

## **Advisory Committees in U.S. Biomedical Regulation**

Proposal for the Ackoff Doctoral Student Fellowship

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### **Descriptive Summary**

This project is a historical study of expert advisory committees in agencies of the U.S. Department of Health and Human Services (HHS). Recommendations from panels of medical and scientific experts are critical to the regulation of medical products such as drugs and vaccines and to the development of national prevention and treatment guidelines. At the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and other health agencies, dozens of advisory committees provide highly influential assessments of the safety, effectiveness, risks and benefits, and cost-effectiveness of medical interventions and health care practices.

The recent controversy surrounding breast cancer screening mammography guidelines illustrated the attention that advisory committee recommendations can generate. Their findings can shape public perceptions of the safety and value of specific medical products and practices, and by extension, opinions of the nation's health care system overall. A system that began as a short-term solution to the surge in FDA workload following the 1962 Kefauver Amendment has become central to the day-to-day regulatory and policy work of federal health agencies. Advisory committee recommendations are routinely followed by their parent agencies, underscoring these groups' profound influence on the fates of the products and practices they review.

A detailed examination of the work of expert advisory committees is a particularly useful way to observe changes in disease concepts and in treatment and prevention strategies throughout the second half of the 20th century and up to the present. In this project, I will trace the development and evolution of advisory committees in U.S. biomedical regulation from their earliest systematic use in the 1960s into the mid-1990s, when their structure, function, and influence largely resembled those of the present.

More than simply a chapter in the history of the regulatory bureaucracy for biomedical science and public health, expert advisory committees have played central roles in shaping medical knowledge, disease definitions, treatment protocols, evaluations of risk and benefit, and general notions of health in the United States and, indirectly, worldwide. These groups mediate the relationship between science, medicine, public health, and public policy, translating and shaping knowledge produced and disseminated throughout each domain. The history of federal advisory committees for the regulation of biomedical science and practice is an essential, as-yet-overlooked component of the history of health, disease, and medical practice in late 20th-century America.

To examine these issues, I will combine a high-level account of the introduction, growth, and influence of advisory committees in federal biomedical regulation with detailed discussions of specific committees, experts, and cases. In particular, I will highlight groups including the CDC Advisory Committee on Immunization Practices, the NIH Recombinant [DNA] Advisory Committee and the FDA Blood Products Advisory Committee. Among the cases to be studied in detail are the development of hepatitis B vaccines in the 1970s and 1980s (one derived from the blood of hepatitis patients, the other based on recombinant

DNA technology), debates over the risks of saccharin, the safety of pain relievers (both over-the-counter and prescription), and changing views on the merits of hormone replacement therapy.

At the core of this project is an examination of how advisory committees have discussed and evaluated contested issues involving risks and benefits, safety, and scientific and clinical uncertainty during their work. When making a recommendation regarding a medical product (such as a new drug) or a practice guideline (such as recommendations for screening), expert advisors must consider the benefits of that intervention in light of its risks, the risks of the condition being targeted, and the risks of doing nothing, all in order to reach a conclusion.

While increasingly sophisticated quantitative modeling has been developed to assist in these decisions, advisors are ultimately asked to use their scientific or clinical expertise to make subjective assessments of the net value—medical and/or economic—of proposed interventions. Through my research, I will trace patterns and changes in the ways in which expert advisors have reached such conclusions, particularly when the available evidence is incomplete, conflicting, or ambiguous. Likewise, I will pay close attention to how social values and other qualitative considerations have shaped committees' interpretation and evaluation of evidence pertaining to risk and safety.

The research for this project will include a variety of archival collections and other primary source materials. By far, the largest and most important sources are materials in the collections in the National Archives, where papers of the CDC (RG 442), FDA (RG 88), NIH (RG 443), and other agencies are held. Numerous other government materials will supplement these sources, including the records of the National Research Council's Drug Efficacy Study (1966-1969), the program that may be viewed as the progenitor of the modern advisory committee system.

The legislative history of the 1972 Federal Advisory Committee Act, the multiple Congressional inquiries into the biomedical advisory committee system over the past 35 years, coverage in the popular and medical press, and reports directly from federal agencies and advisory committees will all supplement this research. I am also seeking access to corporate archives of pharmaceutical manufacturers, such as Merck, that figure prominently in the cases and committees to be examined. Finally, to supplement the documentary record, I will conduct semi-structured interviews with individuals who participated directly in the events I am studying.

There are a number of secondary literatures that will inform this project and to which I hope it will contribute. Space restrictions do not permit a full discussion of the scholarship relevant to my research, which includes work on science advice to government and the role of expertise; biomedical technologies, drug regulation, and the pharmaceutical industry; technological systems and the importance of users; the social construction of risk and disease; and institutional histories of federal health agencies. While the sustained examination of biomedical expert advisory committees proposed here has not previously been a focus of these or other scholars, their research on related topics will be invaluable in my efforts to situate my project within the larger history of health, disease, and medical regulation in 20th- and 21st-century America.

Overall, a historical study of expert advisory committees in American medical regulation has the potential to offer new insights on the history of medicine, public health, and health policy. Working with a diverse assortment of primary sources and a range of relevant secondary literatures, the project will illuminate the important role of these committees in ongoing dialogues among science, medicine, and public policy, dialogues that continue to be central to our evolving contemporary understanding of the prevention, diagnosis, and treatment of disease.

The Ackoff Doctoral Student Fellowship will support three weeks of travel to government archives, federal agencies, and advisory committee meetings in the Atlanta and Washington, DC, metropolitan areas. While multiple archival collections and other primary sources will contribute to my dissertation, none are more essential than the federal government's own archives. (CDC papers are held in the National Archives facility in suburban Atlanta; those of other HHS agencies are in Washington, DC.) While archival research is the primary purpose of these trips, I will also use a portion of my time in Atlanta and Washington to attend meetings of federal advisory committees and to interview agency staff and advisors relevant to my project.

For the research trip to Atlanta, airfare costs were estimated based on a search of travel websites for potential travel dates. Lodging costs are based on the rates of hotels located near the National Archives facility in Morrow, GA and the CDC in Atlanta. For travel to the Washington, DC, area, I will rely on day trips from Philadelphia in order to reduce costs. Advance purchase rail travel between Philadelphia and Washington is virtually identical to the cost of travel by car, using Penn mileage reimbursement rates.

#### Other Research and Travel Funding

I currently have no research or travel funding from my department or other sources (excluding general stipend support). A proposal for a Dissertation Research Fellowship from the School of Arts and Sciences is currently under review. If funded, it would support additional research travel, supplementing the funding requested in this proposal.

#### Signatures

/s/ Jason L. Schwartz

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Jason L. Schwartz, MBE, AM

/s/ Robert Aronowitz

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Robert Aronowitz, MD