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SECRET-PUBLIC VOTING IN FDA ADVISORY COMMITTEES

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Many public decisions are made on the basis of recommendations presented by committees of experts. Consequently, committee composition and how committee operation rules are determined are subject to criticism and reform. Rules governing experts' behavior are modified as actors learn from experience and in response to the specific criticisms elicited by committee operation.

In addition to participant selection and the nature of the information made available to committee members, two aspects of committee activity are particularly important. The first is how discussion among experts is organized—that is, the ways in which they can inform each other of their thinking and exchange arguments; second, how their collective recommendation gets shaped. In some cases, collective expert opinions are definitively determined by voting.

Whether or not debates and voting are public is a crucial variable whose effects—and therefore the consequences that authorities are either hoping for or seeking to avoid—greatly depend on circumstance. Publicity allows external actors to survey experts' work, but that control may be beneficial or harmful, depending on the case and the actors being considered. Moreover, influence not only of external actors on committee members but also of committee members on their fellow committee members has to be monitored and controlled. It is usually considered desirable for experts to influence each other positively during the discussions that precede the actual decision, but preferable for members to *vote* independently. Influence through debate is considered good in the sense of rational and is therefore encouraged; influence of votes on votes—the result of member indecision, member reputation, or maneuvering—is considered bad, and the point of secret voting is to steer as clear as possible of influence during the process in which the decision is actually determined.

So though public voting may be preferred because it allows external actors to monitor expert behavior, secret voting may appear desirable as a means of preventing conformism among experts. Thus, the value of the voting method may depend on of the audience considered: other voters or external actors. There is, however, one procedure that reconciles the benefits of publicity and secrecy, and that is to vote secretly but reveal who voted how after the vote count has been recorded. This method, used in Dominican monasteries in the thirteenth century in a process called the *scrutinium* (Gaudemet 1979, p. 326) and recommended by Bentham (1999, p. 106), may be termed, following Jon Elster (2013), “secret-public voting”.

The following case study examines the workings, consequences and lessons to be learned from a reform of FDA advisory committee decision-making procedures. Up to July 2007, the public

voting practiced in these committees was oral and sequential: members sitting around a table expressed their preference in turn. In August 2007 secret-public voting was introduced, first in the imperfect form of hand-raising, then (a few months later and ever since) more systematically in the form of electronic voting.

FDA advisory committees constitute an interesting case in terms of methodology because they can be studied both qualitatively and quantitatively: debates and voting are public and recorded in full in easily accessible verbatim minutes.

But advisory committee voting is interesting for another reason. The 2007 reform replaced public voting with secret-public voting, but it also replaced oral voting, which left ample opportunity to individual members to express themselves, with “manual” followed by digital voting, which precludes all such expression. It therefore enables us to study two distinct yet intertwined phenomena, a seldom encountered situation of great general value: the history of the shift from public to secret voting, mainly in the area of political elections, has often gone together with changes in the way choices are expressed, and the specific impact of those changes has not always been fully measured. As we shall see in this particular case, the impact of oral voting and of abolishing that method has been underestimated.

I. The 2007 reform of FDA Advisory Committee decision-making procedures

In the 1960s, western states began passing laws and creating organizations to control more efficiently medicine quality. Public agencies were formed whose tasks were to approve or refuse to approve medicines for marketing, oversee medicines’ possible effects, and, if it was deemed necessary, restrict their use or withdraw them from the market entirely.

In fulfilling these functions, agencies have to make “reasoned use of available scientific data” in reaching decisions and transmitting what they consider useful information to prescribers and patients. These decisions and actions must all be founded on reasons; that is, they must be supported by arguments and made in the service of public health. The United States Food and Drug Administration, created in the early twentieth century, was the first such agency to require and organize pre-marketing medicine approval—in 1962.

This text analyzes the decision-making procedures—specifically, the voting procedures—used by FDA “Advisory Committees,” consultative committees of outside experts assembled by the FDA to assist it in performing its medicine evaluation task.

A. The FDA advisory committees

The FDA began using advisory committees systematically in 1972. In fact, the FDA only uses advisory committees for what are considered delicate evaluations —delicate in that the available scientific data renders decision-making particularly difficult and/or the drug or disease involved is controversial¹. It has been demonstrated that FDA's particular use of advisory committees has proved a good tool to protect its reputation (Moffitt, 2010).

The consultative nature of the committees should not lead to underestimating their importance. They are of course not the final decision-makers since their recommendations are not binding. But the general orientations they bring to the fore are decisive for both the FDA, which follows AC recommendations in 70% of cases, and the drug companies, as well as for the public watchdog organizations. Furthermore, though only consultative, ACs are called upon to produce recommendations in ways akin to collective decision-making: experts have to give individual answers to FDA questions by way of voting, and their aggregated votes are understood to reflect the overall committee orientation and its opinion. In sum, advisory committee collective recommendations do not have the normative status of decisions but are reached using classic collective decision methods (Urfalino 2012).

Each committee is composed of members—the standard number is 11—appointed for four years with the status of special government employees (SGEs). Members are selected for their competence. Each committee includes a consumer representative and a drug industry representative; the latter is not an SGE and cannot vote. Each committee has a chairperson. Additional experts may be invited to join the committee for a given meeting as necessary. The number of voting members varies on average from 6 to 18 depending on absences and number of guest specialists of the pathology or medicine being examined. It may go as high as 30.

¹ The FDA is made up of six centers. The one that concerns us here is the Center for Drug Evaluation and Research (CDER), which uses anywhere from 16 to 18 committees (the number varies slightly as new committees are formed and existing ones redefined). Almost all committees are specialized by broad disorder category, in turn related to a set of organs or the relevant physiological function. There is an Arthritis Drugs Advisory Committee, for example, and a Cardiovascular and Renal Drugs Advisory Committee. At different times there have been one or two horizontal committees; e.g., the Drug Safety and Risk Management Advisory Committee, created in 2002.

FDA advisory committee meetings usually last an entire day. At the beginning of the meeting, the FDA services and the drug company that owns the medicine under examination present the relevant data and their own analyses. At this point, any guest members present their interpretation of the question under discussion. Meetings are open to the public, and observers may intervene in the discussions after duly registering themselves. Committee members may in turn put questions to public orators. Members then collectively deliberate on each of the two to six questions set out by the FDA beforehand. Committee members only may participate in these deliberations, but they remain public. On some FDA questions, the deliberation leads to voting. At these points, the chairperson requests each member to vote either Yes or No or say Abstain.

There is great concern to keep the entire process transparent, as attested by the presence of an audience and the fact that the FDA makes the entire content of AC meetings available on its website. Meetings are carefully recorded in their entirety, and one month afterward, a 300- to 500-page full transcript of the meeting may be consulted on the FDA website.²

B. Controversies around conflict of interest in advisory committees

It has been said that the history of the FDA is the history of all official reports that have been written on it. And indeed, caught between the drug industry and consumer representatives, torn between the concern to maintain conditions for fostering innovative therapies and the duty not to allow risky or less than fully effective medicines onto the market, the FDA has been the focus or cause of many public controversies since its creation (Carpenter, 2010). It is kept under critical surveillance by the media and a number of different patient advocate organizations. The U.S. Congress, whose task is to oversee all federal agencies, is quick to launch official inquiries into FDA weaknesses. The 2000s have been marked by controversies around several medicines; the FDA has been accused of showing insufficient concern for American patient safety, having an overly conciliatory attitude toward the drug industry, and not developing adequate means for controlling industry-designed drugs. The largest controversy and the one receiving the most media attention followed 2004 Merck's withdrawal of its anti-inflammatory drug Vioxx®. The FDA and other western agencies were accused of failing to evaluate the real risks of taking the drug and harshly criticized for not withdrawing it from the market before the drug company itself did.

² For a detailed presentation of AC proceedings see Sherman 2004. Transcripts are full verbatim. All documents cited or shown during the day-long meeting are likewise made available for consultation on the FDA AC meeting website. Researchers therefore have exceptionally complete source material for studying AC deliberations and decisions.

Advisory committees themselves have not been immune to controversy. Given that one of their stated functions or purposes is to open up the FDA decision-making process to outside experts and the public, they themselves have become, predictably, the focus of increased attention. Moreover, despite the fact that the FDA's final decisions, which it reaches by consulting analyses by its own inside experts, are likely to comply with advisory committee recommendations, FDA critics accuse the agency of not following AC recommendations often enough.³ For its part, the agency has made these committees into crucial instruments of FDA credibility and decision acceptability.

In this high-visibility position, advisory committees have been sharply criticized—the criticism is of course aimed at the FDA itself—in connection with the issue that comes up most frequently in the drug and medical research sector as a whole: conflict of interest. Federal regulations and internal FDA recommendations are aimed at reducing occurrences of conflict of interest and controlling their effects. Would-be committee experts have to disclose any income they earn from work for pharmaceutical companies, and if that income exceeds a certain amount they may not be allowed to sit on the committee. But given that the FDA is of the opinion (together with a significant proportion of the professional worlds involved) that the most highly competent experts are also those most likely to collaborate at least sporadically with the drug industry, it has also developed a waivers procedure for such potential members (McComas 2005). This means that some proportion of AC members participating at any given meeting is likely to have financial ties with the company whose medicine is being evaluated or with a competing firm.⁴ This state of affairs is often criticized, the fear being that the experts' individual recommendations and the committee's collective recommendation will be biased in favor of some or all of the drug companies involved (Lurie and al. 2006)⁵.

Criticism reached a peak in February 2005 following the work of a committee set up to determine whether or not two of Pfizer's anti-inflammation medicines, Celebrex® and Bextra®, should remain on the market and whether Merck's anti-inflammation drug Vioxx® could be approved again for marketing. The vote—a close one, slightly in favor of the highly controversial Bextra® and Vioxx®—surprised the informed public and raised suspicions, leading *The New*

³ In an open letter published in 2006 in the *Lancet*, three members of Public Citizen's Health Research Group deplored the fact that the FDA had followed AC recommendations in only 51 out of 71 cases from 2001 to 2004, and that AC meetings had been held for a mere 24% of the 147 new molecules under FDA study from 2000 to 2006 (Tapley and al. 2006).

⁴ Competing firms are companies that own medicines in the same therapeutic category as the one being evaluated by the given committee.

⁵ For a nuanced vision of the impact of advisory consultations and of conflicts of interests on the trajectory of new molecular entities see Moffitt (2012).

York Times to commission a study on committee members' financial ties. It turned out that ten members (of 32) had financial ties with one or more drug companies, most with Pfizer (Harris and Berenson 2005; CSPI 2005). As the critics saw it, this was a sign that advisory committees themselves, like FDA top management before them, had come under the influence of the drug industry.

C. The new voting arrangement: still open but simultaneous and visual rather than oral

It was in this overall social and media context, specifically during the drafting of a new federal law on FDA scope and funding, that the FDA reformed its advisory committee voting procedures. That reform is of central importance to this discussion.⁶

The reform has been in effect since July 30, 2007. It stipulates that voting is to be simultaneous rather than sequential. Committee members used to vote in sequence orally: after naming himself or herself; each member voted, then passed the microphone on to another. Now, after discussion of each FDA question and any requests for clarification of the question itself, the chairperson is required to ask all members wishing to vote “yes” to the question to raise their hands at the same time; this procedure is then repeated for “no” and “abstain” responses. Once votes have been counted, the microphone is passed around again so that each voter can repeat his or her vote orally for the record. The microphone then goes around one last time to allow members wishing to do so to explain their vote.

The official reason given for this reform was concern that the first voters would influence later ones (*italics ours*):

There has been much discussion inside and outside FDA regarding sequential versus simultaneous voting. Some have expressed concern that sequential voting, in which members cast public votes in turn, has the potential to compromise the integrity of the result.

For example, scholars and social scientists have studied the risk of “momentum” in sequential voting, exploring whether some sequential voters may be influenced, perhaps even subconsciously, by the votes that precede theirs, *especially if those votes are nearly identical or signal a clear trend*. This potential risk may be aggravated in the advisory committee setting, where votes are often conducted in full view of a passionate public and participatory audience.

In the case of sequential voting, there is also a potential risk that comments made by a committee member or a designated federal officer (DFO) during the vote could inappropriately affect the deliberations of those who have not yet voted.⁷

⁶ The reform was introduced in the form of a “guidance” publicly disseminated in 2007 as a draft open to discussion; it was definitively adopted in 2008. However, the procedure recommended in the guidance actually went into effect for advisory committee meetings on July 30, 2007. Meanwhile a reform went into effect making it harder to obtain a conflict-of-interest waiver (the ceiling for conflict-of-interest income was lowered) and numerically limiting the proportion of waivers the FDA could grant. Guidances do not have the status of laws and must comply with the Federal Act on Advisory Committees, which applies to advisory committees in all federal agencies.

Specifically, as indicated by the clause in italics, the concern was to prevent conformism. This concern was consistent with the substance of most criticism of the FDA and its ACs: they were not being attentive enough to the dangers associated with medicines up for approval, and they had an over-accommodating attitude toward the drug industry. The suspicion was regularly expressed that conformism on the part of advisory committee members worked in favor of the drug companies. That suspicion had been sharpened by the extremely high percentage of unanimous votes and heavy majorities.⁸ Passing this reform worked to protect the conditions that would enable the potential critical minority on ACs to be heard.

A second drawback of the earlier method is also mentioned in the FDA document:

Another potential risk is that comments could alter the meaning (or interpretation) of the question at issue in such a way as to cast doubt on whether all members voted on the identical question. (*ibid.*: 5)

This observation points up an aspect of the reform not directly addressed in the agency's presentation of it. The stated purpose of the reform was to replace sequential voting with simultaneous voting—and this has elicited generally favorable comments. But that change was accompanied by another, which seemed nothing more than its lateral technical consequence: oral voting was replaced by hand-raising.⁹ And the effect of this was to dissociate two acts: the silent vote itself and the necessarily oral one in which each member explains his or her vote.¹⁰ This chronological separation precludes voters from giving their votes even a slightly different meaning from the meaning attached to the “yes” and “no” the FDA has asked for in response to its questions.

There are three remarkable features to the 2007 reform:

-- It did not affect the feature that to everyone both inside and outside the FDA seems the only acceptable way to proceed: voting must be open and public. This perfect consensus will be the focus of part 2.

-- It emphasizes the switch from sequential to simultaneous voting. We examine the impact of this shift in part 3.

⁷ FDA 2008: 4-5.

⁸ Of the set of 94 votes, we assembled between 2003 and 2007 (see Table 1 and Appendix I.), 45 were unanimous—i.e., 48%. Of the 49 remaining votes, in 23 cases the majority was over 75%.

⁹ In 2009 hand-raising was replaced by machine-voting; the rest of the procedure has remained unchanged.

¹⁰ It should be recalled that between these two acts there is another one, also understood to be purely technical: raised hands or electronic votes are translated into “yeses” or “nos” spoken into a microphone for recording purposes.

-- There was a second change, considered merely a technical correlative of the first; namely, the switch from oral voting to hand-raising, now voting by machine. The specific effect of oral voting is the focus of part 4.

Once we understand the reasons for the consensus about voting and the specific effects of sequential voting and oral voting, we will be in a position to say what the adoption of public-secret voting in FDA advisory committees in 2007 has meant.

II. Why open, public voting?

The FDA itself, advisory committee members, the vigilant public, regular FDA critics, and the press—seems to think public voting is the only right way to proceed. This is attested by the fact that no one suggests comparing the advantages and disadvantages of secret and open voting. FDA documents for reforming voting procedures, made public in 2007 and 2008, mention secret voting in passing only once, simply to assert that it would be unsuitable for advisory committees (see II B. for the extremely brief justification of this assertion).

Moreover, the voting procedure reform of 2007 replacing sequential oral voting with simultaneous hand-raising clearly did not affect voting publicity. The main reason given for the shift to simultaneous voting once again indicates that secret voting has never been seriously contemplated; it is in fact sequential voting that facilitates influence, as the choices of first electors can influence those of later ones. Secret voting would effectively counter any such influence, but it is precisely because secret voting seems so obviously undesirable to all concerned that simultaneous voting appeared the only solution.

Given that there are no objections to open voting and that it seems so clearly the right way to proceed that there is little or no need to justify its use, we need to attempt to discover why this procedure is systematically favored. We see three possible reasons, related respectively to a) the benefits to be had from public surveillance of committee operation, b) the nature of the opinions advisory committees are called upon to produce, and c) a shared representation of how opinions get shaped.

A. The publicizing vocation of advisory committees

Bentham's nuanced thinking on the comparative advantages of secret and open balloting brings to light more effectively than unilateral pleas for one or the other could do the conditions in which each type is appropriate. Namely, it shows how virtuous open voting is actually conditioned by the nature of the influence—i.e., whether it serves particular interests or the general interest:

The cases in which publicity would be dangerous, are those in which it exposes the voters to the influence of *seductive* motives more powerful than *tutelary* motives. In judging whether a motive ought to be referred to the class of *seductive* or *tutelary* motives, it is necessary to examine whether, in the case in question, it tends to produce more good or more evil – whether it tends to favour the greatest or the small number (Bentham [1791] 1999: 145).

Publicity is thus considered desirable when the segment of the public attentive to the general interest is larger—and weighs more in the minds of voters—than the segment representing particular interests. Given the assumption that the harmful effect of possible ties between committee members and the particular interests of pharmaceutical companies cannot be countered by secret voting, open voting at least exposes experts to the view—the tutelage, to use a form of Bentham's word—of public overseers, e.g., consumer organizations such as *Public Citizen*. This means that consumer organizations and FDA and drug company critics better represent the general interest than the drug companies themselves and that surveillance of those companies, facilitated by the publicity of debate and advisory committee voting, will induce the FDA to be more respectful of the general interest. This supposition corresponds well, as we see it, to the dominant ideas in this context and is congruent with the purposes that advisory committees were designed to serve.

Since 1972 when they were created, advisory committees have had three stated purposes: to provide the FDA with assistance from highly competent specialists outside the agency; to integrate viewpoints that are not spontaneously represented into the decision-making process; to protect the FDA from criticism by ensuring that its decisions are framed by a public consulting arrangement. The first purpose assumed great importance from the 1970s to the mid 1980s, when scientific procedures for measuring medicine performance were being developed and learned by an increasing number of specialists, including within the agency itself. However, in the 1990s, characterized by reiterated controversies around medicines and FDA decisions, the third purpose came to the fore. Critics and the press are reputed to exert pressure on the FDA and AC members to respect the interests of American citizens—pressure that works against the business

cynicism of the drug companies and what critics consider insufficient FDA vigilance. Advisory committees' vocation for "keeping things public" has thus become increasingly important.

This understanding of where interests lie is congruent with the analytic checklist proposed by Warren (1999) to describe trust in institutions: citizens need to know the tasks that institutions were designed to perform, i.e., to have a "normative idea" of them; they need to know that institution members risk sanctions if they do not perform those tasks as set out; lastly, institutional transparency must be such that outside critics can criticize how institutions are functioning and thereby trigger sanctions. In Warren's schema, critics function as citizen representatives (Warren 1999: 349; Quéré 2005).¹¹ Predictably, critics of the FDA agree with this analysis. More remarkably, it is reasonable to conclude on the basis of FDA public declarations to the effect that advisory committees are essential in fostering public trust in the quality of its decisions that the FDA too shares this analysis.

The publicity vocation of advisory committees, bolstered as it has been with the passage of time, represents a strong plea in favor of the public character of their debates and voting. A "mixed" arrangement might be contemplated: public debate and secret voting. However, the possibility of obtaining secret voting results not in line with the drift of the preceding public debate would induce suspicion of duplicity and cancel out the virtues attributed to public debate. The advisory committee "vocation" thus suggests that both debating and voting should indeed be public. And the reigning idea of the nature of the experts' opinion is perfectly consistent with this.

B. The nature of expert opinions: Reasons and votes

The preference for public voting can also be linked to the dominant notion of the nature of the opinion an expert's vote is supposed to express. Texts on and practices of FDA advisory committees alike make it clear that experts' opinions are thought of as a whole that includes both the expert's vote itself and the reasons he or she gives to support it.

The brief, dismissive mention of secret ballots in the FDA text on preferred voting procedures reads as follows (*italics ours*):

¹¹ It should nonetheless be noted that this configuration is likely to be made more complex (**even** vulnerable) when groups representing a segment of consumers find that their interests converge with the drug companies'. This occurred for a time in the early 1990s in the U.S., when AIDS patient advocacy associations began demanding—for readily understandable reasons—precisely the same thing the drug industry had been calling for years: accelerated marketing approval procedures for new molecules. Since then, patient associations in Europe as well have often made common cause with the drug companies on particular issues. This of course complicates the dominant view of how particular and general interest are distributed.

Transparency and public participation are critical features of advisory committee process. The use of secret ballots, long a hallmark of the American electoral experience, generally is not appropriate in the advisory committee context *because the expert opinion of each member should be clearly understood and identified with that expert.* (FDA 2008: 4)

Once again, this is the only mention of secret balloting we have been able to find in FDA documents, including both studies and critical comments elicited by advisory committee functioning. The passage also very briefly defends the public character of expert voting. That justification is made up of two parts:

- every expert's opinion has to be readily understandable;
- it must be possible to identify each opinion with a particular expert.

The fact that the two ideas are run together by way of an “and” within a single dependent clause suggests how closely they “go together” in collective representations; indeed, they seem inseparable. Secret voting is unacceptable because one advisory committee purpose is to collect the opinion of each expert, an opinion understood as a set that includes both the reasoning that went into it—i.e., the reasons that made the decision-maker favor a positive or negative answer to the FDA question—and that answer itself. On the one hand, the FDA insists on obtaining a vote which is a clear answer to its questions: “Votes can be an effective means of communicating with FDA because they provide feedback on discrete questions” (*ibid.*: 4). In practice the agency is careful to ensure that voting is on extremely precise questions, and answers must correspond to one of only three options: yes, no, abstain. On the other hand, it wishes to collect the reasons that led the expert to vote one way or another. The fact that the two are considered inseparable precludes any “public reasoning”/secret balloting combination.

C. Publicity as transparency: the spectacle of determining opinions

The desire to collect an opinion understood as a whole that encompasses not just answers to FDA questions but also the reasons that led each expert to vote yes or no is manifest in advisory committee procedures: experts are requested to explain their choices. On this point, the aim of the 2007 reform was simply to separate clearly the two distinct phases of voting: simultaneous hand-raising and explaining one's vote. Oral voting had opened experts up to the temptation of linking individual comments, their vote, and their explanation of that vote together in the same moment of speaking. In some instances they were actually invited to do so. Some session presidents encouraged them to do all these things at once; others proposed going around the table a second time to collect explanations and comments.

With this in mind, it is useful to try to circumscribe the exact nature of experts' explanations for their votes. FDA voting session transcripts show that requesting experts to explain their vote

amounts not so much to a real requirement as an ideal that exerts a powerful grip on actors' thinking. First, it should be noted that in a significant proportion of voting situations, “yeses” and “nos” are uttered without any reasons being given. Second, when the voting does go together with comments, those comments are more likely to be recommendations linked to the answer rather than justifications of the answer. Lastly, whenever experts do provide real explanations for their votes, those explanations are very likely to be very short. Experts are likely to mention a single point or consideration each, as if that explained why they voted no rather than yes or vice-versa. But they do not explain—nor are they asked to do so—why the point they mention deserves to be considered more important or decisive than any other.

These explanations, then, cannot be claimed to constitute the whole of the reasoning culminating in the given vote. There is indeed the idea that such reasoning has been done, but the reasoning itself is not presented; at the very least it is not required of experts. This observation also holds for the FDA itself and for medicine evaluation agencies in general: they do justify their decisions, but justification texts seldom go over one or two pages.¹²

It is illuminating to contrast what advisory committees publicize of their deliberations with what is publicized by constitutional courts such as the US Supreme Court. In some constitutional courts, the reasons that led judges to make this or that decision are written up at length; these statements document all stages in the decision-reaching process and how they were connected. Advisory committee decisions also have to be justified and the justifications may be contested. Still, the reasoning that was operative in reaching the decision is not recounted step by step for the purpose of justifying that decision.

This difference between medicine evaluation committees and constitutional courts renders the requirement that advisory committee debate and voting be public more intelligible. In the FDA context—i.e., close surveillance of its activities and frequent contesting of its decisions—public exposure of all committee meetings seems meant to compensate for the fact that it is impossible for members to formulate individual or collective opinions as arguments framed by reference texts and decision interpretation history in such a way that the line of reasoning leading to a given decision can be perfectly, exhaustively recounted in a text. At the very least, there is no habit of proceeding this way. The reason that all advisory meeting comments, exchanges and information

¹²The low proportion and brevity of real explanations for votes do not contradict FDA insistence that it is interested both in votes and experts' reasons for them. The FDA takes into account not only explanations for votes but also reasons mentioned in discussions that precede voting—reasons that voters themselves regularly cite.

have to be transcribed is that, in contrast to what jurists must know how to do, these committees do not have any established means at their disposal for formulating their expert reasoning.

Moreover, in pursuing the comparison between the two types of deliberating bodies, it is important to note that the notion of publicity does not mean the same thing for them. In the U.S. Supreme Court, publicity is mainly ensured by the written word. Judges' exchanges and possible negotiations are not exposed to external viewers. Conversely, though each FDA advisory committee produces a document ranging from 300 to 500 pages and available for consultation on the agency's website, that document is actually a full transcript of recorded meetings.¹³ There is no expression of opinion in writing during or after meetings. The small audience that attends AC meetings and the larger public that reads AC meeting transcripts or watches video recordings of them are directly observing a specific moment or watching a recording of it: the moment when experts meet to produce a recommendation. What is offered to the outside world is a recorded and to some degree dramatized sequence—the “movement” through which opinions were determined. Publicity here amounts to spectacle more than anything else. What has to be made transparent—visible or audible—to the public since it cannot be restored in the form of written argument is the “movement” through which expert opinions were formed, the conditions and process by which they were determined. This movement begins with the as-yet-undetermined will of the expert,¹⁴ proceeds through her reception of information and participation in the debate, and concludes with the move in which she “decides” by answering “yes” or “no” to FDA questions.

III. The influence of votes on votes

The 2007 reform instituted voting by hand-raising, followed by electronic voting, in order to avoid the potential effects of sequential voting. As far as we know, no FDA document offers any evidence that these effects actually occurred, though concern about them was cited to justify the reform. The reform was put in place when the FDA was under fire following the withdrawal of Vioxx from the market and several controversies in which the Bush administration and agency directors were accused of being more concerned about company interests than the health of American citizens. Two fears or suspicions were repeatedly expressed about advisory committee

¹³ Video recordings of some FDA meetings may now be purchased by the public.

¹⁴ The FDA wants experts' opinions to be undetermined at the beginning of the process. If an expert had already formed and publicly expressed an opinion, this would be understood to produce possible intellectual bias (Rettig and al. 1992; O'Riordan 2009; Usdin 2009).

recommendations: conflict of interest and conformity among experts. Having truly independent, vigilant experts who would not balk at going against the majority opinion seemed the best way of ensuring that medication value was being properly assessed and monitored. This context may explain the voting procedure reform. It offered a means of counteracting a possible expert conformity. Before seeing if the concern was founded—that is, if there was a problem of conformity—it should be noted that the question implies distinguishing between several types of influence, some considered good, others bad.

A. Good and bad influence

Here we need to explain what we mean by influence. FDA material and observers' comments offer no definition of influence; the 2008 *Guidance* simply mentions that influence can operate consciously or unconsciously. However, the implicit FDA definition does seem consonant with the more precise one used in the social sciences. It is useful to distinguish between power and influence. In a power relationship, actor A can affect the choices of actor B by making promises or threats, including implicit ones, i.e., by acting on B's future situation; B will then anticipate the costs and benefits of his choice (Crozier, Friedberg 1980; Friedberg 1997). In situations of influence (rather than power), A directly affects B's preferences without changing his present or future situation (Chazel 1992). However, this definition does not specify the range of ways in which influence can exert itself. In fact, influence can be rational—as it is when due to the impact of an argument—or it can constitute an unconscious mechanism: suggestion or imitation. Influence, then, can be rational or not, conscious or not.

This definition enables us to discern good and bad influence at work within ACs. Rational influence, related to argumentation and argumentation-based exchanges among members, is considered good. The switch to simultaneous voting, meanwhile, was aimed at precluding what is considered the non-rational, potentially unconscious influence of one vote on another. Why do actors value the impact produced by reasons and reasoning, even seeking to produce that impact, while disapproving influence of votes on other votes? There seem to be two implicit concerns here:

- 1) to distinguish between reasons and judgment. In arriving at a judgment, the subject fits reasons together to form an overall argument, the purpose being to reach a conclusion; it is then that conclusion that is expressed by his or her vote;

2) to confer different collective statuses on reasons and judgment: it is desirable for actors to share their reasons with each other and thereby influence each other, but the other side of this understanding is that each actor has to reach his or her “own” judgment, in his or her own way.

Reasons, then, are to be shared whereas the judgment reached by weighing or fitting together reasons is to remain autonomous and unshared. It is important to be able to add up judgments without having them influence each other. In *Lettres écrites de la montagne*, Rousseau, working to defend himself against the Republic of Geneva’s machinations against him, offers an excellent illustration of the distinction between the two terms. To show respect for his interlocutor-reader and preserve a chance of convincing him without influencing him, he explicitly asks that reader to listen to his reasons without accepting his judgment:

What, then, would I do, Monsieur, to merit your trust and justify, to the best of my ability, your esteem? This: rightly distrusting myself, I shall tell you not so much my opinion as my reasons, which you shall then weigh and compare, and you shall choose. But go further still: be ever wary—not of my intentions: God knows they are pure—but of my judgment. (Rousseau [1764] 1964: 688, [translation AJ])

Rousseau thus invites his interlocutor to make his own judgment, while hoping to convince him of the value of his reasons. Bad influence, then, is influence that bears on the final determination of the subject’s opinion¹⁵. It can be exercised consciously, as when an expert is tempted to follow the opinion of another committee member whom he thinks of as more competent than himself, or by a phenomenon of which the subject is not herself conscious. In all such cases, influence diminishes the number of fully formed judgments and undermines the truth value of opinion convergence¹⁶. The understanding is that committee’s recommendations should be reached by adding up individual points of view, abilities, and, ultimately, the reasoning of the different members.

We have cited the distinction between reasons and judgment because it seems an accurate representation of FDA vocabulary and the way AC expert committees function. However, other distinctions could have been used, such as understanding and will, a pair long used in philosophy of the mind and chosen by the tandem Bentham-Dumont. Bentham explained that secret voting

¹⁵ The distinction between good and bad influence could be reformulated in terms of avoiding informational cascades where « people use the conclusions of the belief formation process of others as indirect inputs to their own belief formation, without knowing the direct inputs others used to form their conclusions » Elster, 2007, p. 386.

¹⁶ For example if the question gets 10 « yes » and 6 « no », while 4 experts say « yes » because they follow the « yes » of a renown expert, the relevant score is indeed 6 « yes » and 6 « no ».

would not put an end to the beneficial influence of “enlightened persons”: « but happily the secret mode of election does not diminish the influence of mind on mind » (Bentham [1791]1999:146). Dumont added: “[voting secrecy] only bears on the influence of will over will” (Bentham/Dumont [1791]1822: 191)¹⁷. We mention this other way of understanding the dividing line between good and bad influence because it corresponds to the “publicity as transparency” idea prevalent with regard to these committees (Cf. II C.).

B. How much conformity is attributable to sequential voting?

The FDA’s *Draft Guidance* refers to two studies that support the hypothesis that sequential voting gives rise to conformity among experts. But those studies use models for aggregating behaviors that presuppose a vector mechanism at the individual level: a desire to vote for the winning proposition (Callendar 2007) or using prior votes as information source (Banerjee 1992). However interesting they may be, they offer no empirical proof that sequential voting has an impact.

Were there any grounds for the fear that sequential voting by advisory committees whose members were each fully informed about the medicine under discussion produced herd behavior? And if the answer to that question is yes, is there reason to believe that abolishing sequential voting has eliminated the presumed conformity? These questions cannot be answered directly. However, we can ask whether vote distribution, the stronger or weaker convergence of votes, has changed since sequential voting was replaced by simultaneous voting.

To answer the last question, we established pre- and post-reform vote corpuses, from January 2003 until December 2010. We chose the same six committees that Diane Zuckerman (2006) had randomly selected for an earlier study of advisory committee voting. In contrast to her proceeding we examined all votes, not just those determining the final opinion (i.e., whether or

¹⁷ Neither of these distinctions is entirely satisfactory: A) distinguishing between understanding and will establishes a sharper boundary between the public aspect of reaching an opinion and the private one, but only by sacrificing the rationality of the voter’s final decision, which ends up seeming an irrational leap or, at best, an a-rational power to decide, indexed on a metaphor of attention or watching (Ricoeur 1966, 2007: pt I, ch. 4). B) distinguishing between reasons and judgment allows for preserving the rationality of the entire proceeding through which an expert opinion is formed: the expert’s vote becomes the rational conclusion of the chain of reasons he indicated during the debate. In this case the pedagogical virtues attributed to the debate seem to allow each member to explain how it is that the reasons he has cited lead to the conclusion he is preparing to enact by way of his vote. However, this in turn makes it impossible to keep that conclusion a secret. We therefore have a situation characterized by tension between the demand that each expert enrich the forming of his opinion by means of the collective debate and the concern to avoid any influence of votes on votes.

not a molecule should be allowed on/taken off the market), but we did exclude votes not directly bearing on a medicine.¹⁸

We then classified voting scores by degree of opinion convergence (for or against the medicine), ranking them in three categories: unanimity; strong majority (at least 75% of votes cast); majorities (less than 75% but more than 50% of votes cast). Abstentions were not counted for any category.

Pre- and post-reform score distributions (see Table 3 in Appendix 1) clearly show that the change in procedure has had an effect, as is also shown in the following table.

Table 1 : Votes, Percentages, Observed and Expected values, Khi Square

Results	Unanimity votes	Strong majority votes	Majority votes	Total
Pre-reform	45 (48%) 37 <i>Khi-2 = 1,85</i>	23 (24%) 30 <i>Khi-2 = 1,74</i>	26 (28%) 27 <i>Khi-2 = 0,03</i>	94 (100%) <i>Khi-2 = 3,62</i>
Post-reform	34 (31%) 42 <i>Khi-2 = 3,45</i>	42 (43%) 35 <i>Khi-2 = 3,25</i>	32 (30%) 31 <i>Khi-2 = 0,07</i>	108 (100%) <i>Khi-2 = 3,15</i>
Khi-2 =	3,45	3,25	0,07	<u>6,77</u>

[For example, the first cell to the left has to be read: Prior to the reform, 45 of the 94 votes, or 48%, produced unanimity; with the independence hypothesis--i.e., the change in procedure has no impact--the expected number of unanimous votes is 37.]

These results give strong plausibility to the hypothesis that simultaneous voting has reduced expert conformity, against a general background of strong expert opinion convergence: a sharp fall in the proportion of unanimous scores (from 48 to 31%) may be observed after simultaneous voting was instituted. On the other hand, the proportion of strong majorities (equal or over 75%) rose sharply (from 24 to 43%) after sequential voting was abolished. The proportion of weaker majorities (below 75%) is virtually stable (rising from 28 to 30%).¹⁹

It is therefore reasonable to conclude that pre-reform sequential voting induced some degree of conformity when convergence was very strong. This hypothesis is founded on the idea that the

¹⁸ Some meetings focused on questions of method or therapy not directly related to a particular medicine. Votes on methodological questions taken during meetings on a particular medicine were not taken into account.

¹⁹ The overall Khi square value for the table (6.77) allows us to claim (with a 3.4% risk of error; that is, below the 5% conventionally allowed) that the table shows a correlation between “pre-/post-reform” variables and “score types.”

following two phenomena may combine: one, expert opinions tend to converge and not all such cases of convergence can be reduced to or explained by conformity; two, on the contrary, the data on which medicine evaluation is based allows for opinion convergence in the vast majority of cases. Moreover, some experts may be inclined to follow the majority that comes to light during sequential voting *when that majority is very strong*. Strong convergence, then, not just convergence, may be what brought about expert conformity with the sequential voting method. Comparing the two corpuses lends some plausibility to this hypothesis.

The shift from sequential to simultaneous, secret-public voting *has* had an impact: it has reduced the likelihood of unanimous votes. The conformity among experts that the new system may have prevented is the conformity that turns already strong opinion convergence (at least 75% of experts' opinions) into unanimity. The reformers were right to fear the conformism impact of sequential voting and the reform clearly changed the collective voting pattern.

Still, the 2007 reform may have had other equally significant effects that have gone less perceived.

IV. The trouble with oral voting

As explained, the July 2007 reform of FDA advisory committee procedure was presented first and foremost as a switch from sequential to simultaneous voting. But this change implied another that seems to us just as important: oral voting was replaced by hand-raising and more recently by electronic voting. What are the specific properties of the original method, oral voting?

First, most voting procedures—hand-raising, standing/sitting, preprinted ballots, different colored balls—ensure that the voter provides a single, unequivocal response to a motion that can be modeled as follows: “To Question A, do you answer ‘Yes’ or ‘No?’” The precision of the outcome produced by such methods is due to two complementary features: a) voters must choose from among options that were defined before they cast their votes; b) votes for each option are perfectly homogeneous so adding them together is unproblematic. The first point concerns the clarity of each individual decision; the second what Bentham called “the principle of the identity of the motion.”²⁰ These two features are what allow for correctly aggregating

²⁰ Bentham ([1791] 1999: 91) first uses the phrase “the identity of the terms of the motion and those of the resolution”; a few pages on he speaks of the “principle of the identity of the motion” (*ibid.*: 95). Moreover, what led Condorcet to prefer the use of a written ballot was not so much secrecy itself as the discipline imposed by secret balloting: “It is therefore because it ensures opinion precision and exact counting, and accommodates human weakness without compromising truth, that this method should be preferred” (Condorcet [1788] 1986: 345).

individual votes. Oral voting, on the other hand, raises problems for vote aggregation in that individual voters have some latitude when expressing their responses (even when the question immediately precedes the response). And the variation that this is likely to generate renders individual votes less clear and may render the voting result inexact.

A. Analyzing non-discrete answers

To identify manifestations of the latitude implied in voting orally, to measure the effects of such latitude and detect its potential impact on the balloting result and therefore the validity of that result, we determined and systematically studied a balloting corpus comprising all FDA medicine-related advisory committee meetings²¹ that included voting on FDA questions and were held in the years 2005, 2006 and from January 1 to July 29, 2007; that is, the nearly two and a half years of committee meetings leading up to the reform, which officially went into effect July 30, 2007. Our balloting corpus is made up of 13 committee meetings, during which a total of 38 questions were put to a vote and a total of 737 individual votes were cast (see Appendix II).

To analyze vote+additional utterance sequences systematically, we read all the relevant FDA AC meeting transcripts as well as other meeting-related documents (rosters, minutes, etc.). We studied the detailed proceedings of 38 voting sessions; i.e., meeting minutes listing FDA questions and indicating “yes,” “no” and “abstain” scores and full transcripts of the concluding phase of the meetings, consisting in discussions immediately prior to voting, vote-casting, and individual members’ explanations of their votes. For each meeting this phase corresponds to 30 to 50 transcript pages.

We then sorted vote-related utterances into 5 categories by possible status in connection with the vote. An additional utterance can

- 1) explain the speaker’s vote: the committee member substantiates his or her “yes,” “no” or “abstain” answer with one or two reasons for it;
- 2) manifest the difficulty the speaker has clearly choosing one of the three authorized answers (indeterminacy);
- 3) suggest that speaker’s “yes” or “no” is actually a response to a slightly different question than the one posed by the FDA; we have termed such answers “yes but”;
- 4) concern the nature of the FDA’s question or the problem under discussion; such responses have the potential effect of reopening debate;

²¹ Of the same 6 advisory committees selected by Zuckerman (2006) (Cf. III B.)

- 5) amount to a comment or proposal; more generally, non-identifiable as a type 1, 2, 3 or 4 utterance.

There are no specific words in AC members' utterances that allow for making these distinctions. For example, it may not make sense to file a given voter's "yes but" vote in the "yes but" category, since that category is reserved for utterances that call into question the "identity of the motion" corresponding to the FDA question.²² The example of the AC meeting held in February 2005 on three COX2-type anti-inflammation medicines will clarify our way of proceeding. A question on one of these molecules read: "Does the overall risk-benefit profile for rofecoxib support marketing in the U.S.?" To this question, 17 committee members answered "yes," but six of these yes-voters said more than yes. And two of the members voting "no" mentioned other considerations at the moment they cast their vote—remarks that cannot be understood as explanations of their vote. Consider the verbatim answers of the six yes-voters and the two no-voters:

VIOXX® 2005, Q3b²³ :

-- "Yes, but."

-- "Yes, with reservations."

-- "Yes, but at lower dose, 50 milligrams."

-- "Yes, but only for children."

-- "Yes, with restrictions."

-- "Yes, with restrictions."

-- "I would say overwhelmingly no, although if individual patients can petition the company under some mechanism, I would support that."

-- "No, but with a possible compassionate-use program."

(Arthritis Drugs AC and Drug Safety and Risk Management AC, joint meeting of February 16-18, 2005, transcript, vol.3, p. 334-336)

The first two "yes" answers reflect the expert's difficulty deciding; we put them in category 2, manifesting indeterminacy. The next four answers also follow the "yes, but" model and were indeed filed in the "yes, but" category, category 3. Responding affirmatively to the question of whether a medicine should be put on the market while specifying a different dose from the one in the question or adding that the motion should be restricted to children amounts to answering a different question than the one put by the FDA, which in this case bore on approving the

²² We named this category "yes, but" because answers that fit into it are fairly likely to include that utterance. But the utterance "yes, but" alone was neither necessary nor sufficient for ranking the answer in that category.

²³ We follow the convention of designating these examples by the name of the medicine under study—either the international name of the molecule (here rofecoxib) or, for better known medicines, the brand name (here Vioxx®)—followed by meeting year and FDA question number.

molecule for a specific dose and for all adult patients. The meaning of the two “yes, with restrictions” answers is harder to grasp since neither speaker specified what his or her restrictions were. But these answers also seem responses to a slightly different question than the FDA’s.

The two “no” answers are not “no, but” or signs indicating the as yet undetermined opinion or decision of the speaker or supporting explanations. Both those members preferred not to allow the medicine on the market. But they also thought that if for some reason patients could not be treated with other available drugs, they should be able to take Vioxx® as part of a compassionate-use program, regardless of the fact that the medicine had not been approved for sale. In answering this way, they were putting forward a complementary measure that would not affect their decision not to approve sale of the drug. We filed these utterances in category 5, proposals and comments.

Category 1 and 5 answers correspond to what the voter was expected to produce: a non-composite answer + an explanation for it, or a non-composite answer + complementary comments or proposals. The three other types of answers are not what was expected. They illustrate three distinct problems with oral voting, problems that the 2007 reform has undoubtedly helped to resolve. Those problems are:

- the “identity of the motion” problem;
- the indeterminacy problem;
- the problem of distinguishing between debating and voting.

We only have space here to handle the first of these problems.

B. The “identity of the motion” problem

The type of answer that we have called “yes, but” has drawbacks that can affect balloting results and the meaning of collective opinions or recommendations. Bentham noted these drawbacks when examining the method adopted by the “Haute Guyenne” provincial assembly in 1779. That method consisted in reducing progressively, by the way of several successive roll calls, to two the number of opinion options that assembly members could express on a given question, then choosing the one that garnered the most votes. Bentham observed that this way of clarifying the many opinions expressed in the assembly had the effect of confusing the notions of debating and voting, and that the plurality ultimately won by one or the other authorized opinion was likely to be made up of heterogeneous wills that could not logically be added together. The only way to

comply with the “principle of identity of the terms of the motion and those of the resolution” (Bentham [1791] 1999: 91) was to discuss no more than one motion at a time and put that motion to a vote immediately after discussion.

FDA ACs comply with Bentham’s wish for a single “yes” or “no” vote on each motion. But the fact that members vote orally means that remarks can be made at the moment of voting that seem to reopen debate on that motion. The potential effect of this is to imperil “the identity of the motion and the resolution.”

—Let us to define “yes, but” answers as follows: a “yes, but” (or “no, but”) answer in response to a “Yes or no to A?” question is in fact an affirmative or negative answer to a different question: “Yes or no to A’?” where A’ is a similar but distinct motion from A. This means “yes, but” answers cannot legitimately be added to “yes” votes and “no, but” answers cannot legitimately be added to “no” votes.

AC members are seldom attentive to the nature of their responses because those responses seem to them like comments or recommendations of the sort the FDA wishes to obtain and the chair regularly solicits.²⁴ However, a “yes, but” answer is much more than a comment or recommendation. It amounts to changing the motion that conditions the voter’s approval. In some cases—e.g., approving a drug but at a lower dose or for children only—the change may be readily detected by an outside observer. In others it is difficult to say whether what gets added on to a “yes” or “no” answer amounts to a change in the motion or simply a recommendation. In some cases speakers specify that the substance of their additional utterance conditions their vote—a move that attests to the problematic nature of such utterances. Consider the following two occurrences:

FORMOTEROL 2005, Q2a:

Called upon to vote for or against adding a warning on the label of a drug called formoterol, one member switched his vote, explaining :

“Mr Chairman, I want to change my no vote to yes, given that my colleagues also have expressed the caveat that caused me to vote no.”²⁵

ARIFLO 2003, Q3:

²⁴ Speaking immediately before a vote on the dose recommended by the owner company, the chair of the April 24, 2007 Antiviral Drugs Advisory Committee meeting on approving a molecule for treating AIDS said, “I think we should go around now and vote yes/no as we have been asked on this. If you have additional caveats, feel free to put them in” (transcript, p. 313).

²⁵ Pulmonary-Allergy Drugs Advisory Committee, meeting of July 13, 2005, transcript, p. 333. The voting outcome was 12 yes, 0 no, 1 abstain.

Questioned two years earlier on whether it was possible to dismiss a given side-effect as a safety concern of Ariflo, the 12 members of the same committee answered in the affirmative, yet one specified:

“The way I read the question I think everyone’s answer should be no with the caveats, but to go along with what I have heard here so far I would say yes, with the stipulation that there be the kind of follow-up that Dr. Surawicz and Dr. Cross both mentioned.”²⁶

This voter, who clearly did not feel he could say “yes” and leave it at that and who sought to link his approval to a condition affecting the meaning of the motion under examination, may be understood to have hesitated between “yes, but” and “no, unless.”

It also sometimes happens that up against voters’ questions or in reaction to a “yes, but” answer, the chairman or an FDA official will intervene to request the voter to be sure to respond to the exact motion being examined. Such interventions are aimed at maintaining the semantic identity of all “yes” and “no” answers. Consider the following two flagrant examples:

ARIFLO 2003, Q1:

Asking if Ariflo was an effective enough treatment for a given lung disease to justify giving it marketing approval. Just before putting the question to a vote, the chairman asked an FDA official to clarify the meaning of the question. At that point a member named Dr Apter requested consideration of another alternative: “I would like to be able to say yes but with postmarketing recommendations.” The FDA official ruled out this option, saying: “I mean, that can be something which you can put out as a discussion and as a comment that we take, but the voting is really as it is. Am I clear on that?”²⁷ Clearly the FDA official was moving to preclude a “yes, but” answer.

SPIRIVA 2002, Q1:

One year earlier, the same committee was called upon to answer the same question for a different drug. The first voter answered “yes, but,” eliciting a correction from the chairman. Their exchange proceeded as follows:

“DR. PATRICK: Yes, on the basis of the Phase IV recommendation.

CHAIRMAN DYKEWICZ: Well, we have to have an answer though. It can’t be qualified. It has to be yes or no. If you believe that the data that currently exists is sufficient to approve the drug or whether you would defer approval, in which case you would say no. You would say no?

DR. PATRICK: No. Yes. Yes.

CHAIRMAN DYKEWICZ: You would say yes?

DR. PATRICK: Yes.”²⁸

²⁶ Pulmonary-Allergy Drugs Advisory Committee, meeting of September 5, 2003, transcript, p. 235.

²⁷ Pulmonary-Allergy Drugs Advisory Committee, meeting of September 5, 2003, transcript, p. 214. Dr. Apter ultimately said, “My answer is yes, but there have to be postmarketing studies”; his vote was counted as a “yes.” The score was 3 “yes,” 7 “no.”

²⁸ Pulmonary-Allergy Drugs Advisory Committee, meeting of September 6, 2002, transcript, p. 315-316. The final score was 8 “yes,” 3 “no.”

Interventions by the chair can aggravate rather than correct affirmative answer heterogeneity, as in the following example (entire voting procedure quoted, our italics):

CELEBREX 2006, Q2:

“DR. BATHON (Chair): ... So, the question is do the available data demonstrate that Celebrex is safe in the treatment of juvenile rheumatoid arthritis? We will start on this side of the room with Dr. Sandbord. Say your name and yes or no.

DR. SANDBORG: Christy Sandborg, no.

DR. GORMAN: Richard Gorman, no.

DR. DAUM: Robert Daum, yes for the duration of the study that was observed.*

DR. PROSCHAN: Mike Proschan, no, but I think it doesn't demonstrate that it is unsafe either.

MS. DOKKEN: Deborah Dokken, no.

MR. LEVIN: Arthur Levin, no.

DR. WEISE: No less safe than other current uninvestigated agents. Am I allowed to abstain?

DR. BATHON (Chair): Yes.

DR. WEISE: Abstain

DR. MORRIS: Was it yes, short term; no, long term? Is that our vote ?

DR. BATHON (Chair): I think yes or no is what we want.

DR. MORRIS: Just yes or no?

DR. BATHON (Chair): Yes.

DR. MORRIS: No.

DR. HOLMBOE: Yes, only in the time that was studied compared to another agent. That is it.*

DR. BATHON (Chair): Joan Bathon, no.

DR. CHESNEY: Joan Chesney, no.

DR. LEHMAN: Tom Lehman, I think in the context of the rest of what we do the answer is yes.

DR. O'NEIL: Kathleen O'Neil, a very deliberate and considered yes in comparison to other drugs and the standard we use in other drug approvals.

DR. DAVIS: John Davis, yes in the short term compared to other non-steroidals.*

DR. BOULWARE: Dennis Boulware, given the instruction earlier, as compared to the current medications used I would have to say yes.

DR. BATHON (Chair): Dr Turk, can we get your vote?

DR. TURK[answering by phone]: Yes. Can you hear me?

DR. BATHON (Chair): Yes, we can hear you.

DR. TURK: Yes in the context of the short duration.*

DR. BATHON (Chair): So, we have eight “no,” seven “yes” and one abstention. ...”²⁹

The official count was 7 “yes,” 8 “no” and 1 “abstain.” But 4 of the 7 votes counted “yes” were in fact “yes, but” (indicated by an asterisk): the “but” made the voter's approval conditional on a short-term prescription period—identical to the clinical trial period for which the safety of the drug had been demonstrated. And the passage in italics represents another remarkable occurrence. Instead of saying “yes, but for the short term” like the four other “yes, but” voters,

²⁹ Arthritis Drugs Advisory Committee, meeting of November 29, 2006, transcript, p. 304-306.

Dr. Morris asked if it would be possible to vote separately on the short-term and long-term questions. The chair ruled this out after letting one “yes, but” vote go by and before allowing three others. In reaction to these developments, Dr Morris voted “no.” In strict logical terms, all the “yes, but” answers had the same meaning as Dr Morris’s “no” vote. To be consistent, the chair should have applied the same restriction to all the other “yes, but” answers as she imposed on Dr Morris—in which case those three “yes, but” answers would have been counted as “no” and the score would have been 3 “yes,” 12 “no” and 1 abstain. Alternatively, Dr Morris’s “no” should have been considered a “yes, but,” in which case all 5 “yes, but” responses should have been invalidated for not answering the FDA question. The score would then have been 3 “yes,” 7 “no,” 1 “abstain,” and 5 “invalid ballots”. For either of these counting methods, the official “no” vote would have been much stronger.

Three lessons may be drawn from the afore-cited examples:

- 1) What we have identified as “yes, but” votes do indeed affect the identity of the motion.
- 2) Committee members and chairs are unlikely to perceive this; whether they do or not depends on the individual. The point is therefore subject to contingency and varies by individual and from one committee to another. Some members do perceive the identity of the motion problem, as attested by their questions; some chairs and FDA officials also perceive the problem and try, more or less skillfully, to resolve it. But in most cases, “yes, but” answers are confused with comments and recommendations; the underlying assumption being that they are to be added to another set of votes when doing so actually changes the meaning of those votes.
- 3) In strict logical terms, “yes, but” votes should not be added to “yes” votes. In fact, they are more likely to resemble “no, unless” votes, and when they do, it makes sense to add them to “no” votes. In other cases, it would make more sense to think of them as invalid responses or abstentions in that they do not answer the question at hand. The motion A’ that they express an opinion on is clearly different from the motion A that they have been called upon to approve or reject. In committee practice, however, “yes, but” answers are often counted as “yes” votes.

With this established, it is worthwhile examining two questions. The first concerns the number and distribution of “yes, but” answers: Were there many of them and were they fairly evenly dispersed across meetings and votes or instead concentrated in certain periods, committees, meetings? The second concerns their impact on voting results: Did counting “yes, but” answers as “yes” frequently falsify the nature of the majority opinion? We can answer these questions by

examining our systematic corpus of 13 meetings and 38 votes held from 2005 to 2007 by our 6 committees.

Of the 737 votes cast, 18 were “yes, but”; that is, no more than 2.5% of all scores. But they are highly concentrated: 16 of the 18 were cast in two meetings of the Arthritis Drugs Advisory Committee, one meeting held in 2005, the other in 2006, both on medicines of the same therapeutic group, the highly controversial coxib category, encompassing Vioxx®, Celebrex® and Bextra®. Altogether, “yes, but” votes are found in 3 out of 6 committees, 4 out of 13 meetings and 6 out of 38 votes. The following table shows the distribution of the 18 “yes, but” votes.

Table 2: Distribution of “yes, but” votes

Committees/Meetings	Yes	<i>Yes, but</i>	No	Abstain
Arthritis Drug AC 11 mars 2005 - Q2a	32	1	0	0
- Q2b	14	3	13	2
- Q3b	13	4	15	0
Dermatologic and Ophthalmologic Drug AC 24 mars 2005 - Q3	7	1	12	0
Arthritis Drug AC 29 nov. 2006 - Q2	7	4	8	1
- Q3	15	4	1	0
Pulmonaro-Allergy Drug AC 24 janvier 2006	7	1	11	0

[scores giving a majority are in bold]

The table enables us to answer the second question. Only two votes in our corpus of 38 should be revised to reflect the impact of “yes, but” votes. Interestingly, these were the two votes that attracted the most media attention—for other reasons. Both figured in the February 2005 joint committee meeting on Cox-2 drugs. It should be recalled that a few months after Merck withdrew Vioxx® from the market, the informed public was scandalized by two slight-majority AC voting outcomes, one in favor of keeping Pfizer’s Bextra® on the market (17 “yes,” 13 “no,” 2 “abstain”), the other approving returning Vioxx® to the market (17 “yes,” 15 “no”). If the “yes, but” votes had been counted and distinguished from the “yes” votes, the majority in favor of Bextra® would have been smaller still and the tide would have turned against Vioxx®:

- Bextra®: **14 “yes,”** 13 “no,” 3 “yes, but” (“yes, but” in this case meant approval on condition that dose and prescription period be limited) et 2 “abstain.”

- Vioxx®: 13 “yes,” **15 “no,”** 4 “yes, but” (approval on the afore-mentioned conditions).³⁰

In both cases, then, erroneously interpreting “yes, but” as “yes” had a significant impact on the voting result, misleadingly implying that a majority of the committee was in favor of allowing Bextra and Vioxx back on the market. It should be specified, however, that neither of these erroneous vote counts in any way influenced the related FDA decisions.³¹

As mentioned (see I B.), these two votes galvanized FDA critics and moved *The New York Times* to inquire into financial ties between joint committee members and the drug companies affected by this recommendation. However, and despite the critics’ vigilance, all attention was on the showdown between “yes” and “no” voters. That attention was of course sharpened by the suspicion of a financial motive or bias in favor of approval, and this in turn worked to obscure what we consider a remarkable feature of those votes; namely, “yes” vote heterogeneity and the illogic of adding together heterogeneous responses.³² The selective media attention also obscured the fact that the experts might have had reasons—and not just financial motives—for voting as they did.

What conclusion are we to draw from these observations on the impact of “yes, but” votes? Given their relatively low occurrence and the minor impact they had on advisory committee majority recommendations and FDA decisions, it could be claimed that they are ultimately empirically irrelevant. However, it would be a mistake not to examine the phenomenon more closely. The fact that “yes, but” votes do not have greater impact on ballot results is explained by strong convergence of individual expert opinions. Of the 38 votes studied, 17 were unanimous. For 9 votes the majority was over 75%; 5 of those 9 produced a majority over 90%. There would surely be more frequent cases of “yes, but” votes tipping the outcome if there were more small majorities; in that case, packets of 3 or 4 “yes, but” votes could actually shift the majority. In only 7 of the 38 votes was the majority-minority vote difference equal to or below 4.

³⁰ What’s more, 2 of the 13 “yes” votes for Vioxx® were associated with expression of indeterminacy (see IV A. for the definition of this category).

³¹ The FDA, criticized across the board after Merck withdrew Vioxx®, did not follow the committee’s small-majority recommendations. A few weeks after the committee meeting it requested Pfizer to withdraw Bextra®, and it did not encourage Merck to put Vioxx® back on the market.

³² Only one committee member, Dr. Shafer, who had voted “yes” for Bextra® and “no” for Vioxx®, suggested a less stark interpretation of events, and in doing so emphasized the fact that qualifying the meaning of “yes” and “no” votes worked to attenuate the opposition between them: “After the meeting [Dr. Shafer] asked how his vote [on Vioxx®] was counted: ‘no, with exceptions’ or ‘yes, with restrictions?’ ‘Those positions are not very far apart. I think my colleagues on the committee all struggled, as I did, between “no, with exceptions” and “yes, with restrictions” in casting their votes” (Malone 2005).

Even with a low occurrence of “yes, but” answers, oral voting can deleteriously affect the meaning of a vote, but the strength and frequency of expert opinion convergence significantly reduces this risk.

V. Conclusion

We can conclude by underlining three points.

1) *Type of publicity and the understanding of what is implied in making a judgment.* The shared understanding of the nature of expert reasoning has a considerable impact on what type of publicity is considered desirable. Here we have emphasized the contrast between publicity through writing and publicity as transparency. The understanding of what is implied in evaluating medicines and what kind of decision-making this involves oscillates between a) the scientific ideal of demonstration operative in clinical drug trials and b) an understanding of decision-making as an event in which individual decision-makers confronted with a full set of considerations make up their minds through a somewhat mysterious act of will. In b) the decision-making process has the status of a “black box” which, because it cannot be opened or made legible, has to be watched carefully to ensure that no undesirable “input” (interests, dependency, intellectual biases, unconscious influence) gets inside and that all good “input” (information, reasons, discussion) does get inside. In the end, the vigilance meant to ensure that AC meetings proceed smoothly and correctly, the concern for transparency—here, what seems to be valued is the “show” of individual minds being made up—seems closely related to the fact that the notion of decision-making that prevails in these committees is indeed b): a somewhat mysterious determining of the will. In fact, understanding the act of will as a kind of a black box exacerbates the concern to make its functioning transparent. This in turn indicates one possible means of making controversies around decision-making on medicines more intelligible (if not of reducing the degree to which decisions on medicines are contested or the strength of the suspicion that committee members are colluding with the pharmaceutical industry); namely, that the work of formulating opinions on drug molecules could model itself at least partially on the work of formulating judgments in the legal sphere.

2) *Bentham legacy about roll call voting.* Roll call voting combines two features: sequential voting and oral voting. We have seen, in FDA advisory committees, that both had effects that the reformers wanted to prevent and did so with success. The impact of sequential voting is more known than the impact of oral voting, on which Bentham has been a pioneer without followers. Bentham was clearly exasperated by the confusion reigning in pre-Revolutionary French provincial assemblies

between debating and voting (Bentham [1791]1999: 93-100). He stressed, against the roll call voting, one of its probable consequences: the problem of the identity of motion. But, maybe because no written verbatim of these assemblies was available, he did not give precise examples. The FDA advisory committees gave us the opportunity for describing empirical cases of such a problem.

3. *The nature of voting.* Bentham insightful thoughts on oral voting and the case study we provide in this paper give us a more general lesson on the nature of voting. The word “vote” refers more to a large set of practices than to a concept. Using the word, we can have in mind two different conceptions: one is broader and refers to all the ways for expressing an opinion or a preference in order to make a decision; the other is more specified, and supposes a clear cut contrast with debate.

The very notion of oral voting is problematic, and the practice itself weakens the boundaries between debating and voting. Unless speakers practice firm discipline when giving their answers—and this would surely be awkward for all concerned as it would affect each personally: members would be called to order individually, the chair, of course, having to reiterate that intervention—oral voting gets contaminated with something that is not voting and is very likely to lead to utterances that will in some way, at least implicitly, reopen the debate.

The advantage of hand-raising and of electronic voting is that they materially enact the separation between debating, voting, and explaining one’s vote without it being necessary to call anyone to order. These methods thereby ensure that the identity of the motion remains intact while maintaining the requirement that experts make up their minds and firmly separating the sequence in which mutual influence is allowed—i.e. debate—from the voting itself, in which it is important to preclude mutual influence.

The contrast between oral voting and the other procedures also teaches us something about the nature of voting. The characteristics of voting that are violated by the oral variety are :

- segmentation: voting should not be accompanied with comments likely to change the meaning of the vote;
- isolation of the act: voting is a single expressive act, to be detached from the “story” (reasons, motives, hesitations, influences) that led the voter to choose one of the possible alternatives;
- finality of the act: once the voter has voted, the vote cannot be changed;
- semantic invariability: the meaning of the vote is fixed in advance rather than being determined by the individual voter.

This contrast suggests that oral voting is a kind of debating-voting hybrid. It would be aberrant to require debate to exhibit the characteristics that voting requires. “Oral voting” amounts to a particular way of expressing one’s will, but it does not comply with all the demands required of collective decision-making, as a more constraining type of voting does.

(Translation Amy Jacobs)

Appendices

We chose the same 6 randomly selected advisory committees studied by Zuckerman (2006): Antiviral Drugs AC; Arthritis Drugs AC; Dermatologic and Ophthalmic Drugs AC; Gastrointestinal Drugs AC; Pulmonary-Allergy Drugs AC; Reproductive Health Drugs AC.

Appendix I: The pattern of ballots before and after the procedure reform (2003-2010)

Table 3 : unanimities, strong majorities an majorities by years

Number of	2003	2004	2005	2006-07	07-2008	2009	2010
Unanimity votes	21 (51,2%)	7 (46,6%)	9 (52,9%)	8 (38,1%)	24 (43,6%)	6 (21,4%)	4 (16%)
≥ 75% Majority votes	10 (24,4%)	4 (26,6%)	3 (17,6%)	6 (28,%)	17 (30,9%)	13 (46,4%)	12 (48%)
<75% Majority votes	10 (24,4%)	4 (26,7%)	5 (29, 4%)	7 (33,3%)	14 (25,5%)	9 (32,1%)	9 (36%)
Total	41	15	17	21	55	28	25

Appendix II : Pre-reform ballot set (2005-July 29, 2007)

- 6 committees
- time span: 2005 – July 29, 2007
- 13 meetings; 38 ballots
- 1-10 ballots per meeting
- 7-32 voters per meeting
- 737 individual votes, including 4 abstentions

Results:

- 17 of the 38 ballots—45%—were unanimous.
- 9 of the 38 ballots—24%—resulted in majority votes equal to or greater than 75% of votes cast.
- 12 of the 38 ballots—31%—resulted in majority smaller than 75%.

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