	-	-	-	16	16	16	1553
R squared (within)	-	-	-	0.039	0.045	0.065	0.043
R squared (between)	0.078	0.048	0.059	0.402	0.427	0.576	0.089

Note: Individual Yea vote regressed on core posterior beliefs at the time of voting, (θ_j^*), individual and case covariates. Robust standard errors in parentheses for Columns 1-3, standard errors clustered at the committee level (Columns 4-6). Table D.2 in the Appendix presents full specification.

consists of individual voting outcomes $\mathbf{y} = \{y_{ij}\}_{i \in \mathcal{I}(j), j \in \mathcal{J}}$, where $\mathcal{I}(j)$ denotes the members voting in question $j \in \mathcal{J}$. For each question $j \in \mathcal{J}$ and member $i \in \mathcal{I}(j)$, we also observe case/individual characteristics W_{ij} .

We assume that the parameters of the information process $\psi^c \equiv (\mu_A^c, \mu_B^c, \rho^c, \bar{p}^c)$, the discount factor δ^c , and the deliberation rule k^c , are invariant across meetings in the same committee, but allow them to vary across committees. As our identification arguments below hold within committees, we drop the subscript c from the parameters. For every committee $c \in C$, we assume that the condition in Proposition B.1 is met; i.e., that the signals the committee observes are sufficiently informative relative to the heterogeneity of the committee's preference profile.¹⁹ We allow preferences v_{ij} and heterogeneity in prior beliefs κ_{ij} to vary by question j as a function of observable characteristics of the case and the individual i (e.g., whether it is a question about safety or efficacy, whether the individual is an M.D. or a patient representative). We further allow variation

¹⁹Without these assumption, committee members would know the realization of the state and decide immediately, so the information process parameters would not be identified.

along unobservables. In particular, for each i and $j \in \mathcal{J}_c$

$$\tilde{v}_{ij} = \underbrace{X'_{ij}\beta + \xi_c}_{\tilde{v}_{ij}} + \underbrace{Z'_{ij}\eta}_{-\kappa_{ij}} + \varepsilon_{ij}, \quad (5.1)$$

where $\varepsilon_{ij} \sim_{i.i.d.} U[-u, u]$, and X_{ij} and Z_{ij} are subvectors of W_{ij} affecting preferences and prior beliefs, respectively.

5.1 Identification

Information process parameters. In each state $\omega = A, B$, committee members observe signals drawn from a random walk with drift μ_ω and variance ρ . The likelihood of the sequence of signals \mathbf{s}_j in question j given ψ is

$$L_j(\mathbf{s}_j|\psi) = \left[\bar{p} \prod_{\tau=\tau_j^*}^{T_c} \phi\left(\frac{s_{j,\tau} - \mu_A}{\rho}\right) + (1 - \bar{p}) \prod_{\tau=\tau_j^*}^{T_c} \phi\left(\frac{s_{j,\tau} - \mu_B}{\rho}\right) \right], \quad (5.2)$$

and the log-likelihood of observing $\{\mathbf{s}_j\}_{j \in \mathcal{J}_c}$ across all meetings $j \in c$ given ψ is then given by $\ell(\mathbf{s}|\psi) = \sum_{j \in \mathcal{J}_c} \log(L_j)$. Note that the information parameters are identified by standard arguments for mixture models with state-dependent means and invariant variance (see Allman, Matias, and Rhodes (2009) and Hall and Zhou (2003)) provided $T_j \geq 3$. Intuitively, since the realization of the information process is known for every meeting j , μ_A and μ_B are identified by the means of the two latent states, and the assumption that $\mu_A > \mu_B$. Similarly, ρ is identified by the variance of the signal processes, as the variance is state independent, and \bar{p} by the share of the latent state. With ψ known, $\mu'_A = (\rho')^2/2$, $\mu'_B = -(\rho')^2/2$ and $\rho' = \frac{\mu_A - \mu_B}{\rho}$ are identified. The core posterior path for each question j is then identified, since $s'_{j\tau} = as_{j\tau} - b$, and $\theta_{j\tau} = s'_{j\tau} + \theta_{j,\tau+1}$, with $\bar{\theta} = \log\left(\frac{\bar{p}}{1-\bar{p}}\right)$.

Preferences and Heterogeneous Priors. While the information parameters are identified from the data on the informational process, preferences and heterogeneity in prior beliefs are identified by the voting decisions. Recall that member i votes for approval in question j if and only if $\theta_j^* \geq \tilde{v}_{ij}$, where $\theta_j^* \equiv \theta_{j,\tau_j^*}$ is the realized core posterior at the time of voting. Given (5.1), the probability that i

votes to adopt in case j is given by:

$$P(y_{ij} = 1 \mid X_{ij}, Z_{ij}, \theta_j^*) = \frac{\theta_j^* - X'_{ij}\beta - Z'_{ij}\eta - \xi_c + u}{2u}, \quad (5.3)$$

which we can write as a linear conditional expectation:

$$\mathbb{E}(y_{ij} \mid X_{ij}, Z_{ij}, \theta_j^*) = \pi_c + b_\theta \theta_j^* + X'_{ij}b_x + Z'_{ij}b_z.$$

Thus, $u = \frac{1}{2b_\theta}$, $\beta = -\frac{b_x}{b_\theta}$, $\eta = -\frac{b_z}{b_\theta}$, and $\xi_c = \frac{1}{2b_\theta}(1 - 2\pi_c)$ are identified, and so are (systematic) preferences and heterogeneity in prior beliefs,

$$\bar{v}_{ij} = X'_{ij}\beta + \xi_c = \frac{1}{b_\theta} (1/2 - [\pi_c + X'_{ij}b_x]) \quad \text{and} \quad \kappa_{ij} = -Z'_{ij}\eta = \frac{1}{b_\theta} Z'_{ij}b_z.$$

Deliberation rule and discount factor. Given known information and preference parameters, the discount factor δ and the deliberation rule k are identified from the data on committee deliberation. From our analysis in Section 3.2 of the last period in which the committee can extend deliberations, $\gamma(1) = \min\{\tilde{v}_m, \underline{\theta}_{2m-k}(1)\}$ and $\Gamma(1) = \max\{\tilde{v}_m, \bar{\theta}_k(1)\}$, where $\underline{\theta}_{2m-k}(1)$ and $\bar{\theta}_k(1)$ are given by

$$\tilde{v}_{2m-k} \equiv \underline{\theta}(1) - \ln \left(\frac{1 - \delta \Phi \left(\frac{\tilde{v}_m - \underline{\theta}(1) - \mu'_B}{\rho'} \right)}{\delta \left[1 - \Phi \left(\frac{\tilde{v}_m - \underline{\theta}(1) - \mu'_A}{\rho'} \right) \right]} \right) \quad (5.4)$$

and

$$\tilde{v}_k \equiv \bar{\theta}(1) - \ln \left(\frac{\delta \Phi \left(\frac{\tilde{v}_m - \bar{\theta}(1) - \mu'_B}{\rho'} \right)}{1 - \delta + \delta \Phi \left(\frac{\tilde{v}_m - \bar{\theta}(1) - \mu'_A}{\rho'} \right)} \right). \quad (5.5)$$

Note that δ is the only unknown in (5.4) and (5.5). In fact, there is a unique δ that solves those equations as they can be rewritten as linear in δ . Since θ_1 has unbounded support, provided deliberations reach $\tau = 1$ with positive probability, the equilibrium conditions (5.4) and (5.5) pointwise identify δ , as the value that matches the probability of extending deliberations at $\tau = 1$. Thus, δ is pinned down by how often deliberation continues to the last period given variation in posteriors and preferences across meetings, conditional on known preferences and a known information process.

The deliberation rule k is then pinned down by the probability of continuing deliberation in any period $\tau > 1$. To see this, note that since $\tilde{v}_{i,j} \neq \tilde{v}_{i',j}$ a.s. for any two members i and i' and questions $j \in \mathcal{J}$ from (5.1), the deliberation region is non-empty and increasing in k at the true parameter values (ψ^0, δ^0, k^0) .²⁰

5.2 Estimation

Our estimation follows closely the identification discussion. This section outlines our approach and presents our parameter estimates. In Section 6, we use these estimates to evaluate the effectiveness of ACs' recommendations, and to study counterfactual policy experiments.

Information Process. We estimate the information process parameters $\psi^c = (\bar{p}^c, \mu_A^c, \mu_B^c, \rho^c)$ for each committee $c \in C$ by Maximum Likelihood Estimation (MLE), using $\ell(\mathbf{s}|\psi^c) = \sum_{j \in \mathcal{J}_c} \log L_j(\mathbf{s}_j|\psi^c)$, as given by (5.2). We estimate the variance of $\hat{\psi}$ by estimating the inverse of the information matrix and using the information identity. We then directly compute $\hat{\mu}'_A$, $\hat{\mu}'_B$ and $\hat{\rho}'$ by plug-in.

Table 3 presents our information process estimates by committee. For most committees, the parameters μ_A , μ_B and ρ are precisely estimated. Instead, our estimate of the core prior \bar{p} is generally imprecise, due to the relatively small number of meetings in the sample. The results show substantial heterogeneity in the informational content of presenters' speech across committees, as summarized by $\rho' = (\mu_A - \mu_B)/\rho$. While the estimate for ρ' is above 0.64 for committees in the top tercile of the distribution (antimicrobials, pharmcompounding, endocrinologic, oncologic and pediatric committees), it is below 0.40 for committees in the bottom tercile (device, antivirals, reproductive, dermatologic and gastrointestinal committees). All else equal, this implies that members of, say, the oncologic committee, learn faster from presenters' speech, and stop deliberations earlier, than members of the endocrinologic committee.

With the information parameter estimates $\hat{\psi}$, and the realization of signals in

²⁰The equilibrium conditions for extending deliberation at any $\tau > 1$ also contain valuable information to disentangle the discount factor δ from the deliberation rule k . This follows directly from the continuation values – see (C.1) in Appendix for a full derivation. Thus, variation of \tilde{v} across meetings provides identifying variation for k and δ .

Table 3: Information Process Estimates

Committee	\bar{p}	μ_A	μ_B	ρ	#Obs.	# Meetings
device	0.3721 (0.5827)	0.4490 (0.0698)	0.2641 (0.0455)	0.4575 (0.0053)	5898	75
oncologic	0.3539 (0.5130)	0.5293 (0.0420)	0.2262 (0.0386)	0.4705 (0.0074)	3329	57
cardiovascular	0.6970 (0.5037)	0.3857 (0.0369)	0.2015 (0.1092)	0.4151 (0.0039)	3049	32
endocrinologic	0.1031 (0.3236)	0.5920 (0.1869)	0.3088 (0.0380)	0.4223 (0.0063)	2525	42
antimicrobials	0.1603 (0.3801)	0.6234 (0.1234)	0.2875 (0.0462)	0.3905 (0.0069)	1777	35
psychopharmacologic	0.3102 (0.5143)	0.4549 (0.0924)	0.2765 (0.0506)	0.4316 (0.0048)	1069	13
other	0.173 (0.391)	0.568 (0.120)	0.294 (0.052)	0.505 (0.007)	833	16
reproductive	0.6385 (0.9019)	0.4147 (0.1025)	0.3044 (0.1024)	0.4262 (0.0061)	831	12
antivirals	0.7058 (0.8463)	0.3681 (0.0486)	0.2446 (0.2071)	0.3650 (0.0042)	825	10
pharmcompounding	0.0615 (0.4056)	0.6698 (5.6028)	0.3245 (0.0842)	0.4450 (0.0079)	791	17
dermatologic	0.5879 (1.1864)	0.3599 (0.1274)	0.2754 (0.1823)	0.3656 (0.0047)	769	11
blood	0.5975 (0.5279)	0.4392 (0.0491)	0.2639 (0.1161)	0.4038 (0.0061)	702	12
gastrointestinal	0.6867 (6.1431)	0.3753 (0.4126)	0.3051 (0.8913)	0.4204 (0.0063)	560	9
vaccines	0.5204 (0.5563)	0.4192 (0.0956)	0.2654 (0.1088)	0.3600 (0.0060)	453	8
pediatric	0.4404 (0.7500)	0.4364 (0.1412)	0.1619 (0.1591)	0.4311 (0.0166)	256	12

Note: Maximum Likelihood Estimates (MLE), from (5.2), by committee. Committees are sorted by sample size (number of signals across meetings within a committee). Standard errors are computed by estimating the asymptotic variance for MLE using Outer-Product Gradient and closed-form solutions for the score.

each question j , we can compute an estimate of the evolution of core posterior beliefs $\theta_{j,\tau}$ for every question j and time τ , as described in Section 5.1. In Figure 2, we plot the evolution of the estimated beliefs for each question in the sample for the device and oncologic committees.

Preferences. Recall that member i votes for approval in question j if and only if

$$\theta_j^* \geq \tilde{v}_{ij} = X'_{ij}\beta + Z'_{ij}\eta + \xi_r + \varepsilon_{ij} \quad (5.1b),$$

for $r = j, c$, depending on whether the specification allows for question fixed effects or committee fixed effects. Here, $\varepsilon_{ij} \sim_{i.i.d.} U[-u, u]$, and X_{ij} and Z_{ij} are subvectors of W_{ij} affecting preferences and prior beliefs, respectively.

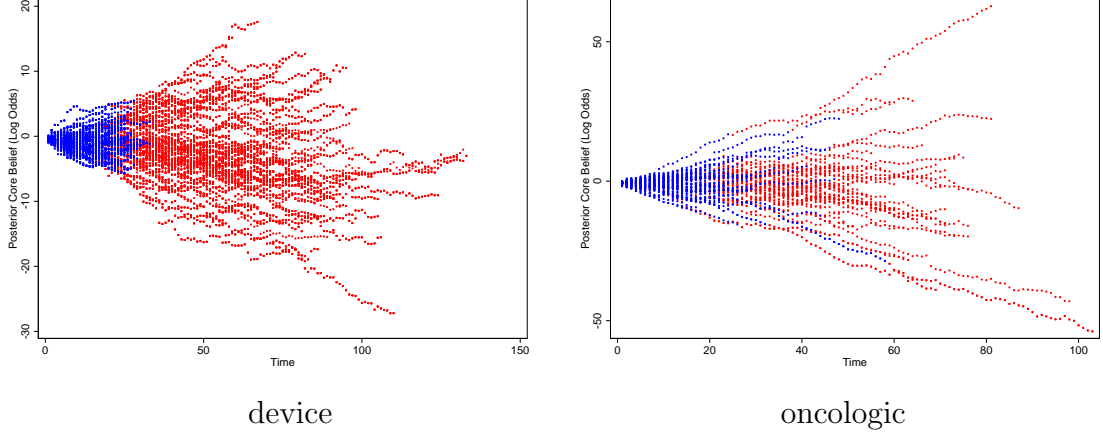


Figure 2: Estimated Posterior Process $\{\theta(\tau)\}$ for selected committees. Blue (red) dots indicate the evolution of beliefs in presentations (Q&A).

Our model allows us to pursue two approaches for preference estimation. First, we can introduce committee fixed effects, thereby allowing us to incorporate covariates that vary at the question level and directly take into account the realized value of the core posterior belief at the time of voting. This point-identifies the scale of the parameters β, η due to question-level variation. Alternatively, we can introduce *question-level* fixed effects. This captures unobserved heterogeneity at the question level, but means that the scale of the preference and prior parameters, β, η, ξ are only identified up to u . Given the limited information available about each case, the latter is our preferred specification. Fixing $u = 1/2$, we have

$$\mathbb{E}(y_{ij} \mid X_{ij}, Z_{ij}, \theta_j^*) = \pi_j + X'_{ij}b_x + Z'_{ij}b_z, \quad (5.6)$$

where $b_x = -\beta$, $b_z = -\eta$, and $\pi_j = 1/2 + (\theta_j^* - \xi_j)$. Note that a positive value of a reduced-form parameter indicates that a higher value of the covariate is associated with a higher probability of voting Yea and a *lower* threshold \tilde{v}_{ij} .

The reduced form parameters (π, b_x, b_z) can be directly estimated by Ordinary Least Squares (OLS) in a linear regression with question fixed effects. For preference covariates X_{ij} , we include gender (and its interactions with whether the question was about safety, effectiveness, or risk-benefit), education, a dummy

variable for the individual being in Government Science, a dummy variable for the committee member working in “Other Government” institutions, and a dummy variable for the member being a Patient Representative. For belief covariates Z_{ij} we include publication scores, employer research scores, and previous experience (together with its interactions with question type).

Table 4 presents the results.²¹ Our preferred specification is column (6), which includes question-fixed effects and no sample restrictions.²² On average, members with more AC experience are more biased for the status quo, in particular when evaluating the risk-benefit of the product. Female and male committee members have no systematic differences in voting behavior, except when evaluating risk-benefit, where female members are more reluctant to approve. Government scientists are generally more biased in favor of the status quo, except when evaluating FDA policy proposals. This is also true, to a lesser degree, for patient representatives. On the other hand, physicians are more favorable for approval and better published committee members have a higher prior for rejection.

From these results, we obtain an estimate of $E[\tilde{v}_{ij}]$, for each member i and question j , by rewriting (5.6) as $\hat{v}_{ij} = \hat{\theta}_j^* - [X'_{ij}\hat{b}_x + Z'_{ij}\hat{b}_z + (\hat{\pi}_j - \frac{1}{2})]$. To facilitate interpretation, we transform $E[\tilde{v}_{ij}]$ into the corresponding quantity in probability space, and plot the empirical distribution of

$$\tilde{V}_{ij} \equiv \exp(E[\tilde{v}_{ij}]) / (1 + \exp(E[\tilde{v}_{ij}])).$$

where member i votes for approval on case j if and only if the posterior probability that the product should be approved exceeds \tilde{V}_{ij} . In Figure 3, we plot the empirical distribution of these estimates by committee, across cases and members, as well as for the median question-specific fixed effects, ξ_c^{50} , to iso-

²¹Figure A.2 shows that the estimates match the data well. The average predicted approval rate at the question level closely tracks the average approval rate observed in the data, due to question fixed effects. The figure shows that the average predicted approval rate at the individual level also closely tracks the average approval rate observed in the data.

²²For comparison, we include alternative specifications. Columns (1)-(3) are regressions without committee or question fixed effects, in the full sample (1) and excluding FDA proposals (2)-(3). Columns (4) and (5) show regressions with committee fixed effects, for the full sample (4) and excluding FDA proposals (5).

Table 4: Vote in Favor of Adoption.

	(1)	(2)	(3)	(4)	(5)	(6)
Experience	-0.019 (0.003)	-0.022 (0.004)	-0.009 (0.005)	-0.006 (0.011)	-0.007 (0.013)	-0.015 (0.004)
Experience Squared	0.001 (0.000)	0.001 (0.000)	0.001 (0.000)	0.001 (0.001)	0.001 (0.001)	0.001 (0.000)
Female	-0.005 (0.010)	-0.011 (0.012)	0.020 (0.021)	0.024 (0.015)	0.023 (0.024)	0.013 (0.011)
MD	0.029 (0.011)	0.023 (0.013)	0.025 (0.013)	0.033 (0.009)	0.027 (0.014)	0.021 (0.009)
Top 10 research inst.	-0.070 (0.018)	-0.069 (0.022)	-0.068 (0.022)	-0.051 (0.018)	-0.053 (0.024)	-0.016 (0.015)
Top 10-20 research inst.	-0.047 (0.022)	-0.030 (0.025)	-0.027 (0.025)	-0.022 (0.026)	-0.003 (0.027)	-0.003 (0.017)
Top 20-50 research. Inst.	-0.072 (0.017)	-0.066 (0.022)	-0.067 (0.022)	-0.055 (0.017)	-0.058 (0.027)	-0.044 (0.014)
Other research inst.	-0.044 (0.015)	-0.037 (0.019)	-0.036 (0.019)	-0.025 (0.024)	-0.016 (0.030)	-0.016 (0.012)
Gov. Science	-0.090 (0.021)	-0.098 (0.024)	-0.087 (0.024)	-0.061 (0.024)	-0.066 (0.031)	-0.058 (0.017)
Gov. Other	-0.036 (0.031)	-0.027 (0.035)	-0.034 (0.034)	-0.039 (0.038)	-0.049 (0.042)	-0.029 (0.023)
Patient representative	-0.074 (0.021)	-0.082 (0.026)	-0.095 (0.026)	-0.028 (0.037)	-0.039 (0.053)	-0.024 (0.018)
Pubs rank-weighted	-0.002 (0.001)	-0.002 (0.001)				
Effectiveness	0.078 (0.011)	0.094 (0.012)	0.110 (0.016)	0.069 (0.028)	0.080 (0.030)	
Safety	0.103 (0.009)	0.111 (0.011)	0.124 (0.016)	0.096 (0.033)	0.084 (0.041)	
Risk/Benefit	0.025 (0.012)	0.029 (0.013)	0.092 (0.017)	0.116 (0.042)	0.117 (0.033)	
FDA policy	0.260 (0.011)			0.312 (0.134)		
Top 10% revenue		0.074 (0.013)	0.077 (0.013)		0.104 (0.053)	
Top 10-25% revenue		0.109 (0.015)	0.110 (0.015)		0.117 (0.048)	
Top 25-75% revenue		0.113 (0.014)	0.112 (0.014)		0.054 (0.024)	
Gov Science x FDA policy	0.043 (0.030)					0.053 (0.024)
Female x safety			-0.003 (0.025)	-0.009 (0.013)	-0.001 (0.018)	-0.003 (0.015)
Female x effective			-0.016 (0.025)	-0.014 (0.020)	-0.010 (0.026)	0.007 (0.017)
Female x Risk Benefit			-0.062 (0.027)	-0.067 (0.032)	-0.049 (0.030)	-0.041 (0.017)
Exp. x Safety			-0.007 (0.004)	-0.005 (0.006)	-0.003 (0.006)	-0.002 (0.003)
Exp. x Effective			-0.007 (0.004)	-0.007 (0.008)	-0.007 (0.009)	-0.001 (0.003)
Exp. x Risk Benefit			-0.017 (0.004)	-0.018 (0.003)	-0.018 (0.003)	-0.007 (0.004)
Constant	0.660 (0.018)	0.598 (0.023)	0.569 (0.024)	0.600 (0.050)	0.610 (0.114)	0.733 (0.014)
Question FE	NO	NO	NO	NO	NO	YES
Committee FE	NO	NO	NO	YES	YES	NO
Disease FE	NO	NO	NO	NO	YES	NO
Individual FE	NO	NO	NO	NO	NO	NO
Field Pub record	NO	NO	YES	YES	YES	YES
# observations	10389	8481	8481	10389	8481	10389
# clusters	-	-	-	15	15	803
R squared (within)	-	-	-	0.034	0.056	0.009
R squared (between)	0.068	0.038	0.051	0.437	0.577	0.006

Note: In all specifications, the dependent variable is the individual vote in favor (1) or against (0) adoption. Numbers in parenthesis denote robust standard errors (specifications 1-3), clustered at the committee (specifications 4 and 5) and question level (specification 6). Field publications and disease categories are described in Tables A.1 and A.2, respectively.

late typical within-meeting variation in preferences. As it is evident from the figure, a large fraction of the overall heterogeneity in preferences corresponds to variation across cases, as opposed to heterogeneity in the preferences of the committee in a given case. This relatively modest preference heterogeneity foreshadows that changes in the deliberation rule will tend to have relative small effects on equilibrium outcomes, as the effective preference of the pivots will not be highly sensitive to changes in the deliberation rule.

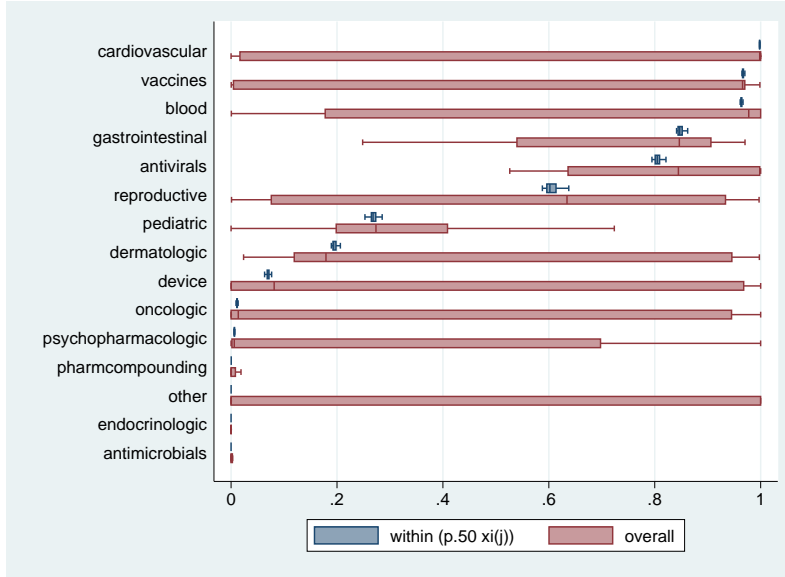


Figure 3: Boxes labeled “overall” plot the empirical distribution of \tilde{V}_{ij} , across questions j and members i , by Committee. Boxes display inter-quartile range of the distribution. Boxes labeled “within” reproduce the exercise for the median question-specific preference fixed effect ξ_c^{50} , to isolate typical within-meeting variation in preferences.

At the median value of the question-specific preference fixed effect ξ_c^{50} , nine committees are “biased” in favor of approval (e.g., antimicrobials, endocrinologic, psychopharmacologic, device), while six committees are biased against approval (e.g., cardiovascular, vaccines, blood). As the figure shows, though, the bias in favor or against approval that we observe at ξ_c^{50} can turn into a neutral stance, or even an opposite bias for/against approval of the product.

Deliberation Rule and Discount Factor. We estimate (k, δ) by simulated method of moments, where we compare simulated deliberation paths along observed posteriors to the actual data. We do so for a grid of possible (k, δ) , where δ varies at 0.025 intervals (up to 0.999, as we require $\delta < 1$), and k takes values between $k = 0.5n$ (simple majority) and $k = 1n$ (unanimity).

We first set the information estimates at their MLE counterparts (Table 3). Then, we set the deterministic component of preferences $(\bar{v}_{i,j})$ at their estimated counterparts (Table 4), but repeatedly draw the random component $\varepsilon_{i,j}^r$, $r = 1, \dots, R$, from the asymptotic distribution of the estimates. We then simulate deliberation outcomes from the equilibrium of the model, for each (k, δ) and question $j \in \mathcal{J}$, and for $R = 100$ simulations. We denote the committee's decision to extend deliberation at period τ in question j given trial value (δ, k) as $d_j^r(\tau | (\delta, k)) \in \{0, 1\}$. The probability that the committee extends deliberations at τ in question j conditional on reaching τ given (δ, k) can be approximated by

$$\tilde{d}_j(\tau | \delta, k) = \frac{1}{R} \sum_r d_j^r(\tau | (\delta, k)).$$

Our estimates of (δ, k) will be those that minimize the average quadratic distance between the deliberation in the data and simulated deliberation. Table 5 presents these estimates.

Table 5: Deliberation rule and discount factor estimates

Committee	$\hat{\delta}$	$k\hat{n}$	Committee	$\hat{\delta}$	$k\hat{n}$
reproductive	0.999	1.0	other	0.999	1.0
gastrointestinal	0.999	1.0	vaccines	0.999	1.0
pharmacompounding	0.999	1.0	oncologic	0.999	1.0
cardiovascular	0.999	1.0	antimicrobial	0.999	1.0
psychopharmacologic	0.999	1.0	antivirals	0.999	1.0
device	0.999	1.0	blood	0.999	0.833
endocrinologic	0.999	1.0	pediatric	0.850	1.0
dermatologic	0.999	1.0			

In all but one case (pediatric committee), our estimate of the discount factor is the highest feasible value of $\delta = 0.999$, implying a low cost of extending

deliberations on pure preference grounds. This is intuitive, as the actual time frame under consideration is short. More interestingly, perhaps, our estimates imply that all committees use a strict majority rule to end deliberations, with fourteen of the fifteen committees operating under an implied unanimity rule to end deliberations. This is fully consistent with the FDA’s guidance for committee chairs that chairs should act so that any comment, insight, or concern that could influence a voter’s conclusions is heard before a vote related to that matter occurs. Overall, both the estimates for the deliberation rule and discount factor generally induce a relatively long span of deliberation, for given preferences and realization of signals along the meetings.

6 Institutions and Outcomes

In this section, we present our main results. In Section 6.1, we use our estimates to quantify the probability that the advisory committees reach correct recommendations. In Section 6.2, we conduct policy counterfactuals to evaluate how alternative institutional designs affect these outcomes.

6.1 Evaluating ACs’ Policy Recommendations

To assess the effectiveness of AC’s recommendations, we compute the probability that an advisory committee makes the correct policy recommendation, both ex-ante and conditionally on the state $\omega \in \{A, B\}$. To take into consideration that in any given period the committee can choose to not take any policy decision, but instead extend deliberations, we compute this measure recursively. Thus, our measure captures the probability that the committee eventually provides a correct recommendation, starting from any given initial belief.

For any $\tau = 0, 1, \dots, T$, define $\alpha_\tau(\theta_{\tau+1})$ (similarly, $\beta_\tau(\theta_{\tau+1})$) as the probability that the committee eventually *correctly* adopts (rejects) the product given that there are τ periods remaining to the deadline given a core belief $\theta_{\tau+1}$. Note that $\alpha_0(\theta_1) = \Pr(\theta_0 \geq \tilde{v}_m | \omega = A, \theta_1)$, and for $\tau \geq 1$, we can write $\alpha_\tau(\theta_{\tau+1})$ recursively, as

$$\alpha_\tau(\theta_{\tau+1}) = (1 - F_\theta(\Gamma_\tau | \theta_{\tau+1}, A)) + \int_{\gamma_\tau}^{\Gamma_\tau} f_\theta(\theta_\tau | \theta_{\tau+1}, A) \alpha_{\tau-1}(\theta_\tau) d\theta_\tau,$$

where $f_\theta(\cdot)$ and $F_\theta(\cdot)$ are, respectively, the pdf and CDF of the posterior given current beliefs and the state. The first term is the probability that the committee correctly adopts at τ , given belief $\theta_{\tau+1}$. The second term is the probability that the committee correctly adopts at some $\tau' < \tau$ in the future, after extending deliberations at τ . Proceeding analogously with $\beta_\tau(\theta_{\tau+1})$, we can write the probability that the committee makes a correct recommendation, as evaluated at the beginning of the meeting, given a prior $\bar{\theta}$, as

$$\Lambda_T(\bar{\theta}) \equiv \left(\frac{e^{\bar{\theta}}}{1 + e^{\bar{\theta}}} \right) \alpha_T(\bar{\theta}) + \left(\frac{1}{1 + e^{\bar{\theta}}} \right) \beta_T(\bar{\theta}). \quad (6.1)$$

Given a distribution over priors $f_{\bar{\theta}}$ – which we approximate with the distribution of the estimates of the core prior $\bar{\theta}$ obtained from \hat{p} – we compute the expected probability that the committee makes a correct recommendation, evaluated at the beginning of the meeting, $\bar{\Lambda}_T = E_{\bar{\theta}} [\Lambda_T(\bar{\theta})]$ through numerical integration. Similarly, we compute the expected probability that the committee correctly approves and correctly rejects products, $\bar{\alpha}_T = E_{\bar{\theta}} [\alpha_T(\bar{\theta})]$ and $\bar{\beta}_T = E_{\bar{\theta}} [\beta_T(\bar{\theta})]$.

To implement these measures in our data, we select a representative case for each committee. First, we select the case with median variance in preferences in each committee. Second, to isolate our results from the particular characteristics of the case, we substitute the case specific shock to preferences ξ_j (measuring unobserved heterogeneity in the characteristics of the case) with the median shock for the committee, ξ_c^{50} , for each $c \in C$. We also compute our output for the 25th and 75th percentiles of the shocks, ξ_c^{25} and ξ_c^{75} , which make the entire committee more favorable and unfavorable for approval, respectively.

Figure 4 plots the ex-ante probability of a correct decision $\bar{\Lambda}_T$ for each committee $c \in C$ and $\{\xi_c^{25}, \xi_c^{50}, \xi_c^{75}\}$. As it is clear from the figure, there is a substantial heterogeneity in outcomes across committees. At the median value of the case-specific shock, ξ_c^{50} , the ex ante probability that the committee makes the correct recommendation is above 4/5 for seven of the fifteen committees in the sample, and below 1/2 for four committees (e.g. antimicrobials, endocrinologic).

In interpreting these figures, it is important to take two issues into consideration. First, $\bar{\Lambda}_T$ is the average ex-ante probability of a correct decision over all

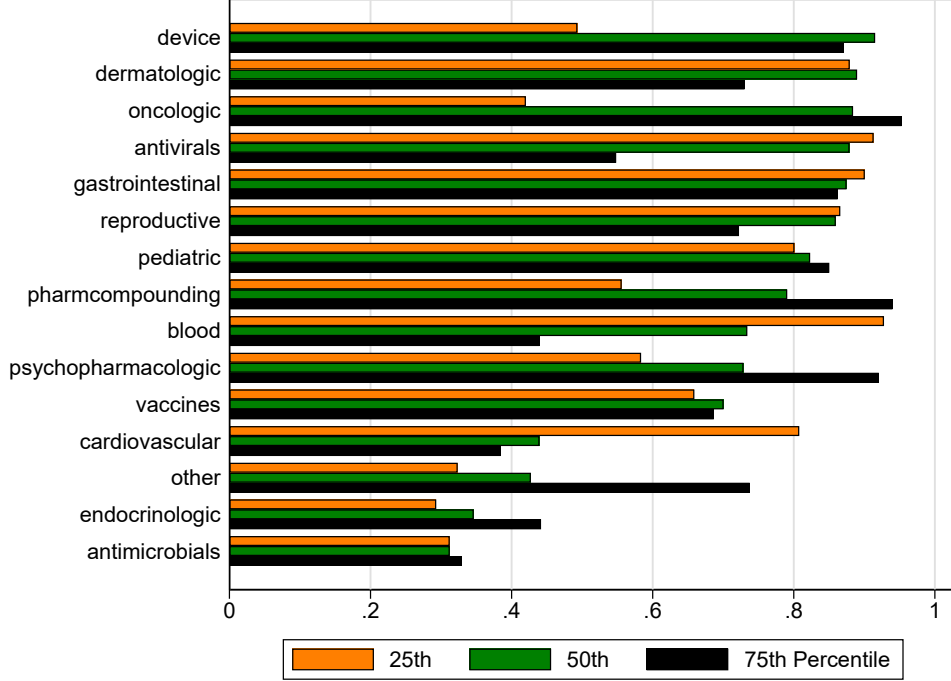


Figure 4: Ex-Ante Probability of a Correct Recommendation. For each committee, we plot the value of $\bar{\Lambda}_T$ consistent with the 25th, 50th, and 75th percentile of the case-specific shocks, $\{\xi_c^{25}, \xi_c^{50}, \xi_c^{75}\}$.

prior beliefs with which the committee can start deliberations. To disentangle differences in performance across varying initial conditions, in Figure 5 we plot $\Lambda_T(\cdot)$ for the top four committees according to expected performance.²³ Given an initial belief \bar{p} , $\Lambda_T(\bar{p})$ gives the probability that the committee eventually reaches the correct recommendation when the committee starts deliberations with prior \bar{p} . As the figure shows, the average in $\bar{\Lambda}_T$ masks substantial variability in $\Lambda_T(\cdot)$ across starting conditions, which ranges from values close to one at low or high core priors (where there is less uncertainty about the true state) to less than 0.8 for less informative priors.

Second, note that while $\bar{\Lambda}_T$ captures the overall ex-ante probability of reaching a correct recommendation, decision-makers and external evaluators can weigh errors in different states differently. To consider this, in Figure 6 we plot the

²³See figure A.7 in the Appendix for all committees (together with counterfactual results).

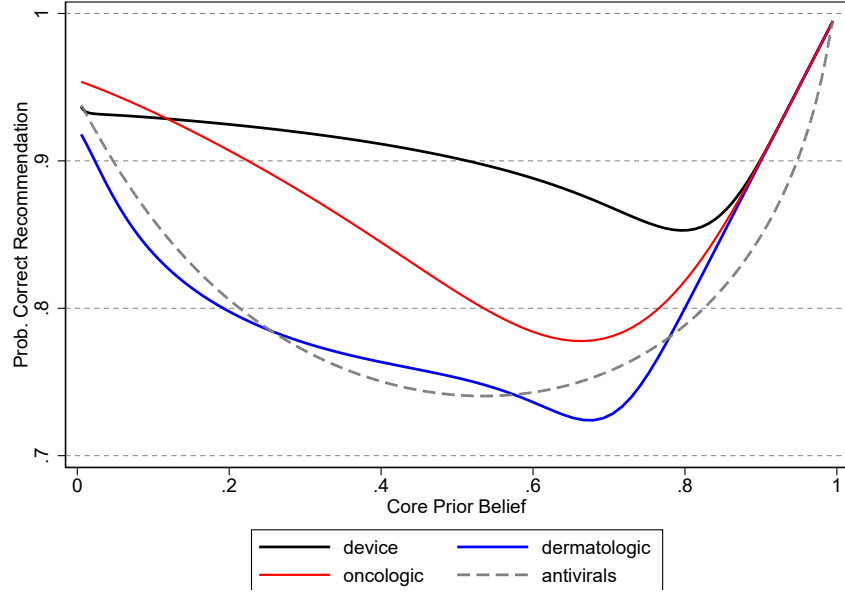


Figure 5: Probability of a Correct Recommendation by Committee, as a function of core prior belief that the product should be approved. Top four committees, ranked by effectiveness.

probability of a correct recommendation conditional on the realization of the state ω .²⁴ As the data reveals, not all errors are created equally. Among the seven committees with the highest ex-ante probability of a correct majority recommendation, there are three distinct groups. The dermatologic, reproductive and antivirals committees have a relatively high likelihood of generating a correct recommendation both when the product should ($\bar{\alpha}_T$) and should not ($\bar{\beta}_T$) be approved. Instead, the device, oncologic and pediatric committees have much larger odds of producing a correct recommendation when the product should be approved than when the product should be rejected. In other words, the most common error in these committees is to approve products that should not be taken to market. On the other hand, the gastrointestinal committee has a greater likelihood of producing the right recommendation when the product should be rejected than when it should be approved. A principal who is most concerned about not approving bad products can therefore rank the work of

²⁴Figure A.6 in the Appendix plots the conditional probability of reaching a correct decision in each state as a function of initial beliefs, $\alpha_T(\cdot)$ and $\beta_T(\cdot)$.

the cardiovascular or blood committees higher than that of the endocrinologic committee, while a principal who is most concerned about not rejecting good products can have the opposite ranking.

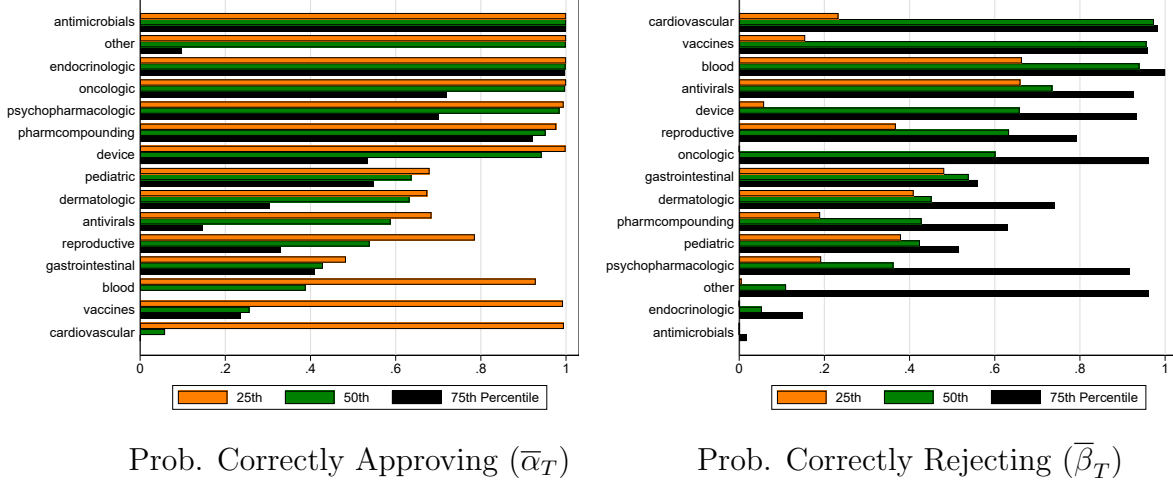


Figure 6: Conditional Probability of a Correct Recommendation, by Committee, with 25th, 50th, and 75th percentile of the case-specific shocks.

The figure also shows that the four committees with the lowest probability of a correct recommendation in Figure 4 do exceptionally well in one state, but badly on the other. The antimicrobials, endocrinologic, and other committees have a probability of correctly approving good products close to one, but have a low probability of correctly rejecting bad products. Instead, the cardiovascular committee excels in the probability of correctly rejecting inferior products, but has a low probability of approving products that should be approved.

Decomposition of Committee Differences. What explains the differences in outcomes across committees? In order to quantify the contribution of preferences v^c , precision of information ψ^c and time devoted to deliberation, T^c to variation in outcomes, we carry out a decomposition exercise. We consider an initial position in which all committees have the same preferences, information technology, and deliberation horizon as a benchmark committee (oncologic). We then switch one factor at a time, until reaching the configuration in the data for each committee. For example, changing first preferences, then information

and then horizon, this is

$$\begin{aligned}
\bar{\Lambda}_T^c(v^c, \psi^c, T^c) &= \bar{\Lambda}_T^{on}(v^{on}, \psi^{on}, T^{on}) \\
&+ \bar{\Lambda}_T^{on}(v^c, \psi^{on}, T^{on}) - \bar{\Lambda}_T^{on}(v^{on}, \psi^{on}, T^{on}) \quad (\text{preferences}) \\
&+ \bar{\Lambda}_T^{on}(v^c, \psi^c, T^{on}) - \bar{\Lambda}_T^{on}(v^c, \psi^{on}, T^{on}) \quad (\text{information}) \\
&+ \bar{\Lambda}_T^{on}(v^c, \psi^c, T^c) - \bar{\Lambda}_T^{on}(v^c, \psi^c, T^{on}) \quad (\text{time horizon})
\end{aligned}$$

Since the contribution of each factor can be order-sensitive, we compute the decomposition for all possible orders, and present the average contribution of each factor across orders in Figure 7.

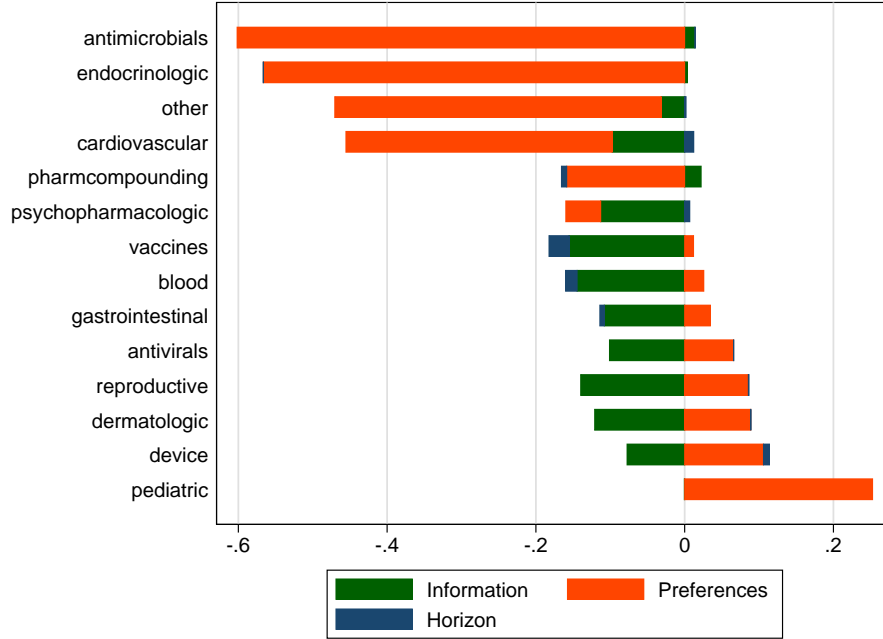


Figure 7: Attribution of differences in the Ex-Ante Probability of a Correct Recommendation relative to the oncologic committee.

We find that the low ex-ante probability of a correct recommendation in the endocrinologic, antimicrobials, other and cardiovascular committees relative to the benchmark is almost entirely due to differences in preferences. These are, as we saw in Figure 3, the most extreme committees in terms of the empirical distribution of preferences for the median case shock. Among the top performing committees, instead (device, dermatologic, reproductive, antivirals, gastroin-

testinal, blood), we observe a much larger contribution of the differences in the quality of information. Differences in the deliberation horizon have a small impact in the differences in outcomes across committees. A similar take-away emerges when we consider the analogous exercise for $\bar{\alpha}_T$ and $\bar{\beta}_T$ (see Figure A.10 in the appendix).

6.2 Policy Counterfactuals

We conduct three classes of institutional counterfactuals. The first two policy experiments involve changes in the deliberation process. First, we consider the effect of changes in the deliberation rule, k . In the previous section, we reported that all but one committee implicitly use a unanimity rule to *stop* deliberation, and the remaining committee (blood) uses a supermajority rule. These strict rules can protect the interests of extreme members of the committee, and lead to improved information while waiting for consensus. Empowering extreme members, on the other hand, can also lead to a higher error rate. To study how the effectiveness of the ACs decision-making vary with the deliberation rule, we compute equilibrium outcomes under simple majority and a 2/3-supermajority. In a second set of counterfactuals, we evaluate an alternative and more direct approach to affect deliberation outcomes, by reducing the amount of time devoted to deliberations. To do this, we conduct two exercises: we reduce T^c by half and, alternatively, we essentially shut down deliberation by taking $T^c = 2$.

In a third set of counterfactuals, we consider changes in the composition of advisory committees. While the FDA appoints individuals with expertise specific to the committee’s function, it also requires committees to “represent all geographic locations and be balanced as far as gender and minority status”. The induced preferences and beliefs of the members can be crucial to policy outcomes, as it directly affects both learning and voting outcomes. We consider two different policy variations. In one, we substitute the current membership with government scientists (FDA, NIH, CDC). In a second exercise, we substitute the current membership with experts from top-10 research institutions. In both cases, we replace current members with randomly drawn government scientists or members from top-10 research institutions from each committee, including all their characteristics (e.g. gender, publication record).

the effect is large in magnitude (more than 10 p.p. for eight committees, and considerably higher in some committees depending on the specification). Similarly, shortening the meetings generally reduces the effectiveness of the ACs. The result that deliberation is valuable is not as obvious as it might seem in this context, as committee members have all previous research studies at their disposal prior to the meeting.

Given the relatively low preference heterogeneity in the typical case, changes in the deliberation rule from unanimity to a 2/3s supermajority or simple majority rule (making it easier to stop deliberations) have a relatively small effect on committees' equilibrium outcomes. In general, though, we observe a negative effect of relaxing deliberation rules on the probability of reaching a correct recommendation. Instead, changes in membership to either government scientists or members recruited from top research institutions can and often do have a small positive effect on the probability of reaching a correct recommendation.

7 Conclusion

In this paper, we study the process of collective learning and decision-making in FDA advisory committees. To do this, we use a structural approach, leveraging detailed data on the deliberation and voting processes in advisory committees.

Our estimates uncover substantial variation in the quality of information and distribution of preferences across committees, leading to variation in the speed of learning and – all else equal – stopping times. However, we find relatively small differences in preferences and prior beliefs among committee members in a given case. This indicates that most of the heterogeneity in preferences within committees stems from changes in the characteristics of the cases under consideration, as opposed to markedly different views among its members. With the parameter estimates at hand, we quantify the probability that each committee provides a *correct* recommendation, both ex-ante, and conditional on whether the product should be approved or not. We find economically meaningful differences in performance across committees, and considerable differences in type I and type II errors.

To evaluate possible reforms designed to improve the effectiveness with which

advisory committees operate, we conduct three classes of institutional counterfactuals. We find that curtailing the time that committee members are afforded to deliberate is generally very costly in terms of the effectiveness of the ACs recommendations. Changes in membership or changes in the deliberation rules, on the other hand, are sensitive to the institutional details, and interact in complex ways. The general lesson is that any institutional change should be tailored to existing conditions, accounting for the information process and committee members' preference profiles.

On a broader note, our paper presents a novel approach to studying collective learning in committees. We proposed a method to transform speech to information, and used the data obtained from meetings speeches to estimate the underlying information process available to members of the committee. The model allows us to relate preferences to information in a way that is not straightforward with a more reduced-form approach. In this way, our research complements alternative approaches to understand decision-making in advisory committees, and committees in general. We hope that the machinery developed in this paper allows others to expand on our analysis, by bringing new data from other advisory committees in the US government and abroad, across different areas of expertise and institutional settings.

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Supplemental Appendix for “Innovation Adoption by Committee: Evaluating Decision-Making in the FDA”

Nathan Canen and Matias Iaryczower

A Additional Figures and Tables

Table A.1: Individual Level Covariates

Variable		Obs.	mean	sd	p.25%	p.50%	p.75%
Votes	% non-voting	1647	0.017	0.099	0.000	0.000	0.000
	% abstain	1647	0.024	0.104	0.000	0.000	0.000
	% Yay / Votes Cast	1630	0.706	0.345	0.500	0.833	1.000
Gender	female	1647	0.328	0.470	0.000	0.000	1.000
Experience	Years FDA experience	1647	1.762	2.810	0.000	0.000	2.750
	# Cases	1647	6.603	8.707	2.000	3.000	7.000
	# Votes Cast	1647	6.308	8.369	2.000	3.000	7.000
Education	Ph.D	1647	0.237	0.426	0.000	0.000	0.000
	M.D.	1647	0.702	0.457	0.000	1.000	1.000
	MPH	1647	0.078	0.268	0.000	0.000	0.000
	Pharm.D	1647	0.027	0.161	0.000	0.000	0.000
Employment	University	1647	0.552	0.497	0.000	1.000	1.000
	Hospital	1647	0.118	0.323	0.000	0.000	0.000
	Top 10 research	1646	0.135	0.342	0.000	0.000	0.000
	Top 10-20 research	1646	0.079	0.270	0.000	0.000	0.000
	Top 20-50 research	1646	0.160	0.367	0.000	0.000	0.000
	Other research institutions	1646	0.290	0.454	0.000	0.000	1.000
	Gov. Science	1647	0.111	0.314	0.000	0.000	0.000
	Gov. Other	1647	0.032	0.177	0.000	0.000	0.000
	Patient rep.	1647	0.097	0.295	0.000	0.000	0.000
Publications	# pubs	1647	112.0	221.0	15.00	58.00	137.0
	# pubs per capita	1647	25.10	53.00	3.700	12.90	30.40
	pubs: Biochemistry & Mol.Bio	1647	0.300	0.854	0.000	0.016	0.169
	pubs: Chemical Engineering	1647	0.072	0.473	0.000	0.000	0.000
	pubs: Chemistry	1647	0.074	0.591	0.000	0.000	0.000
	pubs: Dentistry	1647	0.011	0.109	0.000	0.000	0.000
	pubs: Health Professions	1647	0.187	1.131	0.000	0.000	0.022
	pubs: Immuno. & Microbio.	1647	0.155	0.594	0.000	0.000	0.056
	pubs: Medicine	1647	0.923	2.508	0.018	0.184	0.935
	pubs: Multidisciplinary	1647	0.109	0.372	0.000	0.005	0.060
	pubs: Neuroscience	1647	0.450	2.021	0.000	0.000	0.250
	pubs: Pharmacology	1647	0.121	0.542	0.000	0.000	0.037
	pubs: Psychology	1647	0.036	0.268	0.000	0.000	0.002
	pubs: Veterinary	1647	0.142	0.860	0.000	0.000	0.000

Note: Field publications include Biochemistry, Genetics and Molecular Biology (2104 journals), Chemical Engineering (674), Chemistry (949), Dentistry (210), Health Professions (633), Immunology and Microbiology (578), Multidisciplinary (138), Neuroscience (587), Pharmacology, Toxicology and Pharmaceutics (716), Psychology (1323), and Veterinary (262).

Table A.2: Outcomes by Disease Category

Disease Category	Questions Voted	% Yea	Std.Dev. Yea
FDA Policy	148	0.939	0.240
Behavioral Risk Factor	14	1.000	0.000
Cancer	90	0.545	0.501
Cardiovascular disease	112	0.727	0.447
Endocrine, blood, immune disorders	40	0.775	0.423
Gastrointestinal disorder	33	0.545	0.506
Genetic disorder	18	0.824	0.393
Genitourinary diseases	12	0.667	0.492
Infectious Disease	98	0.750	0.435
Mental illness	40	0.744	0.442
Metabolic disorder	41	0.750	0.439
Musculoskeletal disorder	16	0.688	0.479
Neurological disorder	9	1.000	0.000
Other	39	0.795	0.409
Reproductive Health	16	0.333	0.488
Respiratory Disorders	14	0.429	0.514
Sense organ diseases	39	0.921	0.273
Skin Disorders	24	0.667	0.482
Grand Total	803	0.753	0.432

Note: Summary statistics about the types of diseases related to questions being deliberated upon.

Table A.3: Case-Specific Covariates

Variable	Obs	Mean	Std.Dev.	p.25%	p.50%	p.75%
FDA policy	803	0.184	0.388	0	0	0
q: effective	803	0.254	0.436	0	0	1
q: safety	805	0.310	0.462	0	0	1
q: risk-benefit	805	0.248	0.432	0	0	0
Top 10% revenue	655	0.261	0.440	0	0	1
Top 10-25% revenue	655	0.163	0.370	0	0	0
Top 25-75% revenue	655	0.227	0.420	0	0	0
Other revenue	655	0.278	0.448	0	0	1

Note: Summary statistics about questions being deliberated upon, including the type of question (safety, efficacy) and characteristics of the sponsoring firm.

Table A.4: Top 40 sponsors, by cases.

	Company	Questions Voted	% Yea	Std.Dev. Yea
1	Johnson & Johnson	30	0.533	0.507
2	Amgen	24	0.625	0.495
3	Abbott Laboratories	20	0.950	0.224
4	GlaxoSmithKline	17	0.941	0.243
5	Merck & Co., Inc.	17	0.529	0.514
6	Novartis	16	0.875	0.342
7	Roche	16	0.563	0.512
8	AstraZeneca	15	0.643	0.497
9	Pfizer Inc.	13	0.750	0.452
10	Allergan	12	0.750	0.452
11	Bayer AG	12	0.500	0.522
12	Eli Lilly	12	0.917	0.289
13	Medtronic	12	0.818	0.405
14	Novo Nordisk	12	0.818	0.405
15	Boston Scientific Corporation	11	0.600	0.516
16	Sanofi	11	0.636	0.505
17	Bausch Health Companies	8	0.714	0.488
18	Genzyme Corporation	8	0.500	0.535
19	Gilead Sciences	8	0.875	0.354
20	Astellas Pharma	7	0.857	0.378
21	Otsuka Pharmaceutical	7	0.286	0.488
22	Boehringer Ingelheim	6	0.667	0.516
23	Cempra	6	0.167	0.408
24	Cook Incorporated	6	1.000	0.000
25	H. Lundbeck A/S.	6	0.667	0.516
26	Hologic, Inc.	6	1.000	0.000
27	Aegerion Pharmaceuticals	5	0.800	0.447
28	Alexza Pharmaceuticals	5	0.600	0.548
29	Braeburn Pharmaceuticals	5	1.000	0.000
30	Recordati Rare Diseases	5	1.000	0.000
31	Schering-Plough Corporation	5	1.000	0.000
32	ThromboGenics	5	0.800	0.447
33	Alkermes, Inc.	4	1.000	0.000
34	HRA Pharma	4	0.750	0.500
35	NeuroPace, Inc.	4	1.000	0.000
36	Solvay	4	0.250	0.500
37	Takeda Pharmaceuticals	4	0.750	0.500
38	Acadia Pharmaceuticals	3	1.000	0.000
39	Actelion Pharmaceuticals	3	0.667	0.577
40	AcuFocus	3	1.000	0.000

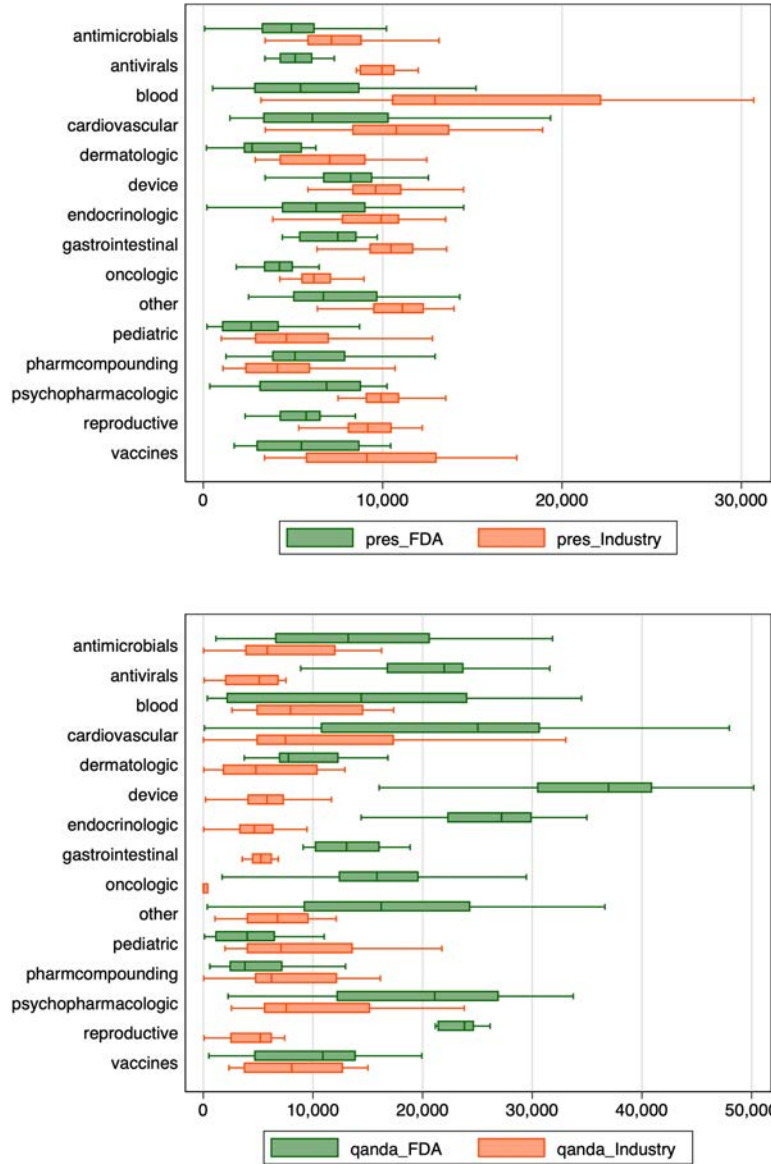


Figure A.1: Presenters' speech length per meeting (empirical distribution). Top (bottom) panel presents speech data from the Presentation (Q&A) section.

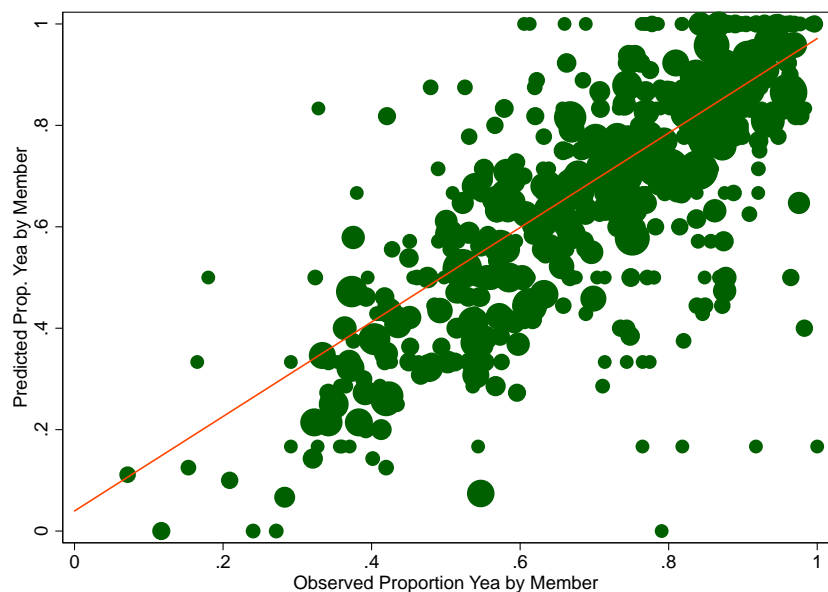


Figure A.2: Observed and Predicted approval rate by individual (all members with at least five votes). Bubble size reflects the number of votes taken by each member.

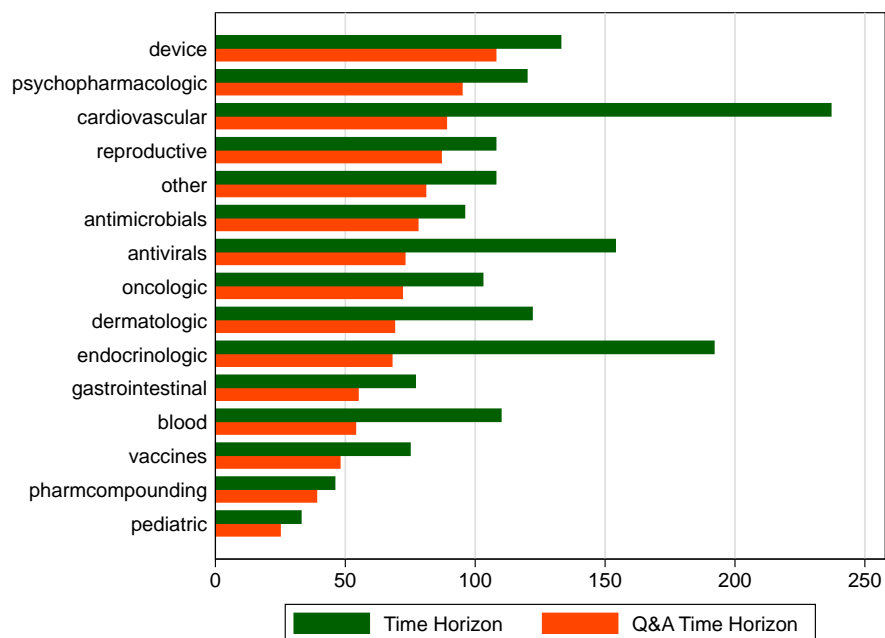


Figure A.3: Deliberation Horizon in each committee in the data.

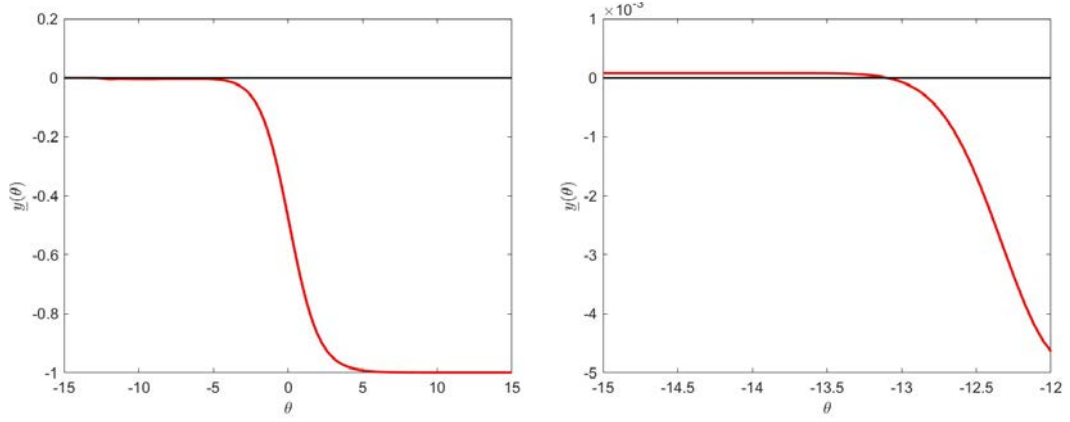


Figure A.4: Example of $\underline{y}(\theta)$ from the Devices committee. Both figures show the results for a representative committee member, halfway through deliberation (i.e., at $\tau = 54$). The left panel shows the whole function $\underline{y}(\theta)$, while the right-panel zooms in to the region of θ where the function crosses zero.

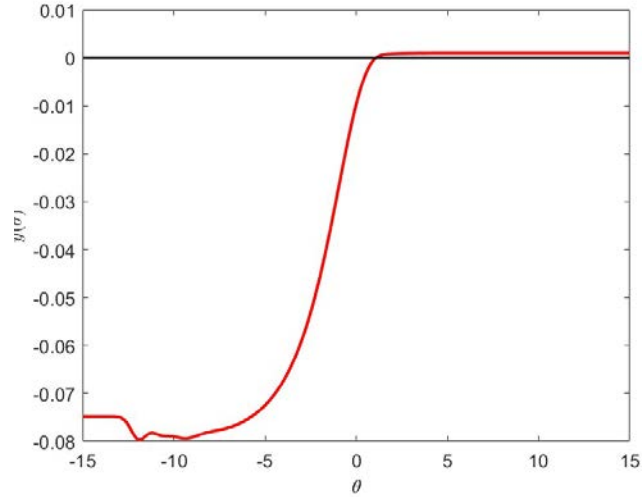


Figure A.5: Example of $\bar{y}(\theta)$ from the Devices Committee. Set at the same individual, period and committee as Figure A.4 above. While the function may not be always monotonic, it only crosses zero once.

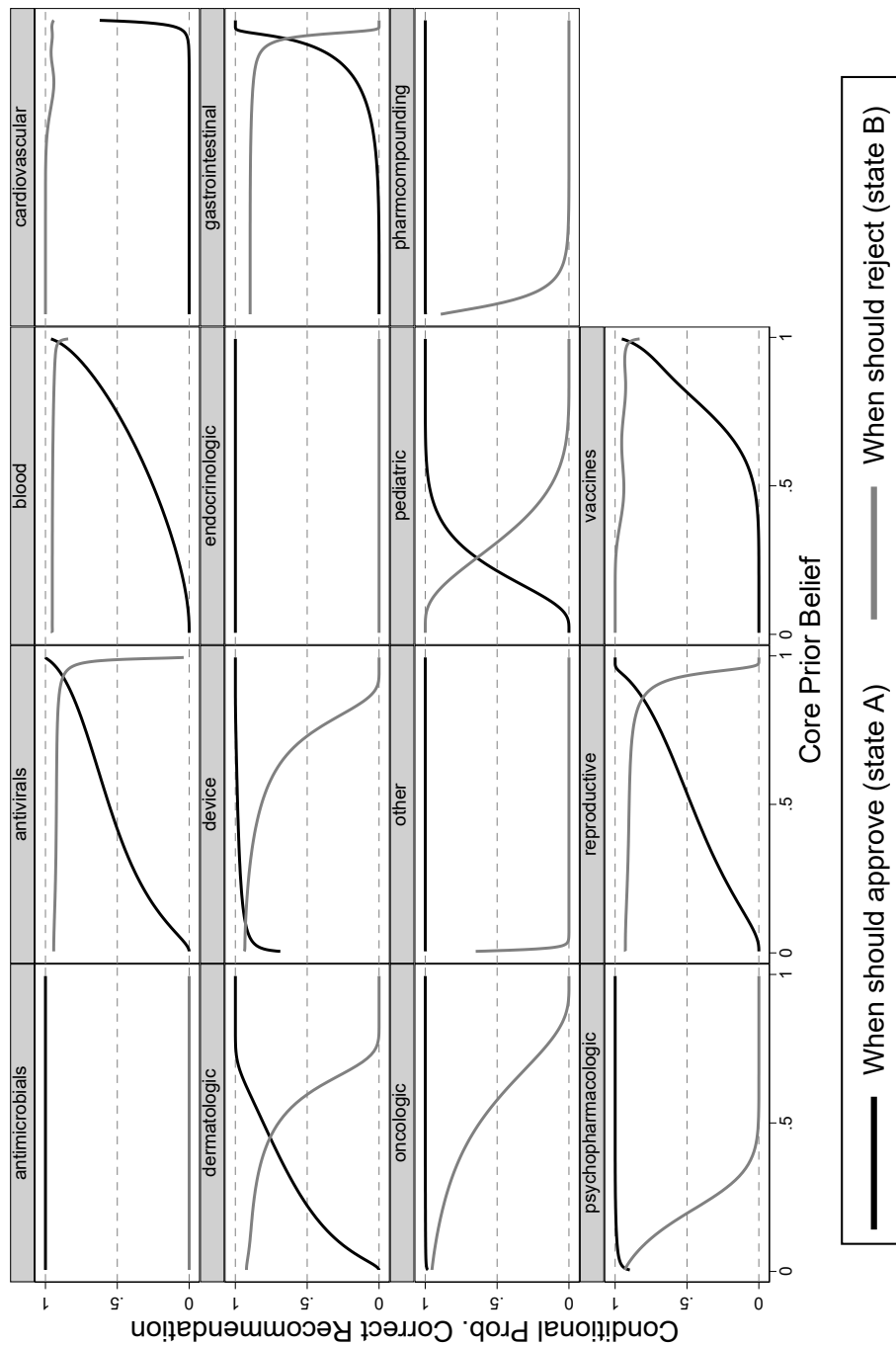


Figure A.6: State-Contingent Estimated Probabilities of a Correct Recommendation as a Function of Prior Beliefs.

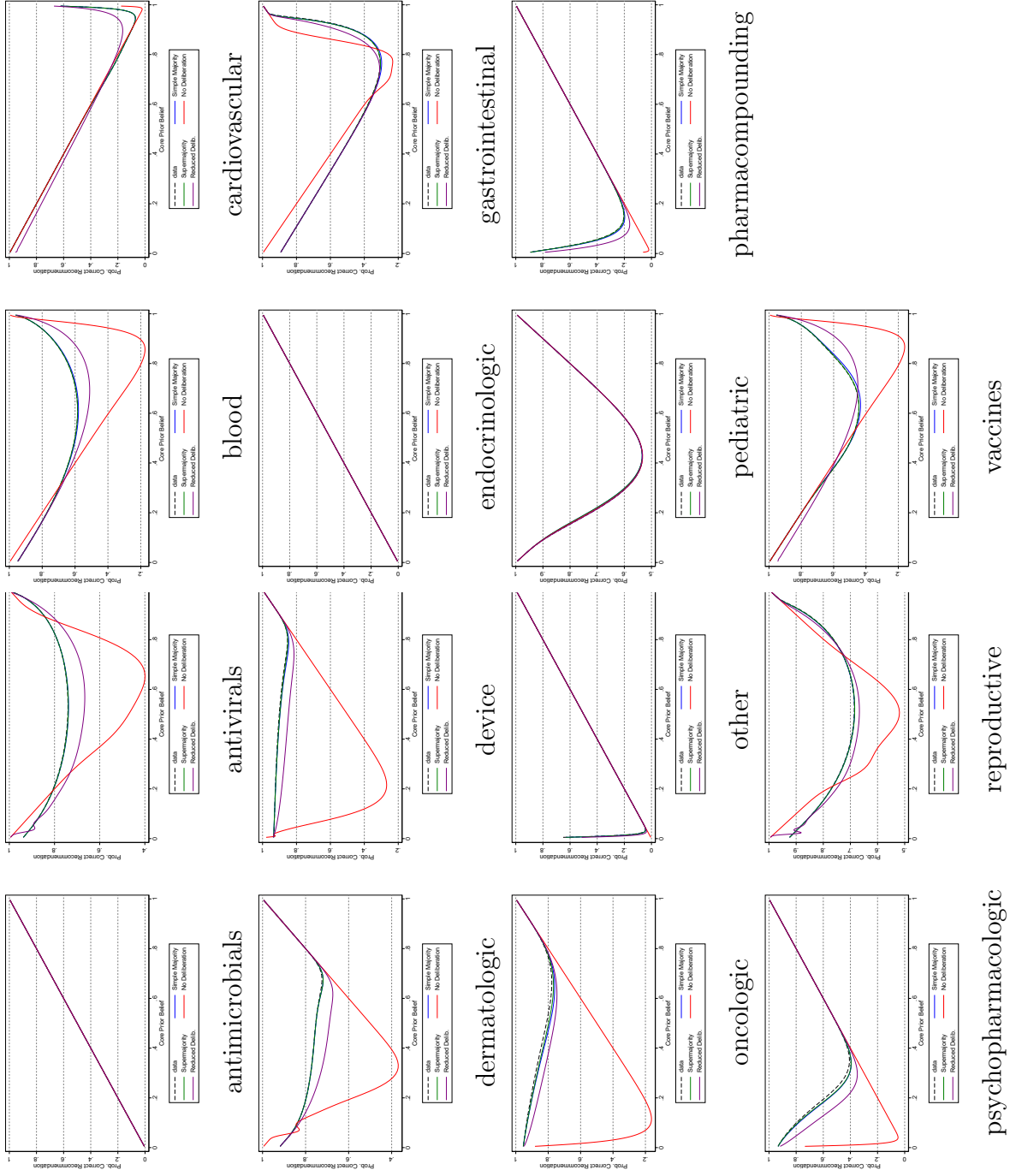


Figure A.7: Counterfactuals: Deliberation rule and Time to deliberate

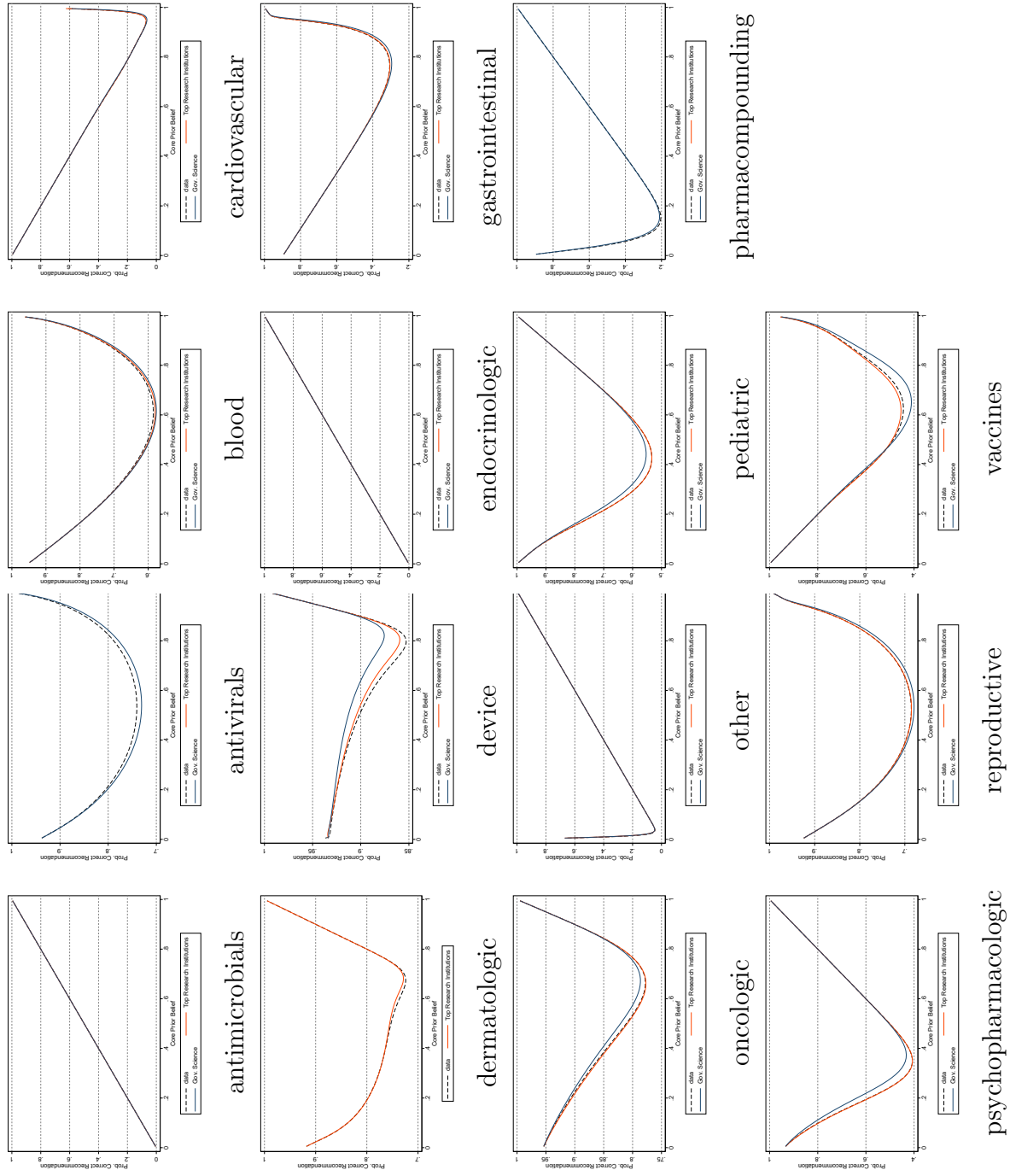


Figure A.8: Counterfactuals: Top Research Institutions and Government Science

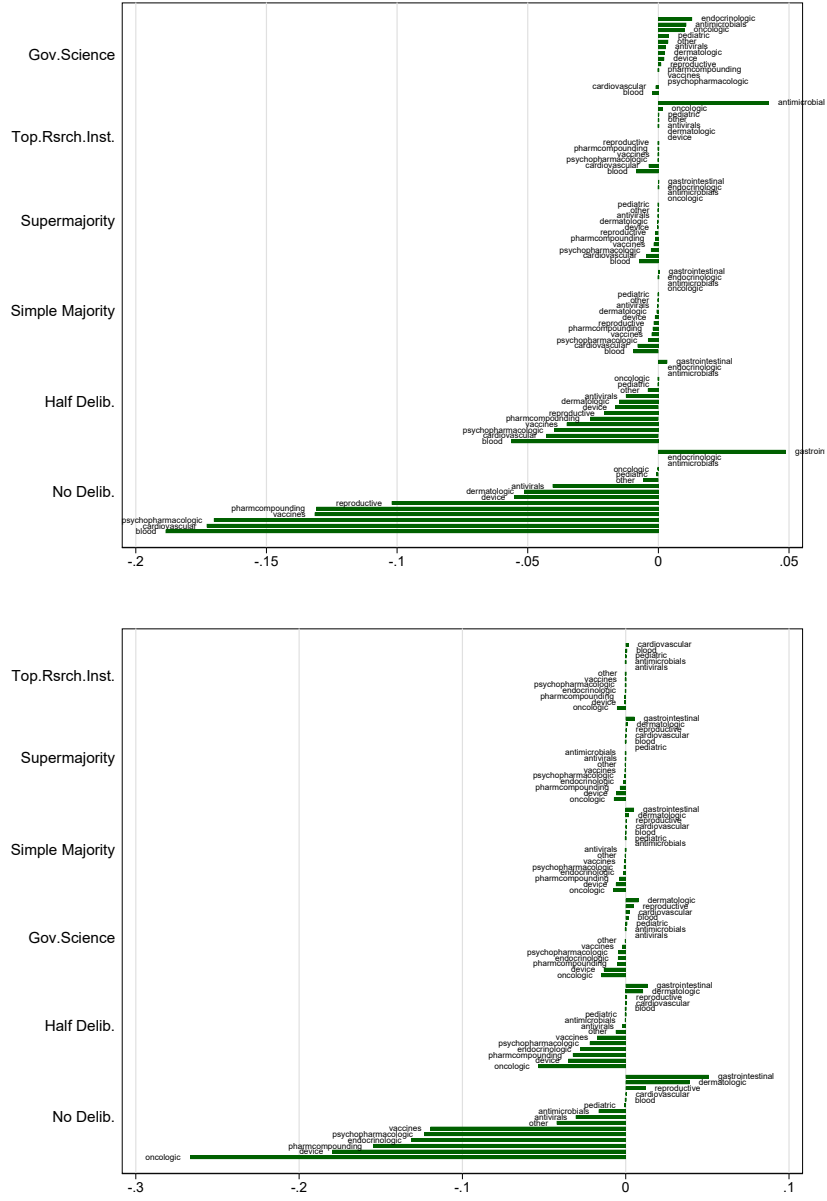
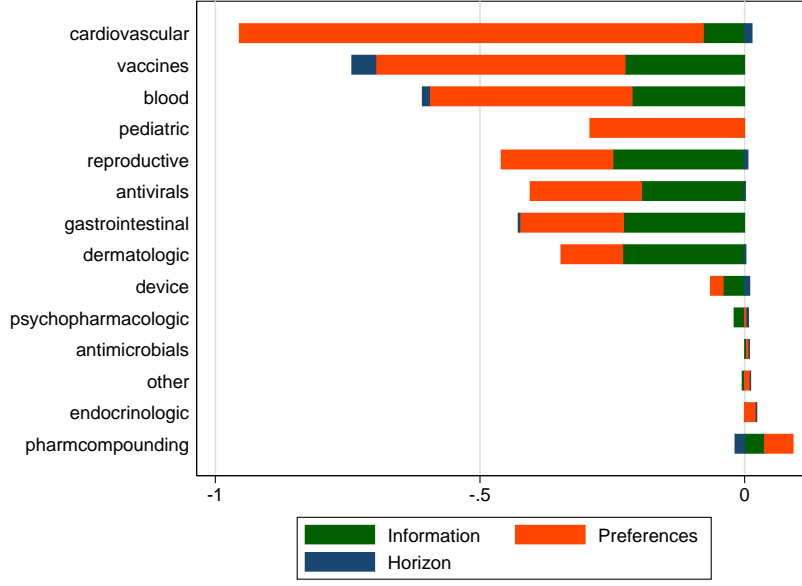
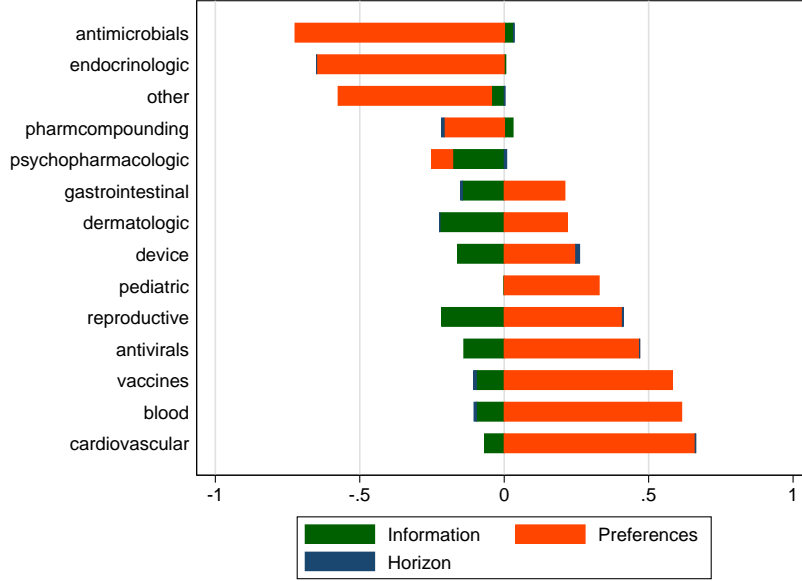


Figure A.9: Change in the ex-ante Probability of a Correct Recommendation relative to the data, for each counterfactual ℓ and committee c ; $\zeta_c^\ell \equiv \bar{\Lambda}_T(\ell, c) - \bar{\Lambda}_T(\text{data}, c)$. Top (bottom) panel presents results consistent with case-specific shocks at the 25th (75th) percentile



Differences in the Prob. of Correctly Approving ($\bar{\alpha}_T^c - \bar{\alpha}_T^{on}$)



Differences in the Prob. of Correctly Rejecting ($\bar{\beta}_T^c - \bar{\beta}_T^{on}$)

Figure A.10: Attribution of differences in $\bar{\alpha}_T^c - \bar{\alpha}_T^{on}$ and $\bar{\beta}_T^c - \bar{\beta}_T^{on}$ to information, preferences, and horizon for each committee $c \in C$ (the Oncologic Committee is the benchmark).

B Proofs

Proposition B.1. (i) *The committee extends deliberations at $\tau = 1$ with positive probability if and only if*

$$\rho' > 2\Phi^{-1}\left(\frac{1}{\delta[1 + \max\{\exp(\tilde{v}_k - \tilde{v}_m), \exp(\tilde{v}_m - \tilde{v}_{2m-k})\}]\right)} \quad (\text{B.1})$$

(ii) *if (B.1) does not hold, $\gamma(\tau) = \Gamma(\tau) = \tilde{v}_m$ for all $\tau \leq T$; i.e., the committee decides immediately, with no deliberation.*

Proof of Proposition B.1. Part (i). The committee stops deliberations at $\tau = 1$ for all θ if and only if $\gamma(1) = \Gamma(1) = \tilde{v}_m$. Note that $\gamma(1) = \tilde{v}_m$ if and only if $\tilde{v}_m \leq \underline{\theta}_{2m-k}(1)$, and thus, at $\theta = \tilde{v}_m$, we must have

$$\tilde{v}_{2m-k} \geq \tilde{v}_m - \ln\left(\frac{1 - \delta\Phi\left(\frac{\tilde{v}_m - \tilde{v}_m - \mu'_B}{\rho'}\right)}{\delta\left[1 - \Phi\left(\frac{\tilde{v}_m - \tilde{v}_m - \mu'_A}{\rho'}\right)\right]}\right) \Leftrightarrow e^{(\tilde{v}_m - \tilde{v}_{2m-k})} \leq \frac{1 - \delta\Phi\left(\frac{\rho'}{2}\right)}{\delta\Phi\left(\frac{\rho'}{2}\right)}.$$

where the second inequality follows since $\mu'_A = -\mu'_B = (\rho')^2/2$. Similarly, $\Gamma(1) = \tilde{v}_m$ if and only if $\tilde{v}_m \geq \bar{\theta}_k(1)$, and thus, at $\theta = \tilde{v}_m$, we must have

$$\tilde{v}_k \leq \tilde{v}_m - \ln\left(\frac{\delta\Phi\left(\frac{\tilde{v}_m - \tilde{v}_m - \mu'_B}{\rho'}\right)}{1 - \delta + \delta\Phi\left(\frac{\tilde{v}_m - \tilde{v}_m - \mu'_A}{\rho'}\right)}\right) \Leftrightarrow e^{(\tilde{v}_k - \tilde{v}_m)} \leq \frac{1 - \delta\Phi\left(\frac{\rho'}{2}\right)}{\delta\Phi\left(\frac{\rho'}{2}\right)}.$$

It follows that for the committee to extend deliberations at $\tau = 1$ with positive probability, we need

$$\max\{\exp(\tilde{v}_k - \tilde{v}_m), \exp(\tilde{v}_m - \tilde{v}_{2m-k})\} > \frac{1 - \delta\Phi(\rho'/2)}{\delta\Phi(\rho'/2)}.$$

or equivalently,

$$\rho' > 2\Phi^{-1}\left(\frac{1}{\delta[1 + \max\{\exp(\tilde{v}_k - \tilde{v}_m), \exp(\tilde{v}_m - \tilde{v}_{2m-k})\}]\right)}$$

Part (ii). Let $\tau \geq 2$. Suppose that in $\tau - 1$, the deliberation region is empty; i.e., $\gamma(\tau - 1) = \Gamma(\tau - 1) = \tilde{v}_m$. Then $\bar{W}_i^{\tau-1}(\theta) = \bar{W}_i^0(\theta)$ for all $\theta \in \Theta$. It follows

that $\bar{\theta}_i(\tau) = \bar{\theta}_i(1)$ and $\underline{\theta}_i(\tau) = \underline{\theta}_i(1)$ for all i , and then in particular, $\gamma(\tau) = \gamma(1)$ and $\Gamma(\tau) = \Gamma(1)$. That is, the equilibrium play restarts (going backwards) after a period with no deliberation. It follows, in particular, that if $\gamma(1) = \Gamma(1) = \tilde{v}_m$, then $\gamma(\tau) = \Gamma(\tau) = \tilde{v}_m$ for all $\tau \leq T$. \square

Proposition B.2. (i) Consider two preference profiles v' and v'' that satisfy (B.1), and such that (a) $\tilde{v}_m'' = \tilde{v}_m'$, (b) $\tilde{v}_{2m-k}'' < \tilde{v}_{2m-k}'$, and (c) $\tilde{v}_k'' > \tilde{v}_k'$. Then,

$$\gamma(1; v'') < \gamma(1; v') < \Gamma(1; v') < \Gamma(1; v'').$$

(ii) Let $k > m$. Consider two preference profiles \tilde{v}' and \tilde{v}'' that satisfy (B.1), and such that $\tilde{v}_m'' > \tilde{v}_m'$. Then, $\gamma(1; \tilde{v}'') > \gamma(1; \tilde{v}')$ and $\Gamma(1; \tilde{v}'') > \Gamma(1; \tilde{v}')$.

Proof of Proposition B.2. Part (i). Note that $\gamma(1; v) \equiv \min\{\tilde{v}_m, \underline{\theta}_{2m-k}(1; v)\}$. Note that $\underline{y}_{2m-k}(\theta|1; v)$ is strictly increasing in v_{2m-k} for any θ . Thus, $\underline{y}_{2m-k}(\theta|1; v') > \underline{y}_{2m-k}(\theta|1; v'')$ for all θ . Since $\underline{y}_{2m-k}(\theta|1; v)$ is decreasing in θ , we must have that $\underline{\theta}_{2m-k}(1; v') > \underline{\theta}_{2m-k}(1; v'')$ to restore the equality. Since (B.1) holds at v' and v'' , $\gamma(1; v'') < \gamma(1; v')$. The same logic implies that $\Gamma(1; v') < \Gamma(1; v'')$.

Part (ii). Note that the increase in \tilde{v}_m does not change the stopping payoff for the pivotal members $2m-k$ and k , but affects their continuation values $\bar{W}_i^0(\theta_1)$. In particular, $\frac{\partial}{\partial \tilde{v}_m} \bar{W}_i^0(\theta_1) > 0$ if

$$\begin{aligned} e^{v_i \phi} \left(\frac{\tilde{v}_m - \theta_1 + \mu'_A}{\rho'} \right) &> e^{\theta_1 + \kappa_i \phi} \left(\frac{\tilde{v}_m - \theta_1 - \mu'_A}{\rho'} \right) \\ \Leftrightarrow \exp \left(v_i - \frac{1}{2} \left(\frac{\tilde{v}_m - \theta_1 + \mu'_A}{\rho'} \right)^2 \right) &> \exp \left(\theta_1 + \kappa_i - \frac{1}{2} \left(\frac{\tilde{v}_m - \theta_1 - \mu'_A}{\rho'} \right)^2 \right). \\ \Leftrightarrow 2(\rho')^2(\tilde{v}_i - \theta_1) &> (\tilde{v}_m - \theta_1 + \mu'_A)^2 - (\tilde{v}_m - \theta_1 - \mu'_A)^2. \\ \Leftrightarrow \tilde{v}_i &> \tilde{v}_m. \end{aligned}$$

where we have used the fact that $\mu'_A = \frac{1}{2}(\rho')^2$.

Since $\tilde{v}_{2m-k} < \tilde{v}_m$ given the assumption that $\tilde{v}_i \neq \tilde{v}_j$ for all i, j , the increase in \tilde{v}_m reduces $2m-k$'s continuation value $\bar{W}_{2m-k}^0(\theta_1)$, and thus increases

$\underline{y}_{2m-k}(\theta_1|1) = e^{v_{2m-k}}/(1 + e^{\theta_1}) - \delta \bar{W}_{2m-k}^0(\theta_1)$ for all θ_1 . Since $\underline{y}_{2m-k}(\cdot|1)$ is decreasing in θ_1 , $\underline{\theta}_{2m-k}(1)$ must increase to restore the equality $\underline{y}_{2m-k}(\underline{\theta}_{2m-k}(1)|1) = 0$. Since eq. (B.1) still holds after the marginal change in v_m , $\gamma(1) \equiv \min\{v_m, \underline{\theta}_k(1)\}$ increases. Similarly, since $\tilde{v}_k > \tilde{v}_m$, the increase in \tilde{v}_m increases k 's continuation value $\bar{W}_k^0(\theta_1)$, and thus reduces $\bar{y}_k(\theta_1|1) = e^{\theta_1}/(1 + e^{\theta_1}) - \delta \bar{W}_k^0(\theta_1)$ for all θ_1 . Since $\bar{y}_k(\theta|1)$ is increasing in θ , $\bar{\theta}_k(1)$ must increase to restore the equality $\bar{y}_k(\bar{\theta}_k(1)|1) = 0$. Since eq. (B.1) still holds after the marginal change in \tilde{v}_m , $\Gamma(1) \equiv \max\{\tilde{v}_m, \bar{\theta}_k(1)\}$ increases. \square

C Equilibrium Characterization for $\tau \geq 2$

Exactly as in period $\tau = 1$, if deliberation ends at τ and the committee takes a vote, then i gets a payoff

$$\frac{e^{\theta_\tau + \kappa_i}}{1 + e^{\theta_\tau + \kappa_i}} \quad \text{if } \theta_\tau \geq \tilde{v}_m \quad \text{and} \quad \frac{e^{v_i}}{1 + e^{\theta_\tau + \kappa_i}} \quad \text{if } \theta_\tau < \tilde{v}_m.$$

So if $\theta_\tau \geq \tilde{v}_m$, i prefers taking a vote now to extending deliberations if

$$\bar{y}_i(\theta_\tau | \tau) \equiv \frac{e^{\theta_\tau + \kappa_i}}{1 + e^{\theta_\tau + \kappa_i}} - \delta \bar{W}_i^{\tau-1}(\theta_\tau) \geq 0,$$

and if $\theta_\tau < \tilde{v}_m$, i prefers taking a vote now to extending deliberations if and only if

$$\underline{y}_i(\theta_\tau | \tau) \equiv \frac{e^{v_i}}{1 + e^{\theta_\tau + \kappa_i}} - \delta \bar{W}_i^{\tau-1}(\theta_\tau) \geq 0,$$

where $\bar{W}_i^{\tau-1}(\theta_\tau)$ denotes the continuation value for member i of extending deliberations to $\tau-1$. Differently than before, if the committee extends deliberations, in the next period the committee can (i) reject (if $\theta_{\tau-1} \leq \gamma(\tau-1)$), (ii) approve (if $\theta_{\tau-1} \geq \Gamma(\tau-1)$) or (iii) wait (if $\theta_{\tau-1} \in [\gamma(\tau-1), \Gamma(\tau-1)]$). Thus, the expected continuation payoff is $\delta \bar{W}_i^{\tau-1}(\theta_\tau)$, where

$$\begin{aligned} \bar{W}_i^{\tau-1}(\theta_\tau) &= \frac{e^{\theta_\tau + \kappa_i}}{1 + e^{\theta_\tau + \kappa_i}} \left[1 - \Phi \left(\frac{\Gamma(\tau-1) - \theta_\tau - \mu'_A}{\rho'} \right) \right] \\ &\quad + \frac{1}{1 + e^{\theta_\tau + \kappa_i}} \Phi \left(\frac{\gamma(\tau-1) - \theta_\tau - \mu'_B}{\rho'} \right) e^{v_i} \\ &\quad + \frac{e^{\theta_\tau + \kappa_i}}{1 + e^{\theta_\tau + \kappa_i}} \delta \int_{\gamma(\tau-1)}^{\Gamma(\tau-1)} \phi \left(\frac{\theta_{\tau-1} - \theta_\tau - \mu'_A}{\rho'} \right) \bar{W}_i^{\tau-2}(\theta_{\tau-1}; A) d\theta_{\tau-1} \\ &\quad + \frac{1}{1 + e^{\theta_\tau + \kappa_i}} \delta \int_{\gamma(\tau-1)}^{\Gamma(\tau-1)} \phi \left(\frac{\theta_{\tau-1} - \theta_\tau - \mu'_B}{\rho'} \right) \bar{W}_i^{\tau-2}(\theta_{\tau-1}; B) d\theta_{\tau-1}, \end{aligned} \tag{C.1}$$

and where for any $\tau \geq 1$, $\bar{W}_i^{\tau-1}(\theta_\tau; \omega)$ denotes the continuation value in τ conditional on the committee having a belief θ_τ and the state being $\omega \in \{A, B\}$;

i.e.,

$$\overline{W}_i^0(\theta_1; A) = \left[1 - \Phi \left(\frac{\tilde{v}_m - \theta_1 - \mu'_A}{\rho'} \right) \right], \quad \overline{W}_i^0(\theta_1; B) = \Phi \left(\frac{\tilde{v}_m - \theta_1 - \mu'_B}{\rho'} \right) e^{v_i},$$

and for $\tau \geq 2$,

$$\begin{aligned} \overline{W}_i^{\tau-1}(\theta_\tau; A) &= \left[1 - \Phi \left(\frac{\Gamma(\tau-1) - \theta_\tau - \mu'_A}{\rho'} \right) \right] \\ &\quad + \delta \int_{\gamma(\tau-1)}^{\Gamma(\tau-1)} \phi \left(\frac{\theta_{\tau-1} - \theta_\tau - \mu'_A}{\rho'} \right) \overline{W}_i^{\tau-2}(\theta_{\tau-1}; A) d\theta_{\tau-1}, \end{aligned}$$

and

$$\begin{aligned} \overline{W}_i^{\tau-1}(\theta_\tau; B) &= \Phi \left(\frac{\gamma(\tau-1) - \theta_\tau - \mu'_B}{\rho'} \right) e^{v_i} \\ &\quad + \delta \int_{\gamma(\tau-1)}^{\Gamma(\tau-1)} \phi \left(\frac{\theta_{\tau-1} - \theta_\tau - \mu'_B}{\rho'} \right) \overline{W}_i^{\tau-2}(\theta_{\tau-1}; B) d\theta_{\tau-1}, \end{aligned}$$

Define $\bar{\theta}_i(\tau)$ as the value of the core posterior θ_τ such that $\bar{y}_i(\theta_\tau|\tau) \equiv 0$ and similarly $\underline{\theta}_i(\tau)$ as the value of the core posterior θ_τ such that $\underline{y}_i(\theta_\tau|\tau) \equiv 0$; i.e.,

$$\frac{e^{\bar{\theta}(\tau)+\kappa_i}}{1 + e^{\bar{\theta}(\tau)+\kappa_i}} \equiv \delta \overline{W}_i^{\tau-1}(\bar{\theta}(\tau)) \quad \text{and} \quad \frac{e^{v_i}}{1 + e^{\underline{\theta}(\tau)+\kappa_i}} \equiv \delta \overline{W}_i^{\tau-1}(\underline{\theta}(\tau))$$

As in $\tau = 1$, with large ρ' , the function $\underline{y}_i(\cdot|\tau)$ is strictly decreasing. To see this, note that

$$\lim_{\rho' \rightarrow \infty} \overline{W}_i^{\tau-1}(\theta_\tau) = \frac{e^{\theta_\tau+\kappa_i}}{1 + e^{\theta_\tau+\kappa_i}} + \frac{e^{v_i}}{1 + e^{\theta_\tau+\kappa_i}}$$

and then for large ρ' ,

$$\underline{y}_i(\theta_\tau|\tau) \approx (1 - \delta) \frac{e^{v_i}}{1 + e^{\theta_\tau+\kappa_i}} - \delta \frac{e^{\theta_\tau+\kappa_i}}{1 + e^{\theta_\tau+\kappa_i}},$$

Therefore, for large ρ' , if $\tilde{v}_m \geq \bar{\theta}_i(\tau)$, then i prefers to stop learning and adopt outright for all $\theta_\tau \geq \tilde{v}_m$. Similarly, if $\tilde{v}_m \leq \underline{\theta}_i(\tau)$, then i prefers to stop learning

and reject outright for all $\theta_\tau \leq \tilde{v}_m$.²⁶ Thus, letting

$$\Gamma_i(\tau) = \max\{\tilde{v}_m, \bar{\theta}_i(\tau)\} \quad \text{and} \quad \gamma_i(\tau) = \min\{\tilde{v}_m, \underline{\theta}_i(\tau)\}.$$

the unique best response for i in WDS is:

$$\sigma_i^\tau(\theta_\tau) = \begin{cases} 0 & \text{if } \theta_\tau \leq \gamma_i(\tau) \text{ or } \theta_\tau \geq \Gamma_i(\tau) \\ 1 & \text{if } \theta_\tau \in (\gamma_i(\tau), \Gamma_i(\tau)) \end{cases}$$

where $\sigma_i^\tau(\theta_\tau) = 1$ denotes that i raises her hand to ask a question at state (θ_τ, τ) and $\sigma_i^\tau(\theta_\tau) = 0$ denotes that i stays silent at (θ_τ, τ) . The unique equilibrium in WDS then has all committee members following this strategy.

Letting $\gamma(\tau)$ denote the k th largest element in $\{\gamma_i(\tau)\}_i^N$ and $\Gamma(\tau)$ the k th smallest element in $\{\Gamma_i(\tau)\}_i^N$, analogously to our definitions for $\tau = 1$, equilibrium outcomes in state (θ_τ, τ) are then given by

$$x_\tau(\theta_\tau) = \begin{cases} \text{reject} & \text{if } \theta_\tau \leq \gamma(\tau) \\ \text{continue} & \text{if } \theta_\tau \in (\gamma(\tau), \Gamma(\tau)) \\ \text{adopt} & \text{if } \theta_\tau \geq \Gamma(\tau) \end{cases}$$

This fully characterizes the equilibrium information acquisition of the model in terms of committee member preferences, the informativeness of the diffusion process, discount rates and the deliberation rule, k , as a function of log odds beliefs, θ , for any period. Finally, the voting outcome follows from simple-majority voting: i.e., after deliberation is stopped at $\tau \in \{0, \dots, T\}$, there is approval if $\theta_\tau < v_m$ and rejection otherwise.

Table B.1 illustrates the equilibrium deliberation region, and our theoretical results, in a simple numerical example. The table contains two panels. In both cases, we fix $\mu_A' = 1$ and $\delta = 0.9$, and compute the deliberation region for periods $\tau = 1, \dots, 5$, for all deliberation rules, $k = 5, \dots, 9$. In the first panel, we set $\tilde{v}' = (0, 0, 0, 0, 0, 0.2, 0.4, 0.6, 0.8)$. In the second, we make

²⁶We check the single-crossing condition at our estimates.

members to the right of the median more biased against the proposal, setting $\tilde{v}'' = (0, 0, 0, 0, 0, 0.2, 0.4, 1.2, 1.6)$. We assume homogeneous priors. Note that this affects the preferences of the right pivot, \tilde{v}_k , without changing the preferences of the left pivot, \tilde{v}_{2m-k} .

Table B.1: Deliberation Region as a function of k and δ (simulation).

Deliberation Region										
$\tilde{v}' = (0, 0, 0, 0, 0, 0.2, 0.4, 0.6, 0.8), \mu'_A = 1, \delta = 0.9$										
τ	$k = 5$		$k = 6$		$k = 7$		$k = 8$		$k = 9$	
	$\gamma(\tau)$	$\Gamma(\tau)$	$\gamma(\tau)$	$\Gamma(\tau)$	$\gamma(\tau)$	$\Gamma(\tau)$	$\gamma(\tau)$	$\Gamma(\tau)$	$\gamma(\tau)$	$\Gamma(\tau)$
1	-0.95	0.95	-0.95	1.17	-0.95	1.34	-0.95	1.48	-0.95	1.64
2	-1.17	1.17	-1.17	1.34	-1.17	1.55	-1.17	1.75	-1.17	1.88
3	-1.28	1.23	-1.28	1.41	-1.28	1.64	-1.28	1.75	-1.28	2.05
4	-1.23	1.17	-1.23	1.41	-1.23	1.48	-1.23	1.64	-1.17	1.75
5	-1.23	1.17	-1.23	1.41	-1.17	1.48	-1.17	1.64	-1.17	1.88
$\tilde{v}'' = (0, 0, 0, 0, 0, 0.4, 0.8, 1.2, 1.6), \mu'_A = 1, \delta = 0.9$										
τ	$k = 5$		$k = 6$		$k = 7$		$k = 8$		$k = 9$	
	$\gamma(\tau)$	$\Gamma(\tau)$	$\gamma(\tau)$	$\Gamma(\tau)$	$\gamma(\tau)$	$\Gamma(\tau)$	$\gamma(\tau)$	$\Gamma(\tau)$	$\gamma(\tau)$	$\Gamma(\tau)$
1	-0.95	0.95	-0.95	1.34	-0.95	1.64	-0.95	1.88	-0.95	2.05
2	-1.17	1.17	-1.17	1.55	-1.17	1.88	-1.17	2.33	-1.17	2.33
3	-1.28	1.23	-1.28	1.64	-1.28	2.05	-1.28	1.88	-1.28	2.33
4	-1.23	1.17	-1.23	1.48	-1.17	1.75	-1.41	2.33	-1.48	2.05
5	-1.23	1.17	-1.17	1.48	-1.17	1.88	-1.48	1.88	-1.64	2.33

Note: Deliberation Region as a function of k and δ , for two preference profiles. In the bottom panel, members to the right of the median (members 6 to 9) are more biased against the proposal.

As we can see in the first row in both tables, the left boundary of the deliberation region in $\tau = 1$, $\gamma(1) = -0.95$, is unaffected by the change. This illustrates that $\gamma(1)$ is only determined by the preferences \tilde{v}_{2m-k} and \tilde{v}_m , and not by the preferences of the right pivot, \tilde{v}_k . We also see that all else constant, increasing \tilde{v}_k or equivalently k expands the deliberation region to the right. In earlier periods of deliberation, though, the increase in $\Gamma(s)$ for $s < \tau$ reduces $\gamma(\tau)$; i.e., as the right pivot stops to approve less often if deliberation continues, the left pivot is willing to deliberate more often, extending deliberations for values of the posterior for which she would have voted to halt deliberations and reject outright.

D Informativeness Measure

Committee members use the information presented – whether in the presentation or in deliberation – when deciding how to vote. Following the vote, they justify their decisions and those justifications are written in the transcripts. Our procedure to measure information uses textual similarity between vote justifications and the unigrams/bigrams in the presentations and deliberations. We assume that the same words that are used more often to justify positive votes are also more likely to be used during presentations/deliberation to convey positive information.²⁷

Denote $y_{i,j} \in \{0, 1\}$ as the voting decision of committee member i in question j in committee c . Denote $x_{i,j}$ as a vector of possible words justifying a vote, with $x_{i,j,d}$ equal to 1 if unigram/bigram d is used by i when justifying his vote on j , and 0 otherwise. Then, our procedure consists of: (i) obtaining the LASSO estimator for parameter β defined in the equation $y_{i,j} = x'_{i,j}\beta + \varepsilon_{i,j}$, (ii) predicting the probability of voting Yea for each given message observed during deliberation on question j by setting $\hat{y}_{t,j} = x'_{t,j}\hat{\beta}^{LASSO}$, where $x_{t,j}$ is a binary vector with entries equal to 1 for words used in the justification of message in period t for question j , (iii) obtaining our signal measure, $s_t = \Phi^{-1}(\hat{y}_t)$ by applying an inverse standard Normal CDF on $\hat{y}_{t,j}$.

In principle, this procedure can be done committee-by-committee. However, due to some committees having a very limited number of votes, we aggregate all words across committees, thereby generating a composite library of possible words for justification. Then, the LASSO estimator, $\hat{\beta}^{LASSO}$, solves:

$$\hat{\beta}^{LASSO} = \underset{\beta}{argmin} \sum_{c=1}^C \sum_{i=1}^{N_c} \sum_{j=1}^{J_c} (y_{i,j} - x'_{i,j}\beta)^2 + \lambda \sum_{m=1}^{dim(\beta)} |\beta|_m. \quad (D.1)$$

The implementation of this estimator depends on the tuning (penalization) parameter, λ , which controls the number of coefficients of $\hat{\beta}^{LASSO}$ that are set

²⁷This is a type of invariance condition on the meaning of words: for example, if committee members justify Yea votes more often with unigram b than unigram d , then when b is used in a presentation/deliberation, we assume they update beliefs more positively on average (and therefore, are more likely to vote Yea) than when they hear d .

to (exactly) 0.²⁸ If $\lambda \rightarrow \infty$, then all coefficients are set to 0. If $\lambda \rightarrow 0$, then the estimator converges to the OLS estimator.

Most applications of LASSO choose λ by cross-validation to minimize Mean-Squared Error (MSE). This is because most LASSO applications care about prediction alone. In this choice, λ balances bias and variance of β (and, therefore, in the predicted $y_{i,j}$). However, in our paper, we care about more than prediction: we also care about the interpretation of $s_{i,j} = \Phi^{-1}(\hat{y}_{i,j})$. After all, the model implies that any empirical measure of $s_{i,j}$ must have enough variance. Otherwise, committee members could perfectly predict the sequence of information.

Hence, we set λ to a positive, but lower value, than its cross-validation counterpart. This guarantees that our predictions have higher variance than those obtained by cross-validation, while still setting enough coefficients to 0 (thereby, minimizing the number of variables). In particular, we set λ to be the value of the parameter obtained by cross-validation divided by 4, which works well in our application. The left panel of Figure D.1 shows the fit of our predictions across values of λ . As we increase λ , the Mean-Squared Error decreases until the cross-validation choice, λ^{CV} . Our own choice of $\lambda = \lambda^{CV}/4$ (i.e., $\ln(\lambda) = \ln(\lambda^{CV}) - 1.386$ still obtains excellent fit, while retaining higher variance. Meanwhile, the right panel of the figure illustrates how increasing λ sets parameters that were estimated as non-zero for small values of λ to 0 with higher values.

Finally, Figure D.2 below shows the coefficients with the largest values across all committees. The predictors with the most negative coefficients seem to be those expressing negative views on the product/question (e.g., “not”, “not feel”, “concern”), adversarial feelings (e.g., “versus”, “bar”) or referring/asking for further information (e.g., “educ”, “trial”, “committee meet” - possibly for another meeting). On the other hand, those at the top suggest positive signs (“anim”, “thank”, “potential benefit”, “impress”), future necessary steps (“label”, “postmarket”, “registri”) or referring to data sources (“consist”, “report

²⁸Coefficients are set to 0 because of the ℓ^1 penalty, thereby differing from ridge regression or other penalization approaches.

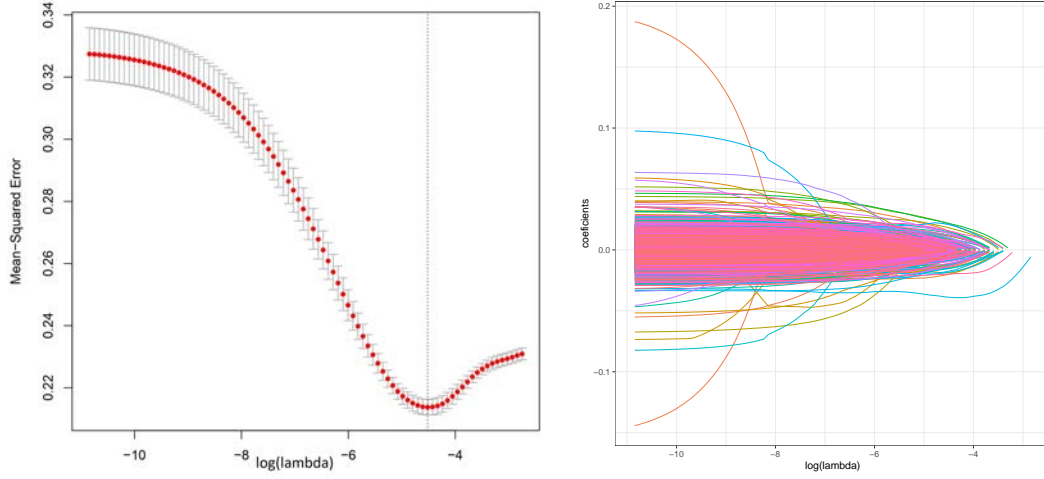


Figure D.1: Fit and Estimators Across λ : The top panel shows how the (estimated) MSE changes with different values of λ in a 5-fold cross-validation. The vertical line shows the value that minimizes MSE, λ^{CV} . We set our λ at $\lambda^{CV}/4$ (i.e., $\ln(\lambda) \approx -5.8$). The bottom panel shows how the coefficients of the LASSO change with λ .

compani”, “fda”).

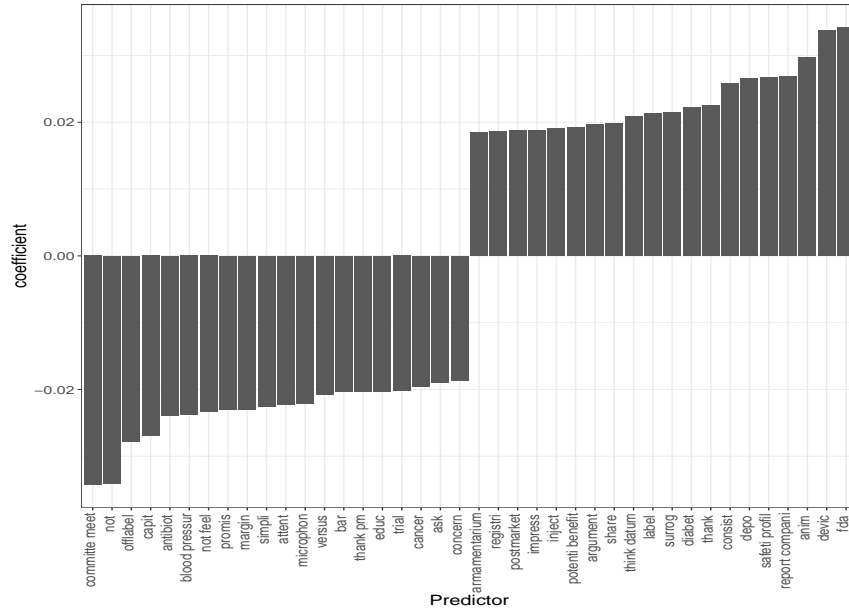


Figure D.2: Top Predictors, $\hat{\beta}^{LASSO}$, Across Committees.

Table D.1: Signals and Meeting Characteristics

	signal	abs(signal)	signal	abs(signal)
	(1)	(2)	(3)	(4)
Q&A	-0.0875 (0.0149)	0.0375 (0.0169)	-0.0802 (0.0122)	0.0501 (0.0100)
FDA speaker	0.0374 (0.0185)	0.0351 (0.0116)	0.0400 (0.0100)	0.0356 (0.0072)
Time in Meeting	0.0004 (0.0002)	0.0004 (0.0002)	0.0004 (0.0003)	0.0003 (0.0002)
Calendar time	0.0004 (0.0002)	0.0003 (0.0001)		
Constant	0.3060 (0.0337)	0.3476 (0.0297)	0.3560 (0.0067)	0.3837 (0.0055)
Committee Fixed Effect	YES	YES	NO	NO
Meeting Fixed Effect	NO	NO	YES	YES
# Observations	23,667	23,667	23,667	23,667
# Clusters	15	15	357	357
R squared (within)	0.0104	0.0081	0.0076	0.0088
R squared (between)	0.0127	0.0052	0.0184	0.0003

Note: In specifications (1) and (3), we regress signal realizations on whether the signal was generated in the Q&A stage (Q&A), whether the speaker was an FDA representative or not (FDA speaker) and time period within a meeting. Specifications (2) and (4) repeat this with the absolute value of signal realizations. Specifications (1) and (2) use committee fixed effects, and include calendar time. Specifications (3) and (4) use question fixed effects. Numbers in parenthesis denote robust standard errors, clustered at the committee or meeting level.

Table D.2: Posterior Beliefs and Voting Outcomes

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
Experience	-0.017 (0.003)	-0.021 (0.004)	-0.009 (0.005)	-0.015 (0.011)	-0.006 (0.011)	-0.007 (0.013)	
Experience sq.	0.001 (0.0003)	0.001 (0.0003)	0.001 (0.0003)	0.001 (0.001)	0.001 (0.001)	0.001 (0.001)	
Female	-0.005 (0.010)	-0.009 (0.012)	0.023 (0.021)	-0.004 (0.010)	0.020 (0.013)	0.024 (0.024)	
MD	0.019 (0.011)	0.022 (0.013)	0.024 (0.013)	0.028 (0.011)	0.029 (0.012)	0.029 (0.016)	
Top 10 research inst.	-0.067 (0.018)	-0.065 (0.022)	-0.064 (0.022)	-0.050 (0.018)	-0.050 (0.018)	-0.050 (0.024)	
Top 10-20 research inst.	-0.046 (0.022)	-0.028 (0.025)	-0.026 (0.025)	-0.024 (0.024)	-0.023 (0.026)	-0.002 (0.026)	
Top 20-50 research. Inst.	-0.066 (0.017)	-0.057 (0.022)	-0.059 (0.022)	-0.055 (0.018)	-0.054 (0.018)	-0.055 (0.027)	
Other research inst.	-0.039 (0.015)	-0.030 (0.019)	-0.030 (0.019)	-0.027 (0.025)	-0.026 (0.024)	-0.016 (0.029)	
Gov. Science	-0.081 (0.021)	-0.085 (0.024)	-0.076 (0.024)	-0.069 (0.019)	-0.065 (0.022)	-0.068 (0.029)	
Gov. Other	-0.035 (0.030)	-0.016 (0.034)	-0.024 (0.034)	-0.043 (0.035)	-0.043 (0.035)	-0.046 (0.039)	
Patient representative	-0.072 (0.021)	-0.072 (0.026)	-0.085 (0.026)	-0.024 (0.038)	-0.031 (0.038)	-0.036 (0.054)	
Pubs rank-weighted	-0.002 (0.001)	-0.001 (0.001)		-0.001 (0.001)			
Posterior Belief	0.0035 (0.0004)	0.0039 (0.0004)	0.0035 (0.0004)	0.0046 (0.0019)	0.0044 (0.0019)	0.0046 (0.0019)	0.0048 (0.0006)
Question: effective	0.090 (0.011)	0.111 (0.012)	0.125 (0.016)	0.055 (0.024)	0.068 (0.028)	0.083 (0.029)	0.057 (0.013)
Question: safety	0.106 (0.009)	0.123 (0.012)	0.132 (0.016)	0.083 (0.031)	0.092 (0.034)	0.084 (0.040)	0.049 (0.013)
Question: risk benefit	0.030 (0.012)	0.039 (0.013)	0.099 (0.017)	0.065 (0.042)	0.118 (0.043)	0.124 (0.035)	0.066 (0.016)
FDA policy	0.267 (0.011)			0.350 (0.155)	0.349 (0.152)		
Top 10% revenue		0.068 (0.013)	0.071 (0.013)			0.099 (0.052)	0.072 (0.018)
Top 10-25% revenue		0.111 (0.015)	0.112 (0.015)			0.125 (0.046)	0.084 (0.023)
Top 25-75% revenue		0.116 (0.013)	0.115 (0.014)			0.053 (0.021)	0.022 (0.020)
Gov Science x FDA policy	0.018 (0.031)				0.011 (0.021)		
Female x Safety			-0.002 (0.025)		-0.006 (0.013)	0.002 (0.019)	
Female x Effective			-0.019 (0.025)		-0.006 (0.018)	-0.010 (0.025)	
Female x Risk Benefit			-0.067 (0.027)		-0.064 (0.030)	-0.050 (0.031)	
Exp x Safety			-0.006 (0.004)		-0.004 (0.005)	-0.003 (0.006)	
Exp x Effective			-0.007 (0.004)		-0.007 (0.008)	-0.007 (0.009)	
Exp x Risk Benefit			-0.015 (0.004)		-0.017 (0.003)	-0.017 (0.003)	
Constant	0.668 (0.018)	0.591 (0.023)	0.566 (0.024)	0.639 (0.054)	0.617 (0.055)	0.662 (0.110)	0.554 (0.123)
Question FE	NO	NO	NO	NO	NO	NO	NO
Committee FE	NO	NO	NO	YES	YES	YES	NO
Disease FE	NO	NO	NO	NO	NO	YES	YES
Individual FE	NO	NO	NO	NO	NO	NO	YES
Field Pub record	NO	NO	YES	NO	YES	YES	NO
# observations	10326	8471	8471	10326	10326	8471	8472
# clusters	-	-	-	15	15	15	1553
R squared (within)	-	-	-	0.040	0.046	0.066	0.043
R squared (between)	0.078	0.048	0.059	0.389	0.413	0.576	0.091

Note: The dependent variable is the individual vote in favor (1) or against (0) adoption. Numbers in parenthesis denote robust standard errors (specifications 1-3), clustered at the committee (specifications 4-6) and individual level (7). Field publications and disease categories are described in Tables A.1 and A.2.