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**Extra-Judicial Decision Making for Drug Safety and Risk  
Management: Evidence from the FDA**

*Hazel McMullin and Andrew B. Whitford*



# Extra-Judicial Decision Making for Drug Safety and Risk Management:

## Evidence from the FDA

By Hazel McMullin and Andrew B. Whitford\*

### I. INTRODUCTION

¶1 Over the last five years, substantial attention has been paid to the arrangements employed in the United States for the regulation and oversight of prescription drug use and availability, much of it with regard to the New Drug Approval process at the United States Food and Drug Administration (FDA).<sup>1</sup> One central mechanism used by the FDA for making regulatory decisions for medications and medical devices is collaborative or team-based decision making. Advisory committees are charged with helping the FDA make decisions; the use of such committees is supported by empirical and analytic research on the power of groups to aggregate, assemble, and weigh complex information for multi-faceted decisions.<sup>2</sup> Of course, the use of decision-making teams is simple in neither theory nor practice.

¶2 The purpose of this paper is to assess the use and value of extra-judicial decision-making (or deliberative) teams in the form of advisory committees for regulation by the FDA. Our theoretical framework builds on common principles offered in organization theory for the design of such coordination mechanisms, and is drawn from literature in economics, decision theory, psychology, political science, and public management. Specifically, we examine the performance in the context of the structure and functioning of the Drug Safety and Risk Management Advisory Committee (DSaRM) in the FDA. Our examination centers on (1) the composition of such teams, and (2) the performance of such teams with regard to standard criteria of effectiveness, efficiency, and fairness of deliberations.<sup>3</sup>

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<sup>1</sup> See, e.g., Daniel P. Carpenter, *The Political Economy of FDA Drug Approval: Processing, Politics and Implications for Policy*, 23 HEALTH AFF. 52 (2004); Richard A. Merrill, *The Architecture of Government Regulation of Medical Products*, 82 VA. L. REV. 1753 (1996); Mary K. Olson, *Managing Delegation in the FDA: Reducing Delay in the New-Drug Review*, 29 J. HEALTH POL. POL'Y & L. 397 (2004).

<sup>2</sup> See, e.g., JAMES SUROWIECKI, *THE WISDOM OF CROWDS: WHY THE MANY ARE SMARTER THAN THE FEW AND HOW COLLECTIVE WISDOM SHAPES BUSINESS, ECONOMIES, SOCIETIES, AND NATIONS* (2004); ANNA GRANDORI, *ORGANIZATION AND ECONOMIC BEHAVIOR* (2d ed. 2001); Matthew J. Gabel & Charles R. Shipan, *A Social Choice Approach to Expert Consensus Panels*, 23 J. HEALTH ECON. 543 (2004); Krishna K. Latha, *The Condorcet Jury Theorem, Free Speech, and Correlated Votes*, 36 AM. J. POL. SCI. 617 (1992).

<sup>3</sup> GRANDORI, *supra* note 2, at 150.

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We first briefly review theoretical proposals about the value and performance of such teams. After that, we discuss the DSaRM as a decision-making body in detail. We then assess the DSaRM's composition with regard to standard criteria for decision-making teams, and then turn to its performance with regard to the criteria we develop. Finally, we offer a discussion of this body of theory, case, and evidence about decision-making bodies in medical decision making.

## II. DECISION-MAKING TEAMS IN REGULATORY SETTINGS

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The use of deliberative teams in regulatory settings encapsulates two threads of theory developed over the past four decades. By “team” we mean “an ensemble of actors with homogeneous preferences, differentiated knowledge and approximately equally valuable resources, who decide and control collective actions in a joint mode.”<sup>4</sup> In the first thread of theory, which centers on *team production*, it is argued that just as public goods cannot be consumed without cooperative action, that “team goods” require cooperative action among producers.<sup>5</sup> The central problem in the use of such teams for production is shirking: each individual asked to contribute to the production of the good has an incentive to decrease their effort level as other members increase their effort levels. The solution that Alchian and Demsetz offer to the problem of obtaining joint effort is to have a supervisor give instructions, observe the participants' input behavior to detect or estimate their marginal productivity, and apportion awards in line with that observation. The past four decades of theoretical development on the design of such teams has centered on finding the proper incentives for the manager (which in the private sector might include an ownership stake in the team's profits). Yet, we know generally that even a manager who observes high quality output from the team as a whole cannot necessarily trace and assign responsibility for that outcome;<sup>6</sup> the manager then is forced to allocate rewards in a fair way, which team members may not trust the manager to do.<sup>7</sup> What can a fair manager do? One solution might be to reward team members on the basis of personal information about each member or information received from the other members.<sup>8</sup> Even more complicated approaches have been offered, although how they are used in practice is less than clear.<sup>9</sup>

¶5

In the second thread of theory, which centers on *team aggregation*, the question is whether individuals acting in concert produce better estimates of hidden information than individuals acting alone. Recent books like *The Wisdom of Crowds*, by James Surowiecki, have popularized the insights of other, older theories on the ability of groups

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<sup>4</sup> *Id.* at 135.

<sup>5</sup> Armen A. Alchian & Harold Demsetz, *Production, Information Costs, and Economic Organization*, 62 AM. ECON. REV. 777, 778 (1972).

<sup>6</sup> Bengt Holmström, *Moral Hazard in Teams*, 13 BELL J. ECON. 324, 328 (1982).

<sup>7</sup> GARY J. MILLER, *MANAGERIAL DILEMMAS* 224 (1992).

<sup>8</sup> Bengt Holmström, *Moral Hazard and Observability*, 10 BELL J. ECON. 74, 80 (1979); Dilip Mookherjee, *Optimal Incentive Schemes with Many Agents*, 51 REV. ECON. STUD. 433, 435 (1984).

<sup>9</sup> *See, e.g.*, Jerry R. Green & Nancy L. Stokey, *A Comparison of Tournaments and Contracts*, 91 J. POL. ECON. 349, 354 (1983); Edward P. Lazear & Sherwin Rosen, *Rank-Order Tournaments as Optimum Labor Contracts*, 89 J. POL. ECON. 841 (1981); James M. Malcomson, *Rank-Order Contracts for a Principal with Many Agents*, 53 REV. ECON. STUD. 807, 808 (1986); James M. Malcomson, *Work Incentives, Hierarchy, and Internal Labor Markets*, 92 J. POL. ECON. 486 (1984); Barry J. Nalebuff & Joseph E. Stiglitz, *Prizes and Incentives: Towards a General Theory of Compensation and Competition*, 14 BELL J. ECON. 21 (1983).

to dampen cognitive biases and produce less-biased estimates of hidden information. For Surowiecki, large numbers of evaluators with independent, diverse views will average away individual-level biases that even experts can experience.<sup>10</sup> These biases include: availability bias, framing bias, overconfidence, and other risk-prone behavior.<sup>11</sup> What popular accounts of team information aggregation ignore, though, is the mechanism that produces efficient estimation by groups. That mechanism is detailed in the Condorcet Jury Theorem,<sup>12</sup> which provides a logic for understanding why a group provides superior estimates to individuals through better aggregation of information. Specifically, the Jury Theorem is a result that majority rule is better than “dictatorship” (aggregation of only one person’s information) when members of a group have similar preferences but different information: that in a two-alternative “election” where people have the same preferences but do not know which alternative best satisfies stated criteria, the group’s view (based on private signals) performs better than any one member’s view.<sup>13</sup> The past decade has seen substantial investment in elaborating the Jury Theorem and the conditions under which it holds. A number of papers show the generality of this result,<sup>14</sup> and recently Condorcet’s intuition has been shown to be consistent with that of Nash equilibrium.<sup>15</sup> This is important because of its concordance with the theory of common interest games – which forms a bridge to the economic theory of teams and team production.<sup>16</sup>

16 The contrast between these two threads of research cannot be clearer. The literature on team production emphasizes the “jointness” of production – the fact that cooperative (or pooled) interdependence and intensive interdependence among individuals<sup>17</sup> allow groups to produce outputs greater than the sum of the individual products (e.g., “generative” solutions). In contrast, much of the work on team aggregation emphasizes the *desirability* (if not *necessity*) of independence of individual views as a way of producing less-biased estimates. Scholars like Ladha have argued that few problems arise when independence loses ground to correlated views among members of the fact-finding team; indeed, a third thread of research on rational deliberation – on the power of discussion among members of a group for negotiation and pragmatic deliberation (for ethical discourse) – accounts for correlations among views (indeed, proposes ways of increasing correlations) in order to arrive and achieve mutually-preferred outcomes.<sup>18</sup> This thread does have its criticisms, many of which relate to well-known group pathologies of “groupthink” or differential risk propensities.

<sup>10</sup> SUROWIECKI, *supra* note 2, at 23.

<sup>11</sup> See Sarah Lichtenstein et al., *Calibration of Possibilities: The State of the Art to 1980*, in JUDGEMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES 306, 331 (Daniel Kahneman et al. eds., 1982).

<sup>12</sup> Jean-Antoine-Nicolas de Caritat, Marquis de Condorcet, *An Essay on the Application of Probability Theory to Plurality Decision-Making*, in CONDORCET: FOUNDATIONS OF SOCIAL CHANGE AND POLITICAL THEORY 131 (Iain McLean & Fiona Hewitt eds. & trans., 1994) (1785).

<sup>13</sup> Andrew McLennan, *Consequences of the Condorcet Jury Theorem for Beneficial Information Aggregation by Rational Agents*, 92 AM. POL. SCI. REV. 413 (1998).

<sup>14</sup> See Ladha, *supra* note 2, at 620.

<sup>15</sup> McLennan, *supra* note 13, at 413.

<sup>16</sup> See Roy Radner, *Teams*, in DECISION AND ORGANIZATION: A VOLUME IN HONOR OF JACOB MARSCHEK 189, 193 (C. B. McGuire & Roy Radner eds., 1972).

<sup>17</sup> JAMES D. THOMPSON, ORGANIZATIONS IN ACTION 54 (1967).

<sup>18</sup> See JÜRGEN HABERMAS, THE INCLUSION OF THE OTHER: STUDIES IN POLITICAL THEORY 250 (Ciaran Cronin & Pablo De Greiff eds., 1998).

¶7 Generally, though, the following proposals are made with regard to the conditions under which correct group dynamics are obtained.<sup>19</sup> First, group members should be involved in problem definition. Second, group members should be independent and free to generate alternatives. Third, conflicts between group members should be around issues and not against other individuals. Fourth, group members should have sufficient common knowledge for dialogue. Fifth, there should be sufficient differentiation of members' roles within the group (e.g., a moderator).

¶8 How do these conditions fit with our understanding of decision-making teams as means for joint production? In joint production, if team members cannot observe one another and if supervisors cannot make inferences about the individual efforts from the final output of the team, the problem of getting the individuals to “do the right thing” is almost equivalent to the canonical incentives problem addressed by bilateral principal-agency theory. It becomes difficult to do so because team members may shirk (“free ride”) their obligations to help the team perform – or team members may form coalitions (“cliques”) with implications for efficient operation.<sup>20</sup> Managerially, it is very difficult to write and implement a first-best contract that solves these problems. Indeed, numerous studies have shifted the debate to emphasize how managers can strengthen a culture of group work.<sup>21</sup>

¶9 Team production emphasizes a strong role for management in setting goals and defining problems, interdependence of team members, and an almost inevitable conflict among members about coordinated action. Team aggregation emphasizes the importance for teams of defining problems as they go, the aggregation of many independent individual valuations, and the construction of teams where conflicts between members are over information and not values. To a degree, both threads of research emphasize sufficient common knowledge and role differentiation (a moderator in the case of team aggregation, and a monitor in the case of team production).

¶10 In practice, and especially in the governmental use of advisory committees, we may observe different emphasis on these two approaches to teams. Are advisory committees like the Drug Safety and Risk Management Advisory Committee designed for aggregating information or producing policy meant to improve drug regulation? Does the DSaRM fulfill the conditions thought to support team production, or the conditions thought to support team aggregation? Conditional on its design as a decision-making team, does it perform effectively, efficiently, and fairly? The next section offers a broad overview of the DSaRM and research on the use of advisory committees specifically at the FDA for medical decision making. Following that, we turn to a structured analysis of the committee as a decision-making (or deliberative) team.

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<sup>19</sup> See GRANDORI, *supra* note 2, at 135; RENSIS LIKERT, *THE HUMAN ORGANIZATION: ITS MANAGEMENT AND VALUE* 155 (1967); EDGAR H. SCHEIN, *ORGANIZATIONAL PSYCHOLOGY* 112 (2d ed. 1970); Norman R. F. Maier, *Assets and Liabilities in Group Problem Solving: The Need for an Integrative Function*, 74 *PSYCHOL. REV.* 239 (1967).

<sup>20</sup> See Bengt Holmström & Paul Milgrom, *Regulating Trade Among Agents*, 146 *J. INST. THEORETICAL ECON.* 85 (1990); Hideshi Itoh, *Collusion, Incentives, and Risk Sharing*, 60 *J. ECON. THEORY* 410 (1993); Jean-Jacques Laffont, *Analysis of Hidden Gaming in a Three-Level Hierarchy*, 6 *J.L. ECON. & ORG.* 301, 318 (1990); Jean Tirole, *Hierarchies and Bureaucracies: On the Role of Collusion in Organizations*, 2 *J.L. ECON. & ORG.* 181, 207 (1986).

<sup>21</sup> Holmström & Milgrom, *supra* note 20, at 85; Itoh, *supra* note 20, at 410; Inés Macho-Stadler & J. David Pérez-Castrillo, *Moral Hazard with Several Agents: The Gains from Cooperation*, 11 *INT'L J. INDUS. ORG.* 73 (1993).

## III. BACKGROUND AND CONTEXT OF THE DSARM

¶11 Advisory committees are widely relied on for providing fair and impartial evidence on the benefits and risks associated with medications and medical devices. The FDA alone has thirty such advisory committees, with around eighty-five advisory committee meetings a year; the members of such committees are considered “special government employees.”<sup>22</sup> We focus on the Drug Safety and Risk Management Advisory Committee, which was initially authorized on June 1, 2002, and resides inside the FDA’s Office of Drug Safety (ODS) in the Center for Drug Evaluation and Research (CDER).<sup>23</sup> The ODS was created in 2001 from the Office of Post-Marketing Drug Risk Assessment with the mission of adding “value to the review of risk management programs and the review of drug safety issues.”

¶12 The purpose of the DSaRM is to advise the Commissioner of Food and Drugs “to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.”<sup>24</sup> It meets four times per year and consists of both standing and temporary appointed members, and of voting and non-voting members (each member has one vote and all votes are of equal weight). Meetings may be for the purpose of information gathering or formal recommendation development; formal recommendations to the Commissioner are reached by vote. Topics that have been considered vary from improving the usefulness of consumer medical information for prescriptions, to the risk assessment program for marketed drugs, and to oral tazarotene for the treatment of psoriasis.

¶13 While a number of studies discuss how such advisory committees can be used for providing topical information for the regulation of medication and medical devices, no studies address medical decision making by these groups in terms of the conditions for team aggregation and production. Most studies are imminently practical, centering on the policy implications of their proposals.<sup>25</sup> Three analyses that examined the structures of these advisory committees bear consideration, though. Steinbrook focuses on the role of independence of members of the DSaRM – independence from the views of regulated entities through provision of conflicts of interest waivers.<sup>26</sup> Specifically, Steinbrook notes that the construction of such groups is difficult if one desires full independence due to the need for specialized information, but also suggested that full disclosure of potential

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<sup>22</sup> Robert Steinbrook, *Financial Conflicts of Interest and the Food and Drug Administration’s Advisory Committees*, 353 NEW ENG. J. MED. 116, 118 (2005).

<sup>23</sup> Talk Paper, U.S. Food & Drug Admin., New Advisory Subcommittee Created on Drug Safety and Risk Management (Dec. 18, 2001), <http://www.fda.gov/bbs/topics/ANSWERS/2001/ANS01127.html>. The DSaRM was originally developed as a subcommittee to the Committee of Pharmaceutical Science.

<sup>24</sup> CENTER FOR DRUG EVALUATION & RESEARCH, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, COMMITTEE CHARTER – DRUG SAFETY & RISK MANAGEMENT DRUGS ADVISORY COMMITTEE 1 (2006), <http://www.fda.gov/cder/audiences/acspage/DSaRMcharter.htm> (last visited March 15, 2007) [hereinafter COMMITTEE CHARTER].

<sup>25</sup> Bruce Goldfarb, FDA Panel Recommends COX-2 Drugs Remain on Market, 2 DOC NEWS 1 (2005), available at <http://docnews.diabetesjournals.org/cgi/content/full/2/4/1>; Eleanor M. Peretto et al., *Evidence-Based Risk Management: How Can We Succeed?: Deliberations from a Risk Management Advisory Council*, 37 DRUG INFO. J. 127 (2003); Kate Traynor, *FDA’s Adverse-Event Surveillance Needs Improvement, Advisers Say*, 62 AM. J. HEALTH-SYS. PHARM. 1336 (2005); Cori Vanchieri, *Researchers Plan to Continue to Study COX-2 Inhibitors in Cancer Treatment and Prevention*, 97 J. NAT’L CANCER INST. 552, 553 (2005).

<sup>26</sup> Steinbrook, *supra* note 22, at 118.

conflicts of interest *so that any differences among members expressed in deliberation were known to be related potentially to differences in values and not just differences in held information*. Similarly, Thompson points out both positives (such as the Committee's use of a facilitator in the form of an executive secretary for efficiency) and negatives (such as the prohibition against members conversing in an organized manner using e-mail for open meetings purposes) that limit and expand the team's ability to aggregate and process information in a timely manner.<sup>27</sup> The DSaRM is not the only example of broader thinking about FDA advisory committees and the conditions under which they are effective, efficient, and fair. For example, Shapiro investigates the FDA's Public Board of Inquiry as a deliberative setting for the adjudication of claims over scientific disputes.<sup>28</sup> The selection of board members, their geographic location, the procedures used by members to deliberate – all of these represent core decision points in the design and operation of that committee as a means for assembling and acting upon technical information with a goal of producing objectively better results. Of course, the issue of effective operation of federal advisory committees is a long-standing concern for those with broad public policy (and especially, scientific) interests. Staffing can be a political choice (an exercise in “deck stacking”),<sup>29</sup> and such concerns seem to be elevated under the current Administration.<sup>30</sup>

¶14 The purpose of this paper is to critically assess the construction and operation of the DSaRM with regard to standard conditions for the design of teams for information aggregation and/or team production. The few existing studies on these kinds of advisory committees indicate how those design elements bind the hands of team members trying to develop views on policy information and perhaps even make policy decisions. While most studies center on those policy views and decisions, the underlying causes of the views and decisions are neglected – and knowledge of those causes, of the conditions for group performance, is a core step toward a better understanding of group decision making on medications and medical devices in the federal government.

¶15 We center our analysis in this paper on the fourteen core committee members consisting of thirteen voting members and one non-voting member over the course of two meetings. We focus on the standing committee members because they constitute a stable research base and represent the primary members necessary for and involved in an aggregation or production decisions. Recently, the Committee has received substantial attention because of its role in high-profile regulatory decisions of the FDA. As one example, in February 2005, the Committee convened jointly with the Arthritis Advisory Committee over the safety of cyclooxygenase-2 (Cox-2) inhibitors. The use of transcript information from two meetings was chosen to attempt to evaluate the ability of the group to meet its stated purpose (effectiveness) in an efficient and fair manner. Our first selected meeting was held May 5, 2004, and was solely for information gathering purposes; it was chosen to focus research on the internal group communication efforts.<sup>31</sup>

<sup>27</sup> Cheryl A. Thompson, *Safety Advisory Group Gets Mixed Marks from Members*, 62 AM. J. HEALTH-SYS. PHARM. 236, 239 (2005).

<sup>28</sup> Sidney A. Shapiro, *Scientific Issues and the Function of Hearing Procedures: Evaluating the FDA's Public Board of Inquiry*, 2 DUKE L.J. 288, 290 (1986).

<sup>29</sup> See SHEILA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS* 6 (1990).

<sup>30</sup> D. Ferber, *Critics See a Tilt in a CDC Science Panel*, 297 SCI. 1456 (2002); Robert Steinbrook, *Science, Politics, and Federal Advisory Committees*, 350 NEW ENG. J. MED. 1454 (2004).

<sup>31</sup> CENTER FOR DRUG EVALUATION & RESEARCH, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, DRUG

The second meeting used was held February 16-18, 2005, as a joint meeting with the Arthritis Advisory Council for the purpose of providing recommendations to the Commissioner of Food and Drugs;<sup>32</sup> this is the Cox-2 meeting. We chose this meeting to provide insight research opportunities about the interactions of the group within a larger setting, as well as for evaluating decision making as it relates to the authorized method of voting by the group. In the next section, we turn to an analysis of the DSaRM as a committee and the application of core concepts of team decision making.

#### IV. TEAM COMPONENTS AND EVALUATION

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We start by arguing that the DSaRM can be considered a team (in the theoretical sense) because it is “an ensemble of actors with homogeneous preferences, differentiated knowledge and approximately equally valuable resources (peers), who decide and control collective actions in a joint mode.”<sup>33</sup> The DSaRM is a selected group of individuals who are appointed by a stated authority (specifically, the FDA Commissioner). The committee is charged with being “knowledgeable in risk communication, risk management, drug safety, medical, behavioral, and biological sciences as they apply to risk management and drug abuse.”<sup>34</sup> Membership is chosen selectively, with one voting member representing consumers and one non-voting member representing the drug industry.<sup>35</sup> Based on this stated guidance, we infer that members selected are meant to have similar interests toward the goal of evaluating drug safety and risk. We do not infer or attempt to determine whether any members have “hidden agendas” at variance with the stated purpose of the committee. Based on curriculum vitae information<sup>36</sup> and the committee roster,<sup>37</sup> the DSaRM members appear homogeneous in their career choices in that all have stated expertise relating to the medical field: four in pharmacology in various forms, two in psychology, three in biometrics or risk analysis, two in medical

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SAFETY AND RISK MANAGEMENT COMMITTEE (DSARM) COMMITTEE MEETING 12 (2004), <http://www.fda.gov/ohrms/dockets/ac/04/transcripts/2004-4040T1.pdf> [hereinafter COMMITTEE MEETING].

<sup>32</sup> CENTER FOR DRUG EVALUATION & RESEARCH, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, 1 JOINT MEETING OF THE ARTHRITIS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE 23 (2005), <http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4090T1.pdf> [hereinafter 1 JOINT MEETING]; CENTER FOR DRUG EVALUATION & RESEARCH, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, 2 JOINT MEETING OF THE ARTHRITIS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE 90 (2005), <http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4090T2.pdf> [hereinafter 2 JOINT MEETING]; CENTER FOR DRUG EVALUATION & RESEARCH, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, 3 JOINT MEETING OF THE ARTHRITIS ADVISORY COMMITTEE AND THE DRUG SAFETY AND RISK MANAGEMENT ADVISORY COMMITTEE 8 (2005), <http://www.fda.gov/ohrms/dockets/ac/05/transcripts/2005-4090T3.pdf> [hereinafter 3 JOINT MEETING].

<sup>33</sup> GRANDORI, *supra* note 2, at 135.

<sup>34</sup> COMMITTEE CHARTER, *supra* note 24, at 1. The DSaRM operates under the provisions of the Federal Advisory Committee Act, Pub. L. No. 92-463, 86 Stat. 770 (1972) (codified as amended at 5 U.S.C. App. § 2 (2001)).

<sup>35</sup> COMMITTEE CHARTER, *supra* note 24.

<sup>36</sup> CENTER FOR DRUG EVALUATION & RESEARCH, U.S. DEPT. OF HEALTH AND HUMAN SERVICES, DRUG SAFETY AND RISK MANAGEMENT COMMITTEE ROSTER (2007), <http://www.fda.gov/cder/audiences/acspage/dsarmroster.htm> (last visited March 15, 2007) [hereinafter COMMITTEE ROSTER]; Channing Laboratory - Richard Platt, <http://www.channing.harvard.edu/platt.htm> (last visited April 22, 2007).

<sup>37</sup> COMMITTEE ROSTER, *supra* note 36.

specialties, one in ethics, and one in public health policy.<sup>38</sup> We argue that all career choices demonstrate reasonable applicability to issues that might be encountered when evaluating and making recommendations concerning drug effectiveness and risk. Our starting point is an inference that the committee members have homogeneous preferences and meet the first defined criterion to be considered as a team.

¶17 The stated structure of the group requires that committee members bring certain types of differentiated knowledge to the group. The expertise fields represented by the group certainly meet both the stated committee structure and provide a variety of applicable but differentiated knowledge backgrounds. The group also displays this differentiation across their current employers: seven members work in academia, three for trade/professional organizations/boards, two are in private business, and one works for a private hospital.<sup>39</sup> This distribution is more heavily weighted in the academic arena, but there still exists a differentiated perspective based on employment choices, thus meeting the second part of the definition.

¶18 We evaluated the peer status by compiling information from the curricula vitae and roster information of the members to determine if their education levels and professional status were similar enough in stature that the members would reasonably recognize each other as peers.<sup>40</sup> Of the fourteen members four are M.D.'s, six hold Ph.D.'s, five hold M.A. or M.S. degrees, four have doctoral level degrees of types other than Ph.D., one holds a J.D., and two have other professional credentials. While some members have more than one of the above credentials, all members have advanced educational credentials.<sup>41</sup> A second evaluation of the professional stature through the use of current job titles shows that one is department chair, three are professors, three are associate professors, two hold the title of President, two of Vice President/CEO and one of Coordinator. Most of these job titles had additional information further defining the job function (such as field of specialty), but we focused on perceived/actual hierarchy typically associated with the main title function.<sup>42</sup> From general perceptions of title and stature all but the "Coordinator" title indicate a high level of status within their appropriate organizations. In further review of the curriculum vitae of the member with the "Coordinator" title, we found this person to have come through a retail pharmacy background into a hospital setting.<sup>43</sup> We expect that the title "Coordinator" has a higher level of status inside this environment, which may be comparable to the easily perceived high-level titles of the other members.<sup>44</sup> The committee members appear to be professional peers as well.

¶19 The structure of the group states that members are either "voting" or "non-voting." Therefore any recommendations made by the committee to the Commissioner of Food and Drugs have been arrived at through a vote count. Voting, in its nature, meets the joint mode criteria. After reviewing the transcripts, we infer that the committee functions

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<sup>38</sup> *Id.*

<sup>39</sup> *Id.*; Channing Laboratory - Richard Platt, *supra* note 36.

<sup>40</sup> COMMITTEE ROSTER, *supra* note 36.

<sup>41</sup> *Id.*

<sup>42</sup> For example, the range of additional information included "Patient Care Coordinator," "Professor of Epidemiology," and "Professor of Bioethics." *Id.*

<sup>43</sup> *Id.*

<sup>44</sup> We admit that this cannot be verified because the title of "Coordinator" varies in meaning across organizations.

in a collective and joint decision-making process even prior to the vote on final recommendations.<sup>45</sup> The meetings are structured around presentations, which allow for questions, answers and debate as well as formal question and answer periods. Additionally, in the February 2005 three-day meeting where formal recommendations were made, any member was given a final opportunity to ask questions, to comment or to seek clarification immediately prior to the vote count. The committee chair accomplished this by asking every committee member individually if the member had any follow-up questions or comments or needed additional information before the vote was taken.<sup>46</sup> While there appeared to be no effort to force opinions on one another or influence vote selections, there was significant effort jointly made by all committee members to ensure that the information was sufficiently covered and presented for the benefit of the formal group process of voting. This meets the last stated team criterion that they “decide and control collective actions in a joint mode.”<sup>47</sup>

## V. TEAM FUNCTIONALITY ANALYSIS

¶20 We next evaluate the DSaRM Advisory Committee team’s ability to function in an effective, efficient, and fair manner. Our evaluation is based on four days of meeting transcripts over two meetings.<sup>48</sup> The first meeting was a one-day meeting held May 5, 2004 of the DSaRM Advisory Committee for the purpose of sharing information about inhalation drug packaging. Ten members of the DSaRM committee were present: nine voting, one non-voting. No votes were required or taken at this meeting. The second meeting was a three-day joint meeting of the DSaRM Advisory Committee and the Arthritis Advisory Committee held for the purpose of ultimately making recommendations to the Commissioner of Food and Drug to use in the determination of whether or not to return VIOXX® and other Cox-2 inhibitor drugs to the market. We reviewed transcripts to determine the type and level of group interactions.

### A. Team Effectiveness

¶21 We define the effectiveness of the group as the ability to meet the purpose of the group, which is stated as “advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which the Food and Drug Administration has regulatory responsibility.”<sup>49</sup> The transcripts indicate that the committee received clear and abundant information for its use. The information included safety data, clinical trial

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<sup>45</sup> COMMITTEE MEETING, *supra* note 31, at 12; 1 JOINT MEETING, *supra* note 32, at 23; 2 JOINT MEETING, *supra* note 32, at 142; 3 JOINT MEETING, *supra* note 32, at 10.

<sup>46</sup> 3 JOINT MEETING, *supra* note 32, at 201.

<sup>47</sup> There were two days of full discussion before a single vote was taken. On the third day, when the first vote came, Dr. Wood called for the first vote, saying:

Any other discussion? Great. Let's go, now – now, I have got strict instructions as to how to do this. So we have to go around the room and everybody has to say their name and then vote yes or no. So you precede your vote with your name. And we are dealing with Question 1.a.

*Id.* at 184.

<sup>48</sup> COMMITTEE MEETING, *supra* note 31, at 1; 1 JOINT MEETING, *supra* note 32, at 1; 2 JOINT MEETING, *supra* note 32, at 1; 3 JOINT MEETING, *supra* note 32, at 1.

<sup>49</sup> COMMITTEE CHARTER, *supra* note 24.

information, specific product information, and risk/benefit assessment information as well as other data. Industry representatives, FDA staff, researchers, and clinicians made most of the presentations. The committee members' willingness to verbally engage in information seeking and sharing, given their knowledge and backgrounds, imply that they had many opportunities to formulate recommendations. While they made no recommendations during the first meeting,<sup>50</sup> they voted on at least seven easily identifiable recommendations during the second meeting.<sup>51</sup> In the case study of the transcripts of this meeting, the Committee met its effectiveness criteria in that it provided formally stated advice for the Commissioner's use.

### B. Team Efficiency

¶22 We evaluated committee efficiency based on the structure of the meetings and, in the case of the second meeting, the ability to achieve recommendations based on vote count by the end of the scheduled meeting time. The transcripts for the two meetings showed that meetings began at or near the stated meeting times and that the published agendas were followed. Information was presented in an organized manner, questions and answers were allowed, and the committee Chair made sufficient efforts to keep each meeting moving in a productive, timely manner. By the end of the meetings Committee members seemed comfortable that information had been adequately presented and that their questions had been asked and answered inside the stated time frames for the meetings. Both meetings met their stated agenda goals within the original time constraints, indicating to us that the group design did function efficiently. But what about *external* efficiency? We were unable to analyze whether issues were presented to the group in a timely and efficient manner or whether the recommendations made by the group were used in a timely and efficient manner. We restrict our research to the efficient use of time during the stated meeting parameters because this is *what the group can control*. We will return to this issue of external and internal control below.

### C. Team Fairness

¶23 To evaluate the criterion of fairness, we use a standard definition of "fair" as "just to all parties."<sup>52</sup> Does this group function in a manner that is "fair" to each individual in that it allows each individual the opportunity to participate? Is this individual participation fair in that members of the group do not unduly influence the participation level of others? Is the participation fair by being reasonably free of the opinion influences of acquiescence and groupthink? Is the process by which final decisions are reached fair? The meeting transcripts from the two meetings cited above were analyzed in an effort to answer these questions and draw a conclusion about the fairness component of a group.

¶24 We analyzed four days of transcripts over two meetings to determine if individuals had fair and ample opportunities to participate by counting the number of times each committee member spoke. Our count included introductions and vote counts as well as

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<sup>50</sup> *Id.*

<sup>51</sup> 3 JOINT MEETING, *supra* note 32, at 337.

<sup>52</sup> WEBSTER'S II NEW RIVERSIDE UNIVERSITY DICTIONARY 461 (Anne H. Soukhanov & Kaethe Ellis eds., 1984).

questions, answers, and commentary, and was done by a name search through each transcript document so that each participant was noted as participating each time the transcriber recorded their name as the speaking individual. During the May 5, 2004, meeting of the DSaRM, nine of the fourteen members were present: eight voting members and one non-voting member.<sup>53</sup> This was an information-gathering meeting consisting of presentations and question and answer sessions with nothing to be voted on. Members were in turn asked to introduce themselves. They were on a first-name basis with each other as noted throughout all four days of transcript material reviewed, so we believe the introductions were for the purpose of getting the participants formally into the recorded document and to inform the public, presenters, and others about the identity of the committee members in attendance. The meeting followed the published agenda and after formalities to open the meeting, consisted of topical presentations followed by a question-and-answer period. While there were some questions asked during the presentations, questions were generally reserved for the question-and-answer periods. During this meeting, committee members individually spoke between 6 and 156 times. All committee members spoke during the meeting. The committee chairman spoke the most, and much of his commentary was procedural, though determining the distribution of commentary between procedural and professional is quite difficult because much of this was entwined. Because the Chairman spoke 129 times more than the next closest committee member, and 939% more than the group average of 16.6 times, we removed his tally from further analysis. After the chairman's tally was removed the members spoke between six and twenty seven times each. *The member who spoke the least was the non-voting, industry representative.* There are a number of reasons why this may have occurred, and we do not have enough information to speculate as to why she spoke the least; however, her tally of six was reasonably close to the next voting committee member who spoke ten times and much closer to the individual group numbers than the chairman, so we did not exclude her numbers from the analysis. The total number of times committee members spoke was 133 during approximately six and a half hours of meeting time. On average each member spoke 16.6 times for an average of 2.5 times per hour over the course of the meeting day.

¶25

We also analyzed the joint meeting of the DSaRM and the Arthritis Advisory Committee that was held from February 16-18, 2005.<sup>54</sup> This meeting was used to determine whether DSaRM members continued to participate in a larger, combined group setting where votes were taken for the approval and where recommendations were made to the Commissioner of Food and Drugs. There were eleven DSaRM members present for all three days including the non-voting member. The tallies for these days also included introductions and voting round participation. Over the three-day period DSaRM committee members spoke 268 times. All members spoke between eight and fifty-one times. While the industry leader spoke considerably less than even the next closest member (who spoke eighteen times), the removal of her participation number from the total did not significantly impact the overall number analysis. During this three-day meeting DSaRM committee members each spoke on average 8.1 times per day for an average of 1.25 times per hour.

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<sup>53</sup> COMMITTEE MEETING, *supra* note 31, at 2.

<sup>54</sup> 1 JOINT MEETING, *supra* note 32, at 1; 2 JOINT MEETING, *supra* note 32, at 1; 3 JOINT MEETING, *supra* note 32, at 1.

¶26 In summary, we claim that the DSaRM committee members had a fair opportunity to participate, since all present participated in each meeting and the average participations per hour indicated ample participation. While the average number per hour in the second meeting was half of that of the first meeting, we attribute the reduction to the fact that there were only 23 total participants listed on the formal meeting transcript for the 2004 meeting while there were an average of 53.6 participants per day listed for the three day meeting in 2005.<sup>55</sup> Clearly, if everyone participated fairly there would be an approximate reduction by one-half when the group size almost doubled from the first meeting to the second. We did not analyze DSaRM participation levels compared to those of the Arthritis Advisory Committee.

¶27 We also concluded, based on the above analysis and a review of meeting structure and procedure, that individual members were not hindering others' participation. All members participated in both meetings, the number of spoken acknowledgements remained similar given meeting size over the course of the two meetings, and procedurally, prior to voting during the second meeting, the meeting chair specifically and individually called upon each member to question or comment one last time before a vote count was taken. The meeting participants were courteous throughout the meeting, even during disagreement, and we perceived that no grandstanding, pontificating, avoidance, or acquiescence was taking place. The transcript indicated that all DSaRM members were able and willing to participate and exchange information freely.

¶28 The last component we looked at to determine fairness was the voting process and its results. The voting process in and of itself is generally recognized as procedurally fair, particularly when it is conducted using the method of one vote per participant with no weighting of votes. Based on the prior analysis and the source information (official transcripts), we did not take into account any possibility of vote manipulation (vote buying or swapping), which could occur. We assumed that all votes were uninfluenced by unethical occurrences outside of the meetings themselves. We analyzed seven easily identifiable recommendation voting rounds taken on day three of the February 2005 meeting<sup>56</sup> in an effort to determine if votes appeared to be cast based on the true preference of each individual and that groupthink was not likely occurring. Over the seven voting rounds analyzed only the votes during rounds one, three, and five had unanimous vote counts of ten "yes" and zero "no" votes. The remaining four voting rounds were diverse in their vote splits as follows:

Round 2	9 yes	1 no	
Round 4	2 yes	6 no	1 abstain 1 pass
Round 6	5 yes	5 no	
Round 7	2 yes	7 no	1 abstain

<sup>55</sup> 1 JOINT MEETING, *supra* note 32, at 2; 2 JOINT MEETING, *supra* note 32, at 2; 3 JOINT MEETING, *supra* note 32, at 2.

<sup>56</sup> 3 JOINT MEETING, *supra* note 32, at 337.

¶29 Since the DSaRM members were part of a larger voting group, there was no need to address the split vote count in Round 6, as the total vote outcome was not evenly split. Based on the above, more than half the time, the DSaRM members displayed disagreement about their voting preferences, indicating their seeming freeness to vote as individuals based on their own evaluations and conclusions. The transcripts showed no effort on the part of the meeting chair to re-vote to a closer vote count, nor did we find any discussion about the vote count or the results once the vote was taken. There were some references to the readiness of the entire group to move to the vote, and some attempts to start the voting round were thwarted because a member was not finished with the information gathering process. A useful step was taken by the committee chair, who appeared to promote fairness and to reduce potential bias when he rotated the starting member for the vote count to a different voting member at the beginning of each round. We could not tell from the transcripts whether the direction of vote taking changed as well (left to right, right to left, etc.). However, the fact that the vote starting point changed for each round indicated to us that additional effort was being made to address the appearance of procedural fairness and the reduction of potential bias as well.

¶30 In summary, the DSaRM seems to meet the fairness criteria. Participants clearly exchanged information freely within the context of a formal meeting setting. The atmosphere of the meetings was courteous. Committee members were on a first-name basis. They were able to state disagreement with presenters and each other and all occurrences of this in the parts of the transcripts reviewed showed the disagreements to be specifically technical. We inferred no incidents of personal attacks. The level of participation by individuals seemed reasonable and the voting mechanism and procedure was appropriate to ensure individual preferences were expressed.

## VI. DISCUSSION

¶31 Recall our five conditions, drawn from a diverse basis in organization theory and economics, which, when met, contribute to the group “maintaining correct dynamics,” presumably leading to a group’s effectiveness and success. These conditions are that the group is involved in problem definition, is free to independently generate alternatives, has conflicts focused on the problem and on other members of the team, has sufficient role differentiation, and allows for the presence of common knowledge. We found that the group clearly met the second, third and fifth conditions, as illustrated in our analysis above. The group clearly is able to communicate openly in a courteous, respectful and friendly environment as reflected in the transcripts. The only conflicts we read in the transcripts solely focused on the technical information presented. We found no personal references about any individuals other than those needed to address or identify members. The DSaRM group had the background knowledge (measured in terms of a common language, competences, and values) such that they were able to understand one another and engage in joint deliberation of ideas.<sup>57</sup> With regard to the first condition, that they participate in problem identification, we found no evidence in transcript or research review to suggest that the committee participates in what issues are brought before them. We discerned formal or informal role assignments only in the case of the Chair and the

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<sup>57</sup> SCHEIN, *supra* note 19, at 82; Robert M. Grant, *Toward a Knowledge-Based Theory of the Firm*, 17 STRATEGIC MGMT. J. (SPECIAL ISSUE) 109 (1996).

Executive Secretary. Generally, we claim that the DSaRM meets more of these principles about effective group dynamics than not – potentially increasing the overall quality and/or timeliness of the product delivered in the form of recommendations.

¶32 Overall, the Drug Safety and Risk Management Advisory Committee meets the definition of a team and it functions under the conditions which should make the group effective, efficient, and fair. In short, the committee members are “an ensemble of actors with homogenous preferences” in that they have similar educational and field of endeavor backgrounds as well as an assumed commitment to the safety of drugs as used by the general population.<sup>58</sup> They bring differentiated knowledge as evidenced by the committee structure requirements and their own individual chosen areas of expertise. They would be considered peers by their comparable formal education levels and their employment status and job titles. They clearly decide and control collective actions of the group together through the voting process.

¶33 They have also met conditions that make the team effective, efficient, and fair. They are effective in that they deliver recommendations to the Commissioner of Food and Drugs and therefore meet their designated and stated purpose. They function efficiently in that they monitor their own activities through the formal meeting structure to ensure that deliverables are produced in the stated time frame for decision making, within the context of the published meeting dates and times. Their communications and decision-making mechanism is fair in that it allows free exchange of information among peers without overt (at least) biases and pressures coming into play.

¶34 The theory behind this group, its structure, its communication ability and its outcomes seems sound and the DSaRM Advisory Committee *is virtually the same as those artificial committees constructed in theory for the aggregation of information and the production of policy.*

¶35 Our analysis focused on the microcosm of the group, its internal ability to function, and its ability to meet the charter stated purpose. The FDA has eighteen drug-related advisory committees who prepare information for the use of the Commissioner. Fifteen of these committees specialize in specific types of drugs, two specialize in the pharmacological issues of drugs in general, and the DSaRM focuses on the generalized safety of all drugs to the general population. While we did not obtain in-depth knowledge of the other committees, we recognize that the DSaRM is one of three committees with overlapping responsibility with any or all of the other committees (the other two possibly being those in pharmacology). We reviewed evidence in the second set of transcripts that shows that the DSaRM functioned jointly with the Arthritis Drug Advisory Committee. We presume that the FDA could ask the DSaRM to consider drugs from any of the fifteen drug-specific committees even though the DSaRM only meet four times a year; the structure and assignments for this committee could significantly delay information review and recommendations based on time availability and the volume of requests from the other committees. In the larger environment, this situation is probably not as functional and efficient as it seems in the microcosm.

¶36 If we take a step further and examine the macro-environment of the general public, we are suspect of placing this organizational team inside the FDA structure. The FDEA uses the results of DSaRM’s deliberations to justify removals of drugs from the market,

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<sup>58</sup> GRANDORI, *supra* note 2, at 135.

returns of drugs to the market, and packaging/labeling issues. Most recently, after the above-reviewed meetings of February 16-18, 2005, the DSaRM committee recommended to the Commissioner that VIOXX® and other Cox-2 inhibiting drugs were safe for use, with some packaging and literature insert adjustments, and that they should be returned to the market.<sup>59</sup> This finding created quite a vocal outcry that was well-covered in the news. Some common complaints were that the FDA does not have the best safety interest of the public at its forefront and that a committee that is under FDA jurisdiction is only self-serving and does not provide independent overview of drug safety issues.<sup>60</sup> Prior to the VIOXX® return-to-market recommendations, the FDA was already under criticism for its self-monitoring structure. Senator Grassley (R-Iowa) stated that he was preparing legislation that would separate the Office of Drug Safety (and assumedly its committees and subcommittees) from the office that approves drugs for market in an effort to have at least one drug approval committee not under FDA jurisdiction.<sup>61</sup> We claim that *even if the DSaRM does internally function as an effective group, in the environment of the general public and its legislators there is a problem at least with its perceived ability to produce unbiased recommendations.*

¶37

We conclude that a team can be an effectively functioning group within its own parameters but not necessarily provide the efficacy to the larger organization within which it is established. The larger organization, here being the FDA, should make a more concerted effort to consider external stakeholders and how such a team may or may not be perceived and utilized by all stakeholders. Given the above situation, the FDA announced in February (prior to the VIOXX® recommendations) that it would create yet another advisory team, to be named the Drug Safety Oversight Board.<sup>62</sup> This Board will also report through the FDA perhaps setting up yet another situation for internal team validity, external inefficiency, and suspect scrutiny.

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<sup>59</sup> 3 JOINT MEETING, *supra* note 32, at 262.

<sup>60</sup> Mike Adams, *With COX-2 Decision, No Longer Any Doubt About FDA Corruption and U.S. Drug Racket*, NEWS TARGET.COM (Feb. 18, 2005), <http://www.newstarget.com/004728.html>.

<sup>61</sup> Vascular Web.com, *Senators plan bill to revamp FDA drug safety* (2006), [http://www.vascularweb.org/\\_CONTRIBUTION\\_PAGES/Patient\\_Information/Medical\\_News\\_Reuters/Senators\\_plan\\_bill\\_to\\_revamp\\_FDA\\_drug\\_safety.html](http://www.vascularweb.org/_CONTRIBUTION_PAGES/Patient_Information/Medical_News_Reuters/Senators_plan_bill_to_revamp_FDA_drug_safety.html) (last visited Mar. 15, 2007).

<sup>62</sup> Gardiner Harris, *F.D.A. to Create Advisory Board on Drug Safety*, N.Y. TIMES, Feb. 16, 2005, at A17, available at <http://www.nytimes.com/2005/02/16/politics/16fda.html>.