CHAPTER 4

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INSTITUTIONAL DESIGN FOR SOCIALLY ROBUST KNOWLEDGE: THE NATIONAL TOXICOLOGY PROGRAM'S REPORT ON CARCINOGENS

INTRODUCTION

The delegation of significant authority from political to scientific actors is arguably the central problem in science policy, both analytically and practically (Guston 1996). Varieties of the central problem of delegation play out through the logic of principal-agent theory, as described by an increasing amount of work that concentrates on questions of the sponsorship of research, the role of research councils, and other aspects of what Brooks (1968) famously called 'policy for science.'[1]

Yet, delegation is central not only to the patronage relationship but also to the advisory relationship. Principal-agent theory can therefore also help illuminate the structure of science policy with respect to questions of 'science in policy.' Such questions include issues of peer review and other aspects of the use of expert advice for making policy decisions. By framing the central problem of science policy as one of delegation, scholars gain perspective on the deceptively simple question that politicians or the public may ask, "How do we trust scientists when they say and do things we have little substantive knowledge about?"

This chapter draws on an in-depth case study (Guston 2003) of regulatory science in the United States – the creation and production of the biennial *Report on Carcinogens* by the National Toxicology Program (NTP) of the National Institute of Environmental Health Sciences. It uses principal-agent theory to make sense of the problems that the actors themselves faced in attempting to design a process to produce what scholars would call "socially robust knowledge" (Nowotny 2003). The first section of the chapter below briefly introduces relevant points of principal-agent theory to articulate a preliminary structure of 'science in policy.' The subsequent sections elaborate how these issues play out in the design of NTP's process for identifying carcinogens: the environment that precipitated Congress's need for a reliable agent; the creation of an intermediary to serve as that agent; the articulation of an explicit set of terms for the performance of that contract; and the avoidance of such rules that agents inevitably engage in. In the discussion and conclusion, I argue that this understanding of NTP's arrangements contributes to questions of institutional design by showing how NTP satisfies a variety of desiderata suggested in recent

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literature, particularly focusing on the benefits of voting over consensus as a method of expressing scientific judgment.

THE STRUCTURE OF 'SCIENCE IN POLICY'

There is a millennia-old perception that experts stand apart from, and superior to, ordinary people over whom they rightfully have authority. The philosophers of Plato's *Republic*, whose rule was underpinned by the Golden Lie, are prototypes of a variety of guardians of the commonweal that appear in the political theories of writers as diverse as Confucius, Lenin, and Skinner (Dahl 1989). Robert Dahl (1989) emphasizes in his critique of guardianship that guardians are a class of rulers to whom authority has been alienated, that is, yielded permanently and unaccountably, and he offers a variety of (surprisingly pragmatic) reasons why such guardianship should be rejected. First, there is no science of governing accessible only to a limited class of people and, even if there were, there would be no reasonable way to identify and train prospective guardians and secure their orderly transition. Additionally, no one guardian could possess the entirety of governing knowledge. Thus – and this point is under-appreciated – any committee of guardians would have to admit decision rules and other kinds of politics into their allegedly objective decision making.

Even if, however, we are freed from the specter of the alienated authority of guardianship, we still may be haunted by the troubles of delegated authority in which experts still rule with a practical if not actual lack of accountability. That there is no solution to the problem of accountability of experts in modern society is, for example, the worry of Stephen Turner (2003) in his recent *Liberal Democracy 3.0*. Asking a version of a question that has plagued pluralist thinkers, Turner asks of the role of experts, can liberal-democracies manage non-democratic sub-systems? I argue that we need not push the question as far as Turner has, and that we can still think of making expert sub-systems sufficiently democratic and accountable through appropriate institutional design.

Insights for this design come from principal-agent theory, used here as a heuristic device to speak somewhat more formally of a relatively ignorant principal who makes a delegation of authority to a relatively expert agent who receives that delegation. That the agent is more expert than the principal raises the prospect of two problems, known in the literature as adverse selection (or hidden information) and moral hazard (or hidden behavior). These problems are often understood by their temporal sequence. Adverse selection is the difficulty of choice the principal first faces in selecting the best agent to accomplish the chosen goals. The information that is hidden is precisely who is the best agent to delegate to or to fulfill the contract. Moral hazard is the difficulty the principal faces after the agent has been chosen and the contract let. The behavior that is hidden is how well the agent works to complete the delegation or to fulfill the contract.

Although the principal-agent literature is often about the control of the agent by the principal, both principals and agents have their own respective interests in the relationship, and these interests not only create the challenges of adverse selection and moral hazard, but they also contribute to sustaining a mutually beneficial relationship over time. Thus, as Sheila Jasanoff (2003a: 158) has asked, "since account-

ability is a two-way street, demanding not only a responsible agent but also a vigilant principal, how can decisionmaking procedures be designed to facilitate the public's supervisory role?"

'Science in policy' questions are primarily structured as problems of adverse selection. Decision makers have questions for which there may be technical answers, and they must choose which experts to believe among the many offering expertise. From a delegation or hypothetical contract between decision makers and experts, the former can receive benefits including: expert knowledge, insight, or early warning; the potential solution to particular problems or questions; and legitimation for decisions that require technical sophistication. The experts receive benefits including: direct payment as consultants or employees; indirect payment through appointments to positions that bestow authority, prestige, or access to specialized or privileged knowledge; and the psychic returns of seeing one's ideas implemented in a legitimated pursuit of the public good.

As initially conceived, this perspective appears to assume that decision makers are sincere in their desire to hear scientific perspectives and that experts are sincere in offering perspectives they believe are correct. Such an assumption, however, is not necessary because sincerity or the lack of it can be included in the framework of adverse selection. That is, some principals or some agents may decide to solve the problems of adverse selection by contracting only with others who are ideologically predisposed to agree. Indeed, this situation may be the prevailing norm of science advice.[2] One would then need to assume only that they want to transact with one another, and leave any speculation about the benefits from the transaction to observing the performance of the contract. Decision makers seeking only legitimation, for example, are likely to behave differently than those seeking early warning. Moreover, it is also plausible that many decision makers who appear insincere are merely overwhelmed by the problem of adverse selection. That is, they may behave as if they were not invested in sincere expert advice because the existing asymmetry of information has allowed insincere experts to convince them of their perspective. That disingenuous experts can deceive decision makers does not mean that decision makers do not desire sincere advice, although it may mean that decision makers can engage in facilitated self-delusion. But more generally it does mean that problems of agency are critical to public decision making.

Embedded in this discussion is a further assumption that the opinions of scientists can and actually do differ. If scientific consensus were truly monolithic, then although the asymmetry of information would still exist between politics and science broadly speaking, there would be no need to select among agents. Once a question was framed as a scientific one, one scientist's opinion would be just as good as the next. Although incorporating elements of adverse selection as well, the framing of 'scientific' or 'non-scientific' would displace the concerns attended to here. But because disagreement – even controversy – is a natural condition of the scientific community, at least three addition problems arise. First, even if closure might be anticipated, many political decisions cannot await eventualities, and decisions must be made in the absence of consensus or closure. Second, scientific consensus or closure is often a temporary phenomenon, ready to be overturned with the appearance of additional, compelling evidence. Third, scientific consensus or closure is not nor-

mally the product of entirely rational procedures, and neither is it the product of impersonal, market-like interactions. Such difficulties mean that political principals cannot rely on autonomously produced consensus or closure among scientific agents, but rather they must devise strategies of choice and delegate to chosen agents.[3]

As in the case of health insurance, those potential agents most actively seeking to join the contract may have the greatest propensity to incur costs for the principals, i.e., potential agents who will benefit most directly from the contract may provide self-serving information to the decision makers. One example is the problem of conflicts of interest among expert advisors. In most situations in the US, potential advisors must have a direct financial conflict, e.g., they must work for a company whose product will be regulated by the contemplated action, in order to be disqualified from participating in a regulatory science analysis. Another typical example of self-serving behavior is the recommendation for more research that experts often offer, even if more research does not reduce uncertainty, lead to greater consensus, or otherwise accord with the decision makers' aims by not actually being a necessary precondition for substantive political progress on the issue.[4]

One can derive a variety of strategies that a political principal would deploy in order to assure – that is, to attempt to overcome doubt about – the soundness of the delegation of authority implicit in the exercise of scientific judgment for policy making. In the case of providing health insurance, the typical strategies to resolve problems of adverse selection involve excluding from the contract any potential agents who are or have a propensity to be ill, and providing incentives for those agents who do become party to the contract to remain healthy. The former solution typically requires the use of a monitor or intermediary, e.g., a physician who will examine potential agents for pre-existing or excluded conditions. This solution, however, raises that timeless, reiterative problem: Who will watch the watcher? The latter solution requires writing a contract with appropriately detailed terms, e.g., discounts for completing fitness courses, although such solutions impose analytical costs in calculating the incentives and adjusting the terms of the contract properly. Nevertheless, principals engage in such strategies of mediation and detailed procedures in their attempts to assure the integrity of the delegation of authority.

The remainder of this chapter applies this nascent framework to help order a case of 'science in policy' in the United States. It frames the discussion around mediation and explicit procedures as implemented by the National Toxicology Program (NTP), a small agency in the US National Institute of Environmental Health Sciences (NIEHS) – which is itself one of the more than two dozen National Institutes of Health. These strategies include NTP's intermediation between politicians and scientific agents, the writing of explicit contracts governing the behavior of those agents, and the promulgation of various rules that make the behavior of the scientific agents more observable. These strategies help to produce socially robust knowledge but they are not, however, perfect, and the scientific agents do in fact find ways to 'shirk.'

THE CASE OF SACCHARIN, PART 1: NEED FOR A RELIABLE AGENT

Saccharin, a derivative of coal tar, has a long and controversial history as a non-nutritive sweetener and food additive (Priebe and Kauffman 1980; Cummings 1986;

Marcus 1997). After Congress passed the Food Additive Amendments of 1958 to the Food, Drug and Cosmetic Act, the scientific and regulatory communities considered saccharin "generally recognized as safe" (GRAS). Subsequent experimental evidence gathered in the 1960s, however, led the Food and Drug Administration (FDA) to revoke saccharin's recognition as safe in February 1972.

FDA also issued an interim guideline forbidding any new uses for saccharin while it awaited a report from the National Academy of Sciences (NAS). The interim guidelines were set to expire at the end of June 1973, but FDA extended them indefinitely, citing studies that found significant increases in the incidence of bladder cancer in the male offspring of test animals fed saccharin (U.S. Senate 1977: 23). In December 1974, NAS submitted its review of the various studies, suggesting that saccharin was a carcinogen, but pointing to serious problems in the studies because the effective agent could have been impurities rather than the saccharin itself. In Canada, a study was designed to resolve this ambiguity, but Senator Gaylord Nelson (Democrat-Wisconsin), chairman of the Select Committee on Small Business, thought FDA was dawdling, and he asked the General Accounting Office (GAO) to investigate FDA's handling of the regulation of food additives (Marcus 1997). In testimony before Nelson's committee in January 1977, GAO critiqued FDA's regulation of saccharin and "recommended that [FDA] promptly reassess … the need for … possibly discontinuing [saccharin's] use in food" (U.S. Senate 1977: 27). Shortly thereafter, the Canadian study found that saccharin, rather than the impurities, caused bladder cancer in rats. Invoking the Delaney clause – a provision in the 1958 Amendments that prohibited any carcinogens from being added to foods – FDA proposed in the *Federal Register* on 15 April 1977 to ban saccharin.

The public reacted to the proposed ban with an outcry over losing the last substitute for sugar, as cyclamate had been banned in the 1960s. Congress responded, in part, by requesting a report from the Office of Technology Assessment. OTA surveyed the available scientific evidence on the carcinogenicity of saccharin, explored its potential health benefits for some consumers, and – in an unusual move for the policy analytic organization – commissioned Ames tests of saccharin's potential mutagenicity. OTA (1977: 5f.) concluded that "[l]aboratory evidence demonstrates that saccharin is a carcinogen," albeit a weak one, and one for which epidemiological studies had not shown a carcinogenic effect in humans. Nevertheless, saccharin seemed to meet the criteria proposed by the Occupational Safety and Health Administration to identify a 'confirmed' carcinogen. Not wanting to completely disregard FDA and the Delaney clause, Congress passed the Saccharin Study and Labeling Act (P.L. 95–203), which placed a moratorium on the saccharin ban, required labeling of all food products containing saccharin, and directed NAS to study the issue further.

Congress could not abide, however, such a sloppy, dilatory process whenever some scientists suspected a potential carcinogen in the food supply. OTA, NAS, and FDA, as well as private sector interests both for and against the continued use of saccharin, had a stake in assessing its carcinogenicity. Which agent should Congress choose: FDA, which applied a troublesome legal standard literally? NAS, which hemmed and hawed and asked for more research? OTA, which confirmed saccharin's mutagenicity but balked on the epidemiology? Industry or patient groups with significant commercial and other interests to protect? Without consensus in the scien-

tific community, and with the presence of patently self-interested advocates, Congress needed a reliable agent to identify carcinogens in future conflicts.

CREATING NTP AND THE *REPORT ON CARCINOGENS*

Not quite one year after it instructed FDA to defer regulatory action on saccharin, Congress passed the Biomedical Research Extension Act (P.L. 95–622) which, among other provisions, required the Secretary of the Department of Health, Education and Welfare (DHEW; now the Department of Health and Human Services, DHHS) to publish an annual report listing substances known or anticipated to be human carcinogens. Congress mandated that DHEW perform the task but delegated the design of a process that would fulfill the mandate. In 1979, DHEW created the National Toxicology Program (NTP) to implement the mandate by publishing a *Report on Carcinogens*.

NTP established an elaborate advisory system to identify human carcinogens. Initially, two review groups, the NIEHS/NTP Review Committee (RG1) and the NTP Executive Committee's Interagency Working Group (RG2), contributed to the *Report*'s decision making. In the first step of a detailed and iterative process, NTP receives a petition from any individual or group nominating a substance for consideration.[5] NTP then solicits public comment through notification in the *Federal Register*, trade journals, and its own publications.[6] RG1 receives the original petition and all public comments and decides if the substance warrants further consideration. If not, the petition is returned to the petitioner, who can resubmit it with further justification. Otherwise, RG1 appoints a primary and secondary reviewer from within its ranks to shepherd the petition through the committee. The primary reviewer identifies relevant articles from only the peer-reviewed literature and, with the assistance of the secondary reviewer, selects those articles to be included in a draft report, which is prepared by staff with the assistance of a contractor.[7] The reviewers then examine the petition, the citations, and the draft report for completeness and accuracy and, after making any necessary revisions, the primary reviewer presents it to RG1. RG1 considers this material, as well as the public comments in response to the petition, and makes a recommendation for listing or delisting. RG1 can also conclude that, after the review, there is still insufficient information and return the petition to the petitioner. The members of RG1 vote on the recommendation, and RG1 forwards the petition to RG2.

RG2 receives the petition, the public comments, and the draft report. It assigns another reviewer, who leads RG2's iteration of roughly the same procedure. RG2 provides comments and recommendations for any changes to the draft report and votes its recommendation for listing or delisting the substance. In the initial design of the process, NTP's Executive Committee would then review the entire record for each substance, vote on each substance, and forward the record with its own comments and voting results to the director of NTP for decision. NTP would then submit the *Report* to the Secretary for review and approval and, finally, to Congress for publication.

Through this process, NTP institutionalized the determination of what substances are or might reasonably be anticipated to be human carcinogens. Through the review

groups, NTP gathered many of the various experts from agencies that might otherwise have offered opinions directly themselves, and it solicited public input in a coherent and informed way. NTP became the analogue of the physician, the agent of Congress who is intermediary to other potential agents who were themselves attempting to assess the carcinogenicity of substances more directly.

This process embodied several strategies to combat the problems of agency. Limiting the agents to government employees minimized the threat of conflicts of interest, as did limiting the information used to the peer reviewed literature. Although NTP sought public comment, no advocates and no information produced purely for advocacy could be dispositive in its decisions. The creation of two advisory committees, with two different constituencies, increased the amount of information produced for the principal.[8] Furthermore, the recommendations of the advisory committees are exactly that – recommendations. Political principals, including the NTP director, the department Secretary, and Congress itself are responsible for the listing or delisting of a substance. This authority is more substantive than simply formal because of the relatively obvious fact that RG1 and RG2 may sometimes disagree. The NTP director must then decide how to cope with a substance despite divergent expert assessments. Such was the case with the decision about saccharin, described further below.

TOWARD A MORE EXPLICIT CONTRACT

NTP followed this procedure until the early 1990s. In the 1993 NIH Revitalization Act (P.L. 103–46), Congress mandated biennial rather than annual reports to provide "timely and useful scientific information to the regulatory agencies and the public while providing savings that would be better spent on testing additional agents" (US Senate 1992: 41). NTP published the first biennial report, and the eighth overall, in 1998 (NTP 1998). The *Eighth Report* also implemented two crucial changes NTP made in 1995: the creation of a new, more public advisory committee, and the revision of the criteria used for listing carcinogens.

Through the first change, NTP expanded its review procedures by adding a third committee – a standing subcommittee of the Board of Scientific Counselors (DHHS 1996). Like RG1 and RG2, this *Report on Carcinogens* Subcommittee appoints a reviewer from within its ranks to guide its discussion about a nominated substance. Unlike RG1 and RG2, however, the *Report on Carcinogens* Subcommittee deliberates in public. Because it comprises members who are not all employees of the federal government, the Subcommittee falls under the jurisdiction of the Federal Advisory Committee Act (FACA, P.L. 92–463). In addition to mandating public meetings, FACA requires that such committees be 'fairly balanced' in their composition. NTP announces meetings of the Subcommittee in the *Federal Register* and other publications, soliciting groups or individuals to submit written comments or to address the Subcommittee during its public meeting. Based on the prior record and any relevant public comment, the Subcommittee makes further recommendations for changes to the draft document and votes on a recommendation for listing or delisting.

By creating this committee of external advisors, NTP invited a greater risk of conflicts of interest, although FACA ameliorates the worst kinds. NTP also extended

the logic of multiple advisory panels to release more information for the principal by including non-governmental experts from industry, academe, and labor.[9]

In 1995, NTP also changed the criteria through which the various advisory committees arrive at their conclusions. As mentioned above, the committees deliberate on four possible outcomes for any nominated substance: the information is insufficient for deliberation; it should be listed as a known human carcinogen; it should be listed as reasonably anticipated to be a human carcinogen; or it should not be listed or be delisted. The original criteria maintained that a substance should be listed as a known human carcinogen if and only if "[t]here is sufficient evidence of carcinogenicity from studies in humans that indicates a causal relationship between the agent and human cancer" (DHHS 1995: 30435). The original criteria maintained that a substance should be listed as reasonably anticipated to be a human carcinogen if and only if:

a. There is limited evidence of carcinogenicity from studies in humans, which indicates that causal interpretation is credible, but that alternative explanations, such as chance, bias or confounding, could not adequately be excluded, or
b. There is sufficient evidence of carcinogenicity from studies in experimental animals that indicates that there is an increased incidence of malignant tumors: (a) in multiple species or strains, or (b) in multiple experiments (preferably with different routes of administration or using different dose levels), or (c) to an unusual degree with regard to incidence, site or type of tumor or age at onset. Additional evidence may be provided by data concerning dose-response effects, as well as information on mutagenicity or chemical structure (DHHS 1995: 30435).

The criteria make precise science policy statements about how the agents are supposed to handle evidence, e.g., they must rely on 'increased incidence of malignant tumors' and not, for example, consider benign tumors or lesions.[10] They also specify the inadequacy of a single animal-system model of carcinogenicity under normal circumstances.

In April 1995, the Board of Scientific Counselors created an ad hoc working group, which held a public meeting to consider revising the listing criteria and procedures (DHHS 1995).[11] The working group did not recommend any changes to the criteria for determining a known human carcinogen. The stated criterion was modified in a modest way to instruct for a finding of known human carcinogenicity when "[t]here is sufficient evidence of carcinogenicity from studies in humans that indicates a causal relationship between *exposure to* the agent*, substance or mixture* and human cancer" (DHHS 1996; changes noted in italics).

The working group did, however, recommend substantive changes to the criteria governing the finding that a substance is reasonably anticipated to be a human carcinogen. The proposed criteria included consideration of route of exposure, mechanisms of action, and sensitive subpopulations. NTP adopted these suggestions, expanding them to include membership in a "well defined, structurally-related class of substances whose members are listed in a previous Annual or Biennial Report on Carcinogens … or there is convincing relevant information that the agent acts

through mechanisms indicating it would likely cause cancer in humans." NTP also added a descriptive paragraph:

> Conclusions regarding carcinogenicity in humans or experimental animals are based on scientific judgment, with consideration given to all relevant information. Relevant information includes, but is not limited to, dose response, route of exposure, chemical structure, metabolism, pharmacokinetics, sensitive sub populations, genetic effects, or other data relating to the mechanism of action or factors that may be unique to a given substance. For example, there may be substances for which there is evidence of carcinogenicity in laboratory animals but there are compelling data indicating that the agent acts through mechanisms which do not operate in humans and would therefore reasonably be anticipated not to cause cancer in humans (DHHS 1996: 50499).

Congress did not impose these specific controls. Rather, the intermediary developed them under the principal's watchful eye in order for the agents to demonstrate their successful performance of the delegation. No one would complain to Congress about NTP if its procedures were more open to FACA, whose requirements for openness as well as balance combat adverse selection.[12] Scientists would not feel abused if NTP's criteria were made more explicit and attuned to 'scientific judgment.' Indeed, NTP director Kenneth Olden held that the new criteria and processes provided for "better science and better responsiveness" (DHHS 1998).

THE CASE OF SACCHARIN, PART II: SHIRKING BEHAVIOR

NTP first listed saccharin as reasonably anticipated to be a human carcinogen in its *Second Report*, published in 1981, and saccharin appeared in all subsequent reports up to and including the *Eighth Report*. Responding to the call for nominations for the *Ninth Report*, the Calorie Control Council (1997) nominated saccharin for delisting "on the basis of NTP's new criteria incorporating the use of mechanistic data."[13] By the end of September 1997, NTP had completed the draft background document on saccharin. In addition to reviewing toxicological and epidemiological studies of saccharin, the draft argued that:

> [t]here is evidence of the carcinogenicity of saccharin in rats but less convincing evidence in mice. Mechanistic studies indicate that … [t]he factors thought to contribute to tumor induction by sodium saccharin in rats would not be expected to occur in humans. The mouse data are inconsistent and require verification by additional studies. Results of several epidemiological studies indicate no clear association between saccharin consumption and urinary bladder cancer. Although it is impossible to absolutely conclude that it poses no threat to human health, sodium saccharin is not reasonably anticipated to be human carcinogen under conditions of general usage as an artificial sweetener (NTP 1997: RC3).

The draft report thus argued that the criterion of multiple sites or species was not fulfilled. RG1 and RG2 voted 7-3 and 6-2, respectively, to delist saccharin (DHHS 1998y), setting off speculation in the press about saccharin's ultimate absolution (e.g., Huber 1997; Kaiser 1997; McGinley 1997).

Table 1: Votes of the members of the Report on Carcinogens *subcommittee on saccharin for the* Ninth Report

Voting to Delist	**Voting to Retain Listing**
A. John **Bailer**, Ph.D. Department of Mathematics & Statistics Miami University	Eula **Bingham**, Ph.D. Departmentt of Environmental Health University of Cincinnati College of Medicine
Steven A. **Belinsky**, Ph.D. Inhalation Toxicology Research Institute Kirland Air Force Base	George **Friedman-Jimenez**, M.D. School of Public Health Bellevue Hospital
Clay **Frederick**, Ph.D. Mechanistic Toxicology Group Rohm and Haas Company	Nicholas K. **Hooper**, Ph.D. Department of Toxic Substances Control California Department of Health Services
	Franklin E. **Mirer**, Ph.D. Health and Safety Department UAW International
Not Voting:	
Arnold L. **Brown**, M.D. University of Wisconsin Medical School (Chair; only votes in case of tie)	Carol J. **Henry**, Ph.D. Health Environmental Science Department American Petroleum Institute (absent)

The *Report on Carcinogens* Subcommittee held its public meeting on 30–31 October 1997 to review the recommendations of RG1 and RG2 and hear additional public comment – offered by the Calorie Control Council in favor of delisting and by the Center for Science in the Public Interest opposed to delisting. The Subcommittee then voted 4-3 to reject the draft report and continue listing saccharin. Table 1 shows the members of the Subcommittee and how they voted.

Press reports suggest that the members of the Subcommittee who voted to retain saccharin on the list displayed a certain precautionary outlook that was outside the scope of the criteria. Nicholas K. ('Kim') Hooper from the California Department of Health Services said, "Delisting is going to weigh on my conscience if I'm wrong" (quoted in Stolberg 1997: A13). Franklin Mirer, the director of health and safety

from the United Auto Workers, International (UAW), found the 'equivocal' data from human epidemiological studies – which showed an increased cancer risk among some subpopulations – reason enough not to delist: "What I'm saying is the epidemiology is perhaps not strong enough to identify saccharin as a carcinogen, but it doesn't rule out that it's a risk" (quoted in McGinly 1997). *The Wall Street Journal* reported that "[a]t least one member of the panel who voted to keep saccharin listed said he probably wouldn't have voted to add saccharin, if that had been the issue, but wasn't comfortable about delisting it" (McGinly 1997).

In confidential interviews with the author, members of the *Report on Carcinogens* Subcommittee diverged in their explanations of the outcome as much as they did in the voting itself. Some attributed the lack of consensus to individually different perspectives on risk-taking. Others attributed it to disciplinary differences. "I suspect that my particular bias," said a Subcommittee member, is "when in doubt, regulate." Still others attributed differences to political agendas, as some "people were determined to delist for political or science policy reason" and some "are very industry oriented and are hesitant to call something a carcinogen, especially when it is on the cusp." Indeed, the Subcommittee members who voted to retain saccharin's status as reasonably anticipated to be a human carcinogen developed a perspective about shirking that contradicts that portrayed in the media coverage, arguing that those seeking to delist saccharin in essence 'nullified the criteria.' Those favoring delisting overemphasized the mechanistic data, which did not logically eliminate mechanisms that could cause cancer in humans. They neglected evidence in female rats that may have contradicted the mechanistic data. They conflated the hazard identification task of NTP – which is simply to determine carcinogenic potential – with a risk assessment for human consumption, which no one believes is high for saccharin. They over-emphasized the worth of human epidemiological data because many cancers that saccharin might cause would not yet have shown up in the study populations.

After the vote of the *Report on Carcinogens* Subcommittee, both the UAW's Mirer and the chairman of the Subcommittee, Arnold Brown of the University of Wisconsin Medical School (who, as chairman, did not vote) "thought that it might be difficult" for NTP director Olden to contradict the panel and delist saccharin. But in December 1998, the full Executive Committee voted 6-3 to delist saccharin.

According to members of the Subcommittee, the mixed vote 'sends a message' about the underlying uncertainty in the data and the conflict of scientific judgment that the advisory committees could not have sent had they operated by consensus rather than reporting votes. The individual votes, and the record among the advisory committees, "should show the level of agreement that the data show," and the record of disagreement "alerts people to the fact that [different opinions were] considered." The full committee's vote meant that saccharin had, like a tennis player, won its match for delisting 7-3, 6-2, 3-4, 6-3. The *Ninth Report on Carcinogens*, finally issued in May 2000, contained 218 entries for substances known and reasonably anticipated to be human carcinogens (NTP 2000). Saccharin was not among them.

DISCUSSION

NTP was established under a delegation from Congress to assure the sound production of information about known and reasonably anticipated human carcinogens. As such, it is an expert agent for Congress, like the physician-intermediary between the health insurer and insurance seekers. NTP is a watcher of other agents – scientists themselves – who deliberate about what substances are or are not carcinogenic.

Recognizing, as Jasanoff (2003a: 159; emphasis in the original) writes, that "[e]xpertise is not so much *found* as *made* in the process of litigation or other forms of technical decisionmaking," NTP made a well-regulated scientific marketplace – what Nowotny (2003) might call an *agora* – in which some degree of consensus and closure, as well as the liberation of a good deal of information, could be expected. Congress did not mandate the architecture of this *agora* but NTP designed its procedures to demonstrate its faithful performance of the delegation. NTP established multiple advisory committees to represent interests both internal and external to the government. FACA protected the integrity of the input from external advisors against such threats of adverse selection as conflicts of interest. NTP promulgated specific science policy criteria, upon which it instructed the members of these advisory committees to formulate their judgments. NTP relied on voting, rather than consensus, to embody the uncertainty in the underlying data and communicate this additional information to political principals.

NTP created a process that also embodies Nowotny's (2003: 155) three characteristics of socially robust knowledge. First, NTP tests knowledge about carcinogenic potential "in a world in which social, economic, cultural and political factors shape the products and processes resulting from scientific and technological innovation." FACA and the open hearings of the *Report on Carcinogens* Subcommittee assured this after the 1995 procedural changes. Second, NTP 'extends' expertise throughout society in a similar way – not only by validating the participation of diverse interests through diverse committees and FACA mandates, but by allowing public comment to initiate scrutiny of substances, by soliciting public comment at all stages of its deliberations, and by preserving the discretion of a political appointee to make the final determination. NTP also crucially relies on science policy decisions – the rules under which individual experts operate – which are open to greater public scrutiny and influence than are the decisions about carcinogenic potential themselves. Third, NTP provides a forum for claims about carcinogenic potential to be 'repeatedly tested, expanded and modified.' New research and new rules created a situation in which saccharin was delisted. New research could create a situation in which saccharin could be relisted. NTP's *Report on Carcinogens* process seems to be an example, again quoting Jasanoff (2003a: 161), in which "a bounded but candid deliberation among the holders of divergent viewpoints could lead to … a more accountable exercise of judgment, and eventually a better analysis."

Special attention should also be paid to the nature of voting in NTP's *agora*. Although, as realists often assert, one cannot repeal the law of gravity by voting, voting occurs more than is generally recognized in a variety of traditionally technical venues (Guston, under review). Balloting in this *agora* does not absolutely determine what

substances are or are not human carcinogens, for a political actor still makes that specific determination, but the voting here certainly more than hints at the outcome.

I want to suggest that voting serves a number of specific functions, beyond this hinting. First, in the context of principal-agent theory, voting is a preferable method of aggregating the preferences of the participants because it liberates more information than does consensus, through which the agent speaks with only one voice.

Table 2: Votes of the members of the Report on Carcinogens *subcommittee on all substances, in comparison to the majority*

Name	More	As	Less
Bailer	1	21	1
Belinsky	0	18	5
Bingham	2	9	1
Frederick	1	18	2
Friedman-Jimenez	0	17	0
Henry	0	7	3
Hooper	3	19	1
Mirer	3	18	0
Hecht	0	12	0
Kelsey	1	14	0
Medinsky	0	8	2
Russo	1	7	2
Zahm	0	13	0

Second, voting assists in accountability because, in conjunction with rules on openness, voting connects individuals to their stances. Thus, the previous Table 1 can be replicated for every substance on which the *Report on Carcinogens* Subcommittee votes, and both analysts and the public can see how individual members of the Subcommittee vote. Aggregating the votes in particular ways, for example, by the sectoral or disciplinary affiliation of the Subcommittee member, can provide additional information about the balance of the Subcommittee under FACA. In Table 2, 'more' represents how many votes the individual cast that were 'more protective' than the majority of Subcommittee members cast for any substance, 'as' means how many votes were 'as protective' as the majority, and 'less' means how many votes were 'less protective' than the majority. A more protective vote would be voting to list as substance as 'reasonably anticipated to be a human carcinogen' when the majority voted not to list the substance, or voting to list it as a 'known human carcinogen'

when the majority voted to list it as 'reasonably anticipated.' A 'less protective' vote would be the other way around.[14]

Table 3 sums the votes by sectoral and disciplinary affiliation. One can readily note that the industry members are less protective overall than other members, and that the single labor member does not 'balance' out the other industry representatives, thus providing some empirical evidence about the satisfaction of FACA. In the disciplinary analysis, Subcommittee members affiliated with laboratory disciplines (e.g., toxicology) were less protective, those affiliated with populations and statistics (e.g., bio-statistics, epidemiology) were right in the middle, and those affiliated with organismal studies (zoology, medical doctor) were more protective. Laboratory disciplines were also more frequently represented than either of the other two.

Table 3: Votes of the members of the Report on Carcinogens *subcommittee on all substances, aggregated by sector and disciplinary group*

Sector/ Disciplinary Group	More	As	Less
Academic	5	80	4
Government	3	50	6
Industry	1	33	7
Labor	3	18	0
Stats/Pop	1	34	1
Organismal	7	65	3
Laboratory	4	82	13

That one can perform this admittedly crude but still potentially revealing analysis suggests a third reason to commend voting, as its analysis may open the door to a different kind of politics around such committees and around FACA – one that encourages empirical inquiry relevant to the selection of such committees.

CONCLUSION

After examining NTP's *Report on Carcinogens*, several levels of conclusions can be offered. The first concerns the framing of the case by principal-agent theory, which proves a handy map for issues of 'science in policy,' helping demonstrate how a political principal delegates authority to a scientific agent and how that agent adopts strategies to demonstrate its fulfilling the delegation in a competent way. Second, the chapter suggests that by focusing on the structure of delegation, relationships that meet reasonable normative criteria about expertise can be met. That is, through the appropriate design of institutions the production of socially robust knowledge can be successfully delegated rather than alienated. Such design elements include balanced

participation from interested experts (as provided by FACA), clear science policy rules about how to come to scientific judgments, multiple sources of advice operating under similar rules and information, and open and transparent voting rules for expressing the scope of agreement of scientific judgment. Together, these elements provide both the democratization of expertise and the expertizing of democracy that Libertore and Funtowicz (2003) have called for.

Third, these design elements improve the conditions for accountability by teasing apart what Jasanoff (2003b) has identified as the 'three bodies of expertise': the individual experts themselves, the bodies of knowledge on which they draw, and the advisory bodies they constitute. The ability of experts to cloak their authority by speaking from a position of consensus, determined by unspecified procedures, prevents the differentiation, specification, or identification of responsibility that is needed for accountability. By designing institutions to provide expert advice according to these elements, we may be able to stave off asking Turner's unanswerable question about the compatibility of liberal-democratic governance with authority alienated to experts.

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NOTES

1 This work includes Braun (1993, 1998), Braun and Guston (2003), Caswill (1998), Guston (1996, 1999, 2000), Morris (2000) and van der Meulen (1998).

2 It is certainly what US Representative Henry Waxman (Democrat, California) believes is the norm of the Bush Administration, as Waxman released a report purporting to document dozens of episodes of the inappropriate politicization of science (US House of Representatives 2003).

3 This argument is similar to that in Guston (2000) in which the political principal cannot rely on the autonomously produced integrity or productivity of the scientific agent and must therefore create new institutions to assure these requisites.

4 Some believe this to be the case, for example, in the research agenda for climate change (e.g., Pielke and Sarewitz 2002).

5 NTP may consider an "agent, substance, mixture, or exposure circumstance," but I will simply refer to "substance."

6 This account is derived from NTP (1998), appendix C.

7 This process of writing and reviewing the report is similar to the preparation of the criteria document for the National Ambient Air Quality Standards under the Clean Air Act Amendments of 1977 (see Jasanoff 1990: 102)

8 Information from the confidential interviews supports this perspective, as informants distinguished between RG1 as an internal organ of NTP more concerned with toxicological evidence and RG2 as a broader, higher level committee more concerned with the political and regulatory consequences of decisions.

9 In interviews, members of the Subcommittee supported this interpretation, distinguishing the Subcommittee from RG1 and RG2 by its public (as opposed to bureaucratic) constituency and its greater expertise in epidemiology, public health, and human exposure.

10 See Jasanoff (1990) for documentation of conflicts in regulatory science committees over exactly such science policy issues.

[11] Another such meeting occurred 27–28 January 2004.

[12] This is one of the lessons from the literature on "fire-alarm oversight" by Congress over executive agencies (McCubbins and Schwartz 1987 [1984]).

[13] The Calorie Control Council represents the low-calorie and reduced-fat food and beverage industry. See http://www.caloriecontrol.org. In January 1997, FDA revoked a rule prescribing the display of warning signs at retail establishments about the sale of saccharin (DHHS, 1997z); FDA initiated the action following a petition from the Calorie Control Council and under authority of a bill to amend the Federal Food, Drug, and Cosmetic Act to repeal the saccharin notice requirement (P.L. 104-124) (DHHS 1996y).

[14] Each individual does not have the same number of votes because some may have joined the committee at different times in its deliberations, some may have missed meetings, and some may have abstained or declared conflicts of interest. All votes, however, are on substances considered for the ninth report.

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