

SANIOR PARS AND *MAIOR PARS* IN CONTEMPORARY AREOPAGES:
Medicine evaluation committees in France and the United States
(first draft)

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How best to foster collective wisdom in collectives of the wise?

The question is directly relevant for a number of commissions or committees with important decisions to make for a social group, decisions whose nature requires members who participate in making them to have a specific competence or expertise.

It is in this sense that such committees are composed of sages, “the wise.” Group member competence is the first guarantee of group decision quality. But since the decisions or formal opinions of these groups of sages are arrived at collectively, the question of their wisdom may be broken down into two more specific questions:

-- How best to ensure that the group’s collective work will enable each member’s wisdom to be used and expressed to the full. At issue here is the impact of the collective process on the quality of deliberations and the quality of each member’s contributions;

-- How best to ensure that cooperation among several sages culminates in a quality collective decision or opinion. There are in turn two aspects to this question: method chosen for turning individual opinions into a single collective opinion; quality of the decisions this method allows for producing.

When the entity called upon to give an opinion or make a decision is a group, there can be no certainty that all the group’s members, though endowed with the virtually same appropriate competence for handling the matters in question, will reach the same opinion. The group of sages must therefore have a decision-making rule. Given that lot-drawing and delegating judgement to a single member are not relevant means of proceeding in this type of committee, there is a good chance that the committee will use an electoral technique. Any such technique implies the expression of member opinions and some means of counting those opinions.

The use of voting raises concerns that are probably as old as the appearance of the practice. How to ensure that the decision that results from it is a good one? What relation obtains between numbers and reason? How can the voting procedure that allows for concluding the decision-making process work together with the reasons that should guide the process of reaching a good decision? In sum, and to paraphrase a comment by Pliny the Younger often cited in critical discussions of voting (*Letters*, II, 12), how can votes be simultaneously counted and weighed?

Western monastic orders, which played a decisive role in the rediscovery of electoral practices that occurred in the Middle Ages, took on just this problem and developed a series of solutions to it, though the solutions were not used in any stable way and they ultimately led to the triumph of number; that is, the absolute or qualified majority rule (Moulin 1958a and 1958b). However, it would be mistaken to see this episode in the history of electoral techniques as merely a transition toward the majority rule. In the study of expert committees that concerns us here, the experience of the monasteries provides an extremely rich range of

attempts to solve the problem. I will focus here on one central idea of this legacy: that of finding a compromise between the wisdom and numbers requirements—called at the time *sanior pars* and *maior pars*.

The fundamental experience behind thinking on collective decision-making rules was the matter of naming the head of the monastery in such a way as to reflect the monks' wishes. Both the quality of the decision (that is, the value or wisdom of the monk chosen) and the quality of the voters was taken into consideration. The rule conceived by St. Benedict served as a touchstone for all thinking on the matter. Benedict envisioned three possible solutions: unanimous choice of the right decision; unanimous or majority choice of a wrong decision; lastly, a wise minority that would favor the right decision. Curiously, he did not imagine a majority of voters choosing the right decision. The thinking took off from the observed impossibility of applying the preferred rule on every occasion. That preferred rule was unanimity, the solution that might be hoped given the understanding that each monk was divinely inspired. In Benedict's judgment, if not everyone could agree on the right candidate, it was necessary to name "the one chosen by a part of the community, even if it amounted to the fewest in number, as long as its judgment was the wisest" (Moulin 1958a: 376-377). This solution proved unstable because it did not provide a means of settling the inevitable discord on how to define either the wise segment of the electorate or the right decision. The instability explains in large part why the majority rule was ultimately adopted.

A remarkable particularity of the committees of sages that concern us here is that the collective decisions or recommendations they reach have to be justified by argumentation. For convenience' sake, I will call such expert committees *aréopages*. Because they have to reach a collective decision, *aréopages* have to attend to the number of members whose opinion converges toward a single option. But because they also have to produce arguments to justify the decision they make, they cannot be content with numbers only. They thus run into the same problem as the one bedeviling Middle Age monasteries.¹

The experience of these monasteries and the attempt to combine the "wise" and "majority" parts continues to help us understand the problem of contemporary *aréopages* and the solutions they use. This can best be seen by trying to specify what is involved in combining the *sanior pars* with the *maior pars*. That move amounts first to splitting collective decision-making into two: on the one hand, there are each participant's judgment and vote; on the other, evaluation of individual judgments and of the result of aggregating them. The move then implies using a hierarchical ordering principle: since there are no universally shared criteria—if there were, there would be no need for collective decision-making—the work of determining what is wisest necessarily falls to individuals, official bodies, or judgments endowed with a type of authority that is prior to and possibly external to the collective decision-making process.

In this text I present two very different examples of a contemporary means of finding a compromise between *sanior pars* and *maior pars*, a practice in which we find precisely the features just indicated: a split form of collective decision-making and a hierarchical ordering principle. The examples are taken from the area of medicine evaluation. I studied committees called upon to present opinions either on the value of proposed medicinal remedies—their work is to determine if and under what conditions a molecule can acquire the official status of

¹ The great difference between monasteries and contemporary *aréopages* being that the latter do not elect candidates but rather make decisions or recommendations on actions to be taken.

medicine and be put on the market—or, for molecules already on the market, whether they should be withdrawn or whether changes need to be made in conditions for prescribing them. I focus on two such bodies: France’s committee for drug approval and the advisory committees used in the United States Food and Drug Administration.

The presentation is mainly descriptive: the point is to see how the problem of the quality of collective decisions made by expert bodies whose opinions have major implications for public health is conceived and handled in these two contrasting cases. Description is the thing—any evaluative thrust is secondary, lateral and subordinate to the description requirement.

I first present the striking characteristics of these expert committees. In the second part I present the French committee for drug approval, whose particular decision-making rule may be qualified as reaching decisions by exhausting objections. The third part is on the advisory committees used by the section of the FDA that handles drugs; those committees practice public balloting.

1. What is an *aréopage*?

By the term *aréopage*, I mean a specific class of collective decision-making situations that I will try to isolate bit by bit and through iteration in a combination of detailed examination and comparison of empirical cases. I will refer in particular to constitutional courts and drug approval committees—my most direct knowledge is of the second—but I hope the features identified will prove applicable to other committees as well.

1. *Aréopages* are groups that deliberate to make decisions (or present opinions for other authorities to use in making decisions) that are applicable to a larger group. Such decisions may be of the sort that concern and impact on all the citizens or the entire population of a given country.
2. Members of an *aréopage* are appointed rather than elected. They are appointed first and foremost for their competence in the matters that the decisions are to be made on and as possessors of the knowledge recognized as relevant to those matters. The general understanding is that the appointment process, the conditions under which the *aréopage* acts, and even in some cases members’ earlier professional trajectory will ensure them a sufficient degree of independence when it comes to using their expertise within the *aréopage*.
3. *Aréopage* decisions are partially predefined by the nature of the institution in which those decisions and the *aréopages* themselves are inscribed. In this they are different from political assemblies, whose decisions may affect all elements and dimensions of a political entity’s social life. *Aréopage* decisions concern only certain components or dimensions of social life. The terms of those decisions may be strictly formatted. A constitutional court determines and declares whether or not this or that part of a law it has been called upon to examine complies with the constitution. An expert commission in a health agency, whose role is to approve drugs for marketing, either does or does not grant that approval according to extremely detailed specifications fixed by the history of public health control of medicinal drugs in the country in question (indications may include health problem(s) the drug is to be taken for, dose, length of treatment, kind of prescribing physician, etc.). *Aréopage* decision-making can have extremely wide impact, but decision formulation follows a strict format.

4. The collective work of the *aréopage* bears on to both the decision itself and argumentation to support and justify that decision. *Aréopage* members' task is not only to reach a decision or a position, but also to formulate the reasons that decision appeared the right or necessary one. They must collectively produce a decision and reasons for it, the understanding being that the decision is the effect of the reasons cited. The decision has to have the status of the culminating point of a line of reasoning. The relative impact of reasons and the decision varies by case:
- Maximally, the line(s) of reasoning justifying the decision is/are of greater consequence than the decision itself. This is the case for the courts, as the reasons cited may be used in later decision-making;
 - Minimally, the justification requirement is as important as the requirement to reach a decision.

5) Individual *aréopage* members have to practice the discipline of arguing their position in accordance with certain validity requirements, at least while the collective decision is being produced. If the last phase of the decision-making process is a deliberation, there is a good chance it will be characterized by the requirement that each member practice this argumentative discipline.

The word discipline introduces a constraint feature that affects the reasons and lines of reasoning *aréopage* members can use when participating in collective decision-making. As I see it, four types of demands are operative in this argumentative discipline:

A. *Justification: reasons override motives.* X cannot simply say he wants or prefers Option A; X has to mention reasons Y and Z why, as he sees it, Option A is preferable to Option B.

B. *The justification has to be substantial: one reason does not suffice, an entire line of reasoning is required.* This is how Aristotle distinguished between dialectic and rhetoric. In dialectic, an argument has to be able to hold over a long chain of reasons, whereas in rhetoric it is enough for the orator to say he supports X for reason y (Ryan, 1984 ; Bodeüs, 1992). A participant in a political assembly could say he supports a given policy because it is good for employment. In an *aréopage*, he would be asked to explain in what specific way it is good for employment.

C. *The argumentation has to be appropriate: this is specialized argumentation adapted to the matters handled by the given *aréopage*.* This requirement has a positive component: the argumentation has to follow the canons of reasoning recognized as relevant for the given issues and the *aréopage* itself. Legal reasoning and a certain legal corpus are relevant for constitutional courts; *aréopage* work in health agencies requires the types of reasoning and knowledge relevant in evaluating medicine quality as well the particular rules in effect for balancing decision-making criteria. The requirement also has a negative component: certain types of arguments are not only not relevant but prohibited because they are understood to have a damaging effect on collective deliberation. "Gag-rules" may exist (Holmes, 1988), such as the one in effect in the French drug approval committee prohibiting mention of medicine costs: in this commission's evaluations, health questions alone may be taken into account.

D. *Contextual validity: arguments have to be adapted to the case at hand.* It is not enough to meet requirement C; the matter under study calls for certain types of arguments only among all those that may legitimately be used in the given *aréopage*.

2. Making decisions by exhaustion of objections: the case of the French Drug Approval Committee

2.1 Conditions for creating the French Drug Approval Committee

The Drug approval committee was created in 1978, together with a new department of the French Health Ministry's national-level administration. It was at that time that the minister of health realized that France was behind in medicine evaluation compared to the evaluation level in other countries—the United States, of course, but also European countries such as Great Britain and Sweden.

Creation of the commission was motivated by the following observation: the administration did not have and could not hire the competent personnel required for modern evaluation of medicines; it therefore had to turn to a new generation, the first generation of doctors and hospital officials with knowledge of clinical pharmacology or with the competences required for this new type of evaluation. The commission was to be composed of representatives of this new generation, experts brought in from outside the administration. At any given time between 1978 and 2000, it had approximately 30 members.

While the minister had the last say on the AMM (in 1993 this became the prerogative of the director of the Agence Française du Médicament called in 1998 AFSsAPS²), it is the drug approval commission that definitively evaluates medicines. There is no reassessing of the commission's findings by any health administration body. It can therefore be said that the commission makes the decisions.

2.2 Decision-making by consensus and rejection of voting

The newly created commission was made up of young specialists appointed for their competence though without particular authority in the medical milieu. Conversely, a doctor and professor of medicine enjoying great medical authority but without any particular expertise on medicines per se was appointed to head the commission. The commission's first president, Dr. Legrain, imposed a decision-making rule that has remained in effect ever since.

Dr. Legrain set up a style of collective working that involved discussion, attentive listening, and reaching decisions by consensus rather than voting. There were two defensive dimensions to this quest for a consensus that would reflect the opinion of the scientific community in question: first, it was a response to the fear that their new arrangement might be contested by both pharmaceutical firms and the medical milieu; second, collective discussion seemed a suitable means of collectively mobilizing recent knowledge and practices. And 30 years after it was created, the AMM commission is still using the same decision-making mode. The use of decision-making by consensus—together with the extensive use of experts from outside the administration and the fact that the commission has been granted relatively full decision-making power—constitutes an original feature of the French approval setup. And the fact that that decision-making mode, defined by the quest for consensus, has been made permanent suggests the need for a rigorous definition of it: what exactly is decision-making by consensus?

² AFSSAPS for the French Agency for Safety of medical products.

What emerges from the statements collected³ is that a decision has been made when a consensus is reached; that is, when everyone shares the same view point on the decision to be made (as we have seen, these are not “yes or no” decisions but ones involving a list of items). With rare exceptions, reaching decisions by voting is rejected.⁴ Medicines experts therefore seem to reach decisions according to Jürgen Habermas’ communicative action model, which starts with a model of interaction among specific, co-present interlocutors and introduces into it Pierce’s idea that consensus constitutes the horizon of the indefinite progress of scientific knowledge. According to this model, the only thing that should count is the strength of an argument, and participants should be granted all the time needed to exchange arguments with the purpose of resolving or absorbing differences. Participants’ remarks are congruent with this interaction model:

“In most cases there is no voting. That may seem surprising; it’s fundamentally very good. This is supposed to be scientific decision-making, so it has to be a consensus. If it isn’t, that means some mysterious things remain. ... If we can’t manage it, we postpone it rather than voting. For X [a medicine], it took us a year to reach consensus” (E1).

“Usually, we manage to agree—if we don’t, we haven’t worked together enough. ... We proceed by going around the table. ... On many subjects, there’s a tendency, broad directional lines, if not on everything. But the consensus has to be a consensus. If there are some who don’t agree, they have to say so. There’s nothing worse than secret ballot voting” (E2).

The fact that decision-making by consensus was adopted and maintained is thus linked to the understanding that voting is not an appropriate means of reaching decisions of a strongly epistemic nature and that discussion of dossiers on medicines can culminate in opinion convergence.

Still, the notion of a gradually emerging consensus that allows decisions to be definitively reached raises two questions. The first pertains to the theory of knowledge: under what conditions does reflection facilitate the converging of minds? This question is not as simple as it looks because after all, it is perfectly plausible that pursuing collective thinking could elicit, increase or further sharpen divergences. I will not take up the problem of the conditions for convergence until the end of this section, but instead turn immediately to the second question,

³ In 2000 Emmanuelle Bonetti conducted approximately 20 interviews of standing AMM commission members and members who belonged to the commission at various periods since its creation. Interviewees are cited anonymously; each interview has been arbitrarily attributed a number, indexed E1, E2, etc.

⁴ All interviewees mentioned and approved rejection of voting. Voting is reserved for the extremely rare case of major disagreement that endures over several months. Our observations confirm interviewees’ statements: during the five sessions we attended in 2000 (we were the ones to choose the sessions), there was not a single instance of voting. Since March 2006, AMM session reports may be consulted on the site of the AFSSAPS (Agence Française de Sécurité Sanitaire des Produits de Santé). In spring 2008, 37 reports are accessible: voting was used only once, and the result was “unanimity minus 2 abstentions.” Moreover, the voting process have been used to give solemnity to the decision upon exposure to outside observers (a pharmaceutical company threatened to sue) rather than to resolve any deep internal disagreement.

because it concerns the very nature of collective decision-making. If there is indeed consensus, how do participants realize it has been reached? For AMM commission members—as for political philosophers and political experts who apply communicative action to decision-making situations—the mention of consensus seems a way of indicating that the collective decision-making process has reached its end—as it does when there is a vote, but instead of voting, participants can be thought to put forward arguments until they all agree. This description leaves out one important step, however: *recognizing* that the collective decision has been reached and that the process has therefore been concluded. There is necessarily a phenomenological dimension to collective decision-making, in the first sense of the word phenomenon: that which *appears*. In order for the collective decision-making process to be concluded, not only does an intention to act have to be determined or fixed, but the fact that it has been fixed has to be perceived and attestable to by each and all. In voting, decision-fixing occurs simultaneously with the perception that the decision has been fixed. But saying a decision has been reached by consensus generally does no more than indicate the means of fixing that decision; i.e., its content has been accepted by all. This is at best an incomplete description of what happens in consensus decision-making, for the question remains as to how, without any vote, participants manage to realize that their opinions have finally converged.

The interviews alone do not allow for identifying the decision-making mode used, for while participants' statements justify the use of consensus and mention the opposition to voting, they do not describe the exact means of decision-making involved in this process understood as distinct from voting. In fact, without some form of voting, even highly informal—head nods, for example—the experts could not know whether or not they have reached a consensus, simply because they are not transparent to each other. They therefore could not know if the discussion is over or needs to be pursued. It is not interview statements but rather direct observation of how drug approval committee proceeds that enable us to resolve this enigma, and to grasp the exact nature of this decision-making mode. This is what direct observation shows:

Once any non-member reporters have left the room, commission deliberation begins with the purpose of reaching a decision. After an exchange of views on the dossier at hand as a whole and the most debatable individual points in it—i.e., points likely to open up onto several alternative responses—the discussion takes off from a proposal by the commission president running the meeting. Some features of this proposal elicit reactions, expressions of disagreement or doubt, specifications, suggested additions. The arguments presented in support of these reactions are then discussed by the chairman himself or other members. The chairman then makes another proposal which is meant to represent a synthesis of the preceding discussion. That second proposal may again elicit partial objections or suggestions of ways to improve it. Discussion progresses thus, punctuated by the president's successive proposals. The discussion acquires the status of a made decision when it appears that none of the participants has any more objections to make. It should be noted that at the time the president calls for reactions to what will soon become his last proposal, some participants overtly approve but most abstain from any overt expression of their opinion.

2.3 Reaching decisions by exhaustion of objections

The decision-making mode used by drug approval experts is in fact quite widespread and used currently in a variety of contexts, despite the fact that it is not very well known and often

inaccurately designated “consensus or unanimity” decision-making. Though the use of this mode implies a different spirit depending on context, we are actually dealing with the same decision-making rule, which may be minimally defined as follows: a decision is understood to have been reached when there are no longer any objections expressed to a proposal for action, a proposal understood to reflect the preceding discussion.

Apparent consensus

I have suggested calling this practice and decision-making rule “apparent consensus decision-making.”⁵ It follows a specific sequence and presents two major characteristics:

A. In a typical procedure, 1) a member presents to the assembly the nature of the problem requiring a decision, together with an initial formulation of already stated options; 2) the members discuss this presentation of the issue; 3) the same member or another synthesizes the discussion and indicates which option seems to him/her to have emerged out of it; 4) at this point there are two possibilities: a) no one speaks out against the consensus proposal just presented, in which case even if most participants remain silent and only a few explicitly manifest their approval, that proposal becomes the decision, or b) at least one participant explicitly or implicitly contests the synthesis proposal, in which case discussion starts up again until the same member or another one offers a new synthesis, which once again gives rise to situation a) or b); 5) if all successive consensus proposals are contested, the decision-making process for that particular problem may be postponed until the next meeting.

B) There is no systematic expression or counting of opinions. In this aspect, decision-making by apparent consensus is radically different from voting. In apparent consensus decision-making, the fact that the decision has been reached—i.e., that an intention to act has been determined and fixed—is attested by collective noting of an *absence*: the absence of any overt opposition. The consensus is thus apparent in two ways. First, it clearly *appears* that no one objects to the proposal—in order for that proposal to acquire the status of a reached decision, the absence of opposition to it must be observable, it must become *apparent*. Second, the consensus that can be assumed to have been reached on the basis of this absence is in fact *only apparent*—i.e., it may be misleading—since those who remain silent do not necessarily approve the proposal.

C) Apparent consensus is distinct from unanimity: not explicitly rejecting a proposal is *not* the same as visibly unanimously approving it. In this decision-making mode, each participant has veto power since he/she can contest the synthesis proposal and thereby prevent it from becoming the decision. Reaching the decision does not require unanimity; what is required is that for whatever motive, those who disapprove the proposal no longer contest it.

These are the identifying features of the decision-making by apparent consensus. In fact, the French drug approval committee uses a variant of that mode, for there are at least two ways of using it, ways deemed relevant or not depending on context.

⁵ For a detailed analysis of what characterizes this decision-making mode and the description-related problems that often get in the way of apprehending and defining it clearly, see Urfalino, 2007. An english translation (by Amy Jacobs) is available on <http://cesta.ehess.fr/document.php?id=126>

Rejection or objection

The variations have to do with *how* the proposal is contested. A proposal may be rejected, in which case the validity of the rejection will be unconditional, or it may be objected to, with the understanding that the validity of the objection is in turn open to discussion.

In African *palabre*, for example, participants have an unconditional veto right. This means that any instance of disagreement, however discreet or indirect and regardless of whether any argument is presented to support it, has the effective value of a veto. What is conditional in this case is the use of the veto right: not everyone can use it with equal ease. The status and resources an assembly member has at his disposal strongly determine his ability to reject a proposal: he could expose himself to retaliation from members in favor of a proposal likely to be adopted, members with various resources that may not be related to the affair being debated but that would (or would not) allow them to buy the silence of potential opponents. In this case, decision-making by apparent consensus opens up a wide range of negotiations for generating or preventing rejection of a given proposal (El Hakim 1978; Coleman 1990).

In the case that interests us here, speaking out against the proposal constitutes an objection and does not necessarily amount to a veto. In order for the objection to be a veto, it has to be accepted; that is, the other members have to deem it valid. The context here is one where deliberating members usually do not have interests at stake, have nothing to negotiate and nothing to fear or hope for from speaking out—except the matter of the value will be attributed to what they say. Use of the option to contest a proposal here is not conditioned by any resource external to the decision-making process; rather the value of the contention content, its veto power, is conditioned by whether or not the arguments used against the proposal are recognized as valid.

There seem therefore to be two dominant variants of apparent consensus decision-making, depending on how a stated proposal is contested:

--either by outright rejection, rejection permitted by the rules in effect in the context in question; this is the equivalent of an unconditional veto right and the possibility of using it is conditioned by statuses and outside resources not necessarily related to the decision being made;

--or by objecting, a move permitted both a priori and by context rules; however, the degree to which a given objection is effective is conditioned by its argumentative content and by the other members' explicit or tacit recognition of its validity.

2.4 *Sanior pars* and *maior pars* in decision-making by exhaustion of objections

What becomes of an objection? It may be deemed invalid by at least part of the assembly and become itself the focus of a debate which will determine whether it gets accepted or rejected. Or it may be accepted immediately, or at least tacitly recognized as valid in that its substance gets integrated into the discussion that follows. In any case, in order for an objection to be distinguished clearly from rejection, members must practice what I have called the *aréopage's* argumentative discipline, since recognition of an objection as valid, as well as any contesting of that objection, are framed and made possible not only by member competence but by

argumentative discipline, discipline that each member imposes on himself but also—and above all—on the others.⁶

It follows from this that the silence of a member who says nothing when the session president proposes a decision—a silence that may help turn the proposal into a decision—“reflects” one of the following three situations:

- 1) The silent member is convinced that the proposal is the right one and should become the decision;
- 2) The silent member doesn't really know if the proposal is good or bad, and for some reason—inattention, fatigue, having worked less on this particular application, feeling less competent than others on the medicine in question—he delegates his judgment, counting on the others to see whether the proposal is inadequate and if so to contest it;⁷
- 3) The silent member is not convinced by the proposal and may even feel the committee is not moving towards the right decision, but he doesn't have a good argument—that is, an argument that complies with *aréopage* argumentative discipline and is likely to be judged acceptable or has in fact been accepted earlier.

To better grasp the specificity of this decision-making rule, it is useful to see what happens when voting categories are applied to it. Projecting voting vocabulary on a decision-making rule that differs from voting in that there is no counting of opinions brings out a clarifying contrast. We can say that at every step in the process of decision-making by exhaustion of objections, the majority comprises three groups: those voting in favor of the proposal (the convinced), abstainers (their silence amounts to delegation of judgment) and opponents who cannot vote against because they do not have any valid arguments. This unusual distribution of yes-votes, abstentions and no-votes with or without arguments—I am still using voting vocabulary—is due to the specific constraints on preference expression and value of preference expression operative in this decision-making mode. This is at least partially illustrated by the following table:

The relevant numbers	A virtually silent majority	An “objecting” minority
Value of the expressed opinion	In favor of the proposal as it stands	Against the proposal as it stands
Expression	Explicit approval or No expression	Explicit disapproval
Mental state and reasons	- convinced - indeterminate = delegation of judgment - not convinced but having no objection that one deems validatable or having made an objection deemed invalid by the others	- not convinced and having an objection that one deems validatable or that has been validated by the others

⁶ Argumentative discipline presupposes that there by no strongly divergent approaches to evaluating medicines, a point handled further on.

⁷ The issue of judgment delegation, a weak point of this decision-making mode, is considered in greater detail further on.

If we continue to project voting categories on decision-making by exhaustion of objections, we have to add that the “election” is always won either by a minority (temporarily) or unanimously (apparent unanimity, defined by absence of opposition) since, as explained, the objection of any one participant, if deemed valid, is enough to counterbalance those who approve the proposal or do not manifest their opinion of it; and when there are no more objections, the proposal becomes the decision thanks to what may be called negative unanimity; i.e., absence of observable objections. In any case, “saniority”—wisdom—prevails over number: explicitly recognized objection validity is all that is needed for successive proposals to be rejected, and the proposal that is ultimately arrived at is considered wise because it was the one that exhausted all objections, *not* because it would have won everyone’s vote.

Clearly the objection procedure on the one hand, and on the other the reversing of the quest for convergence through counted instances of approval (voting) into a quest for the absence of observable disapproval—a double negative that does not produce a simple affirmative—constitute a system, a system in which *sanior pars* and *maior pars*—reason and number—are constantly working together.⁸

Moreover, in this form of decision-making we find the two previously identified features that fit together the parts of wisdom and the majority: a split decision-making process and a hierarchical ordering principle.

First, collective decision-making is clearly split in two. But this occurs within the assembly and during the process. The reactions elicited by each new proposal form several partitions depending on whether we focus on members’ mental states, reasons and preferences, or opinion expression and its value. A classic collective decision-making process would go no further than this; an aggregation rule would then be applied to transform the individual preference distribution (for or against the proposal) into a collective preference. But here that distribution is only the starting point; it may well be followed by a minority critique of the majority’s judgment.

Second, the *sanior pars* hierarchical ordering principle operates in two ways: A) expression of reasons prevails over expression of preferences; B) inequalities in individual member influence are understood to be legitimate.

- A. The prevalence of reasons over preferences operates not only through a norm that by definition applies in all *aréopages*—I’m referring to the requirement of justifying preferences, the first feature of argumentative discipline—but also through the constraint of having only two ways to express preference for a proposal: not contesting it or opposing it with reasons. The only thing that can stand against a proposal’s reasons are other reasons. This means that “votes” are indeed “weighed” before being “counted”—and once again, the counting is implicit, in intaglio as it were.
- B. Unequal member influence is recognized as legitimate. To the prevalence of reasons over preferences corresponds the recognized authority of certain participants over others. This argument is cited by committee members themselves as a critique of

⁸ It is of great interest to note that, consistent with the typology of Saint Benedict mentioned in the introduction and usually considered rather odd, there is no “wise” majority: the *sanior pars* is incarnated either by a minority, often amounting to one objector, or unanimity.

voting: voting wrongly attributes the same weight to all members, whereas consensus-seeking permits the play of legitimate inequalities of influence related to differences in competence:

“Voting’s not good because it gives everyone the same weight. If we’re handling an application for a heart medicine, my cardiologist colleague should have more weight than me.” E3

“We always reach a consensus, that’s much better. There’s never been a vote. It’s preferable for people to explain what they mean. Let those who know explain. We’ve got official members representing the Medical Academy, the Pharmacology Academy, INSERM [Institut National de la Santé et de la Recherche Médicale]. They’re representative, but they haven’t got any particular qualifications. The experts, on the other hand, are qualified. The problem with voting is that it gives everybody equal weight.” E4

It is important to specify that competence or authority inequality distributions are not fixed once and for all. Several medicines are examined in the same session, and they often involve different medical specialties, so competence inequality distribution varies by drug. But accepted influence inequality points up one of the two weak points in the decision-making rule operative in the French drug approval commission.

2.5 The fragility of making decisions by exhausting all objections

The decision-making mode we have been examining has two weak points that may in some cases call into question the wisdom of using it. The first—also the most serious because it can negatively impact the quality of decisions made—is that it readily tolerates delegation of judgment. The second is related to the fact that this mode implies fully shared conceptions of medicine evaluation.

As explained, silence amounts to approval of the decision proposal made at a given moment by the session president. But silence may just as easily “mean” that the silent member has not yet formed a clear opinion on the question as that he or she approves the proposal (we will leave aside the silence of a member who is not convinced but does not have a good argument on which to base an objection). The norm by which silence is interpreted as approval is what allows for judgment delegation. Some members may simply “rest” their judgment on that of colleagues they deem better informed on certain medicine applications, or on the seriousness and reliability of the committee chairman and his or her team, who almost always preside the sessions.

Given the possibility of member judgment delegation, there are two corollaries to the adoption and maintenance of this mode of decision-making: A) the commission chairman has an extremely important role and considerable influence; B) the use of experts gets adjusted in such a way as to resemble a kind of division of labor.

A) The chairman plays an essential role in the decision-making dynamic by formulating the successive synthesizing proposals. He has to be able to elicit opinions, reactions to objections, and to integrate them or get them integrated into a new decision proposal. The scope of this role was increased by the personalities and competence of successive drug approval

committee chairmen from 1978 to 2000.⁹ The degree to which the two commission chairmen active from 1984 to 2000 mastered the applications the commission was called upon to evaluate was recognized by the other commission members, and this necessarily meant they had great influence on the proceedings overall, as was expressed in no uncertain terms by two of the experts interviewed, one of whom expressed himself thus:

“In my opinion they were hyper-professional and got carried away by their enthusiasm. The commission had to debate, they let it debate. But they had an answer to everything, all the weak points, all the positive ones—it often seemed we were dealing with a foregone conclusion” (E5).¹⁰

B) In complementary manner, decision-making by exhaustion of objections allows for member workload adjustment. These experts are not government administration members, and they all have heavy responsibilities elsewhere, often in hospitals. They are paid very little for their commission work. Often, then, they do not devote the same amount of study to all of the applications, which they only receive a few weeks before the meeting. Members who feel less competent on certain applications or who have done no more than peruse an application do not participate as much as others in the deliberation and do not make objections; they are likely to rally to proposals by the president or certain colleagues rather than really approve them.

If there is too much judgment delegation, this then affects the value attributed to one feature of collective committee deliberation and decision-making; namely that of enriching the discussion with multiple views from different individuals. Decision-making by exhaustion of objections can thus deteriorate into another form of collective decision-making, where a limited team of highly specialized, motivated experts present evaluation proposals to a larger group of less committed colleagues, hoping thereby to elicit a few additional useful points and corrective adjustments.

The second weak point in this decision-making rule is that it presupposes profound agreement on how to evaluate medicines. Despite real international homogenization and standardization of evaluation procedures and diffusion of fixed evaluation canons (double-blind clinical trials, balancing risk and benefit), there are still significant variations in evaluation approaches. These are only partially explained by differences between countries' medical histories (Daemmerich 2004; Hauray 2006); they can also be linked to different and even diametrically opposed “evaluation philosophies.” Dr. Alexandre, the highly influential French commission chairman from 1984 to 1994, presented the possibility of reaching consensus thus:

⁹ The chairmen in this period were Drs. Legrain, Alexandre and Caulin. As mentioned, this mode of decision-making has been used virtually exclusively and is still in effect today, but the study my arguments are based on here runs only from 1978 to 2000.

¹⁰ The two interviewees were specialized in pathologies for which there were then no recognized remedies. They were therefore never in a position to bring their particular competence to bear. And they were the only experts to express the feeling that, at the extreme, the commission was useless.

“Consensus can be sought and obtained if all commission members are dealing with the same data, follow the same rules, evaluate using shared criteria, and receive the same opinions from the experts or groups of experts the commission calls in.”¹¹

Reaching consensus thus implies using shared criteria. And assuming those criteria are in place (which is almost always the case), consensus requires having the same way of comparatively weighting those criteria (which is not always the case). Without a community-shared conception, the danger is not that objections will multiply but rather that despite observance with argumentative discipline it will be impossible to agree on the status of objections.

In 1995, Dr. Alexandre was appointed chairman of the drug approval commission of the newly created European Agency for the Evaluation of Medicinal Products, a commission made up of experts from all European Union countries. At the EMEA, he tried to implement the decision-making-by-exhaustion-of-objections rule he had seen applied by Dr Legrain in the French commission and that he himself had practiced, as chairman, in that commission for 11 years. But after a while he was forced to abandon his preferred mode of decision-making. The committee then approved majority voting, and that rule remains in effect in the European agency.

(Part 3 and conclusion yet to come)

¹¹ Excerpt from “Responsabilité de l’expert et sécurité juridique,” paper given by Dr. Alexander to a conference held on Oct. 3, 2001; AFSSAPS, p. 40. Available on the AFSSAPS website.

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