

GLOBAL KNOWLEDGE, GLOBAL LEGITIMACY? TRANSATLANTIC BIOMEDICINE SINCE 1970

Conference at the German Historical Institute Washington, September 6-7, 2019. Co-sponsored by Deutsche Forschungsgemeinschaft. Conveners: Axel Jansen and Claudia Roesch (GHI Washington). Participants: Anna-Carolin Augustin (GHI), George Aumoithe (Princeton University), Jamie Cohen-Cole (George Washington University), Mario Daniels (Georgetown University), Donna Drucker (Technical University of Darmstadt), Elisabeth Engel (GHI), Ricardo Gomes Moreira (University of Lisbon), Markus Hedrich (University of Hamburg), Stephen Mawdsley (University of Bristol), Raúl Necochea López (University of North Carolina), Todd Olszewski (Providence College), Atiba Pertilla (GHI), Jeffrey S. Reznick (National Library of Medicine), Sarah Rodriguez (Northwestern University), Mathias Schütz (University of Munich), Susan L. Speaker (National Library of Medicine), Gaëtan Thomas (École des Haute Études en Sciences Sociales), Richard F. Wetzell (GHI). Guests: Teresa Huhle (University of Bremen), Chelsea Schields (UC Irvine & GHI).

All aspects of the biomedical enterprise, including laboratory and clinical research, drug and device development, and public health applications, have become global in scope during the past fifty years. In the process, global research practices have prompted support and resistance informed by varied beliefs and worldviews, some with transnational scope and with an impact on national laws as well as on the regulation of research and therapy. Cultural, moral, or religious considerations have affected the ways in which scientific insights or technologies were enabled, received, or restricted. Concerns about the availability of therapies has sparked public debates and led to national and global responses by advocacy groups, foundations, political parties, and governments. Biomedicine is, in fact, an area where many social, political, and economic developments since 1970 come together, and this conference was organized to explore how the history of medical science and biotechnology might function as a gateway to understanding the broader history of the era.

In their welcome address, Axel Jansen and Claudia Roesch noted the many ways that the bioscience enterprise has shifted since the 1970s, including the role of science in society at the national and global levels, and the changes in regulation, research, and social movements. They also observed that national frames for biomedicine

are increasingly those of “identity issues” or individual rights rather than “national mission.” They asked the conference participants to consider what narratives we might draw from the past 50 years; what this era says about current patterns and issues; how we relate advances in biomedical research to the ways we legitimize it, how definitions of “expert” have changed, and how the legitimacy of knowledge is negotiated; and how social movements have framed criticisms of science, and the ways that both critics and advocates have organized at transnational levels.

The first panel, moderated by Mario Daniels, dealt with international public health. Gaëtan Thomas’s paper re-examined the French controversy over hepatitis B vaccine use during the 1990s. The broad campaign to immunize against hepatitis B was shut down (apparently) due to alleged side effects, especially multiple sclerosis. But Thomas showed that the controversy also reflected concerns about the close relationship between France’s public health establishment and the World Health Organization (WHO), especially the latter’s growing acquiescence to aggressive pharmaceutical industry pricing of the vaccine. Raúl Necochea López’s study described how the Pan American Health Organization (PAHO) reinvented its cervical cancer control strategy in response to the United Nations “Decade for Women” initiative from 1976 to 1985. PAHO’s original cancer screening effort (begun in the 1960s) was limited to Pap smears and targeted mainly middle-class women in their reproductive years. The new program was much broader, encompassing prevention, patient education, and research on the biological, cultural, social, economic, and political determinants of women’s health. Equally important, it sought to educate a “critical mass of health professionals” in the gender contexts of health.

Elisabeth Engel chaired the second panel, which focused on international regulation and business interests in biomedical debates. Claudia Roesch looked at the controversies surrounding the market introduction of the abortion pill RU 486 (Mifepristone) in the late 1980s and early 1990s, showing how social and political movements shaped drug development and marketing. While anti-abortion protests initially delayed its introduction in France, the French state soon nationalized the patent and made RU 486 available. Yet the manufacturer, Roussel Uclaf, only distributed to France and Britain, and was reluctant to expand into the U.S. and Germany. Anti-abortion activists drew on the Nazi-era history of the parent company (Hoechst

AG) to protest the drug and threatened to boycott Hoechst's other products. At the same time, transnational networks of pro-choice women's health activists used conferences and petitions to demand access to RU 486, focusing on economic benefits and other possible uses of the drug, rather than moral implications. Stephen Mawdsley's paper explored an unusual occupational disease, aerotoxic syndrome, reported by airline crews in the 1980s. The likely cause was TOCP (triorthocresylphosphate), a known neurotoxin used in lubricants and plasticizing agents. Air crews could be exposed when aerosolized chemicals (including TOCP) from jet engines were passed through the cabins during the pressurization process. Flight crews' efforts to have aerotoxic syndrome recognized as a legitimate (and compensation-worthy) illness were resisted by the airline industry and regulators, who pointed to lack of clear evidence for the syndrome. Victims and their advocates gathered their own data, from personal accounts to toxicological screening, and searched the medical and scientific literature for documentation of TOCP's effects. While they eventually succeeded in changing some practices and airplane design, the story highlights a debate over "evidence" reminiscent of those regarding tobacco- or asbestos-caused diseases.

Atiba Pertilla moderated the third panel, titled "Laypeople in HIV Research and Medicine." George Aumoithe's paper examined the development of the AIDS movement's lay expertise in the National Institutes of Health (NIH) AIDS Clinical Trial groups, highlighting the roles that race, racism, sexism, and gender played in that process between 1987 and 2003. The study followed negotiations between professional and lay groups, and the ways their interactions shaped AIDS control and therapeutic agendas, challenged the apolitical stance of bench scientists, and changed the character of the groups themselves.

Sarah Rodriguez's paper looked at the ethical debate that developed around international clinical trials of AZT (azidothymidine) to treat HIV-positive pregnant women, in 1997. The clinical trials aimed to assess the effects of AZT on "vertical" transmission of HIV from mother to fetus and compared full-course treatment to placebo, rather than to short-course treatment. Critics focused on the research ethics. But, Rodriguez said, there are other stories that might be told, e.g., the dangers of the women subjects knowing their HIV status (a requirement for participation) in the regions where studies were done, and the social, economic, and political structures that defined

HIV-infected women as valuable subjects only in relation to their fetuses/babies.

The papers presented in the final Friday panel, chaired by Richard Wetzell, highlighted the ways in which biomedical research projects, particularly “inclusive” genomic studies examining a wide range of populations, are negotiating (or not) shifting notions of race and diversity, and the possible social, political, and scientific outcomes of new definitions. Markus Hedrich discussed the persistence of colonial-era racial assumptions in the African Genome Variation Project, which studies disease resistance, genetic diversity, and ancestry in sub-Saharan populations. In highlighting differences via genomic variation, he argued, the project relies on an old paradigm, in effect applying a molecular-level “colonial gaze.” Hedrich called for a decolonizing of big-data biomedicine and noted that current efforts to connect “ethnicity” and “infectious disease” could backfire. Ricardo Moreira looked broadly at how genetics has helped redefine “difference,” and at the recent turn toward “ancestry” rather than “race” in population studies (ancestry, unlike race, is always a mixture, and study must begin with individual genomes). This changing scientific view of diversity originated not just with “inclusion and difference” research policies, but with quantum leaps in data technologies, statistical methods, and biobanking. Scientific networks that have developed around genomics are generating new frameworks for dealing with “race,” much as the post-World War II “Atoms for Peace” initiative redefined “atomic power.”

The conference resumed on Saturday; the first session, chaired by Anna-Carolin Augustin, focused on medical research and human reproduction. Donna Drucker’s presentation looked at the strange career of the cervical cap contraceptive device from 1976 to 1993. Though not a new technology in the 1960s, the caps were unavailable in the U.S., and the primary manufacturer in Britain, Lamberts Dalston, hoped to phase out production. American women’s health advocates wanted to import the devices as alternatives to birth control pills and IUDs but the U.S. Food and Drug Administration (FDA) required clinical trials to reclassify caps as class II devices. When Lamberts Dalston, wary of lawsuits, wouldn’t organize the trials, the non-professional citizen-activist National Women’s Health Network took on the task, setting up trials at 11 women’s health centers. The FDA eventually approved one type of cap, but Lamberts Dalston chose only one U.S. distributor (unconnected with the activists), which

regulated the product so tightly that U.S. marketing wasn't sustained. The story illustrated the difficulty of establishing national regulatory frameworks that support international cooperation for the research, testing, and approval of biomedical technologies.

The last conference panel, chaired by Jeffrey Reznick, focused on trans-national medical ethics. Todd Olszewski's paper examined how the National Institutes of Health struggled to redefine its mission starting in the 1970s, following two decades of explosive growth and expanding influence. Was it a research agency or a "health" agency? With growing health care costs and public distrust of both government and medicine in that era, the NIH increasingly caught criticism for the lag between research discoveries and clinical application. Olszewski's study showed how NIH leadership tried to formulate mission statements (and 5-year funding plans) that reflected commitment to multiple constituencies: scientists, patients, consumers, and the biotech industry. It also demonstrated that tension between the various stakeholders remains. Mathias Schütz's presentation asked why biomedical ethics standards formulated in the U.S. and widely adopted elsewhere after the 1960s were taken up only slowly in the Federal Republic of Germany. Although the new bioethics were actively introduced and well-received in Germany, the German biomedical professions were reluctant to cede the legitimacy of their own local "medical ethics" to the more "global" definitions.

In a lively final discussion session led by Axel Jansen, participants identified themes that emerged from the presentations and returned to the initial question, i.e., how could we use these recent histories in global biomedicine to inform historical accounts of the decades since 1970, perhaps as an alternative to, or complementary to, historical narratives demarcated by wars and other political events. Globalization of science and biopolitics, expansion of international agency missions, and shifting demands and expectations regarding health issues characterize this period. One recurring theme was that of increasing lay participation in the biomedical enterprise, whether through consumption of health products, advocating for or against particular disease research, or grassroots activism focused on broader social change, and the dynamism of that participation. While individual rights are a common focus of these decades, conservatism and resistance to change also run through these histories. Negotiations (and conflicts) regarding knowledge and the locus of expertise formed another theme. One prominent thread in the papers and

discussions was the risks of what Steven Epstein calls the “inclusion and difference paradigm,” the current research and policy focus on including diverse groups as participants in medical studies and measuring the differences across those groups. Epstein notes that while this approach has expanded knowledge about formerly neglected populations, focusing on categorical identity (e.g., ethnicity, gender, age) can obscure other ways in which health risks are distributed in society. And by emphasizing the biology of difference, such studies encourage the belief that qualities such as race and gender are essentially biological, and that social inequalities are best remedied by attending to biological particularities. Current studies of difference are also still haunted, even threatened, by a long history of gender and ethnicity research done mainly to confirm social notions of superiority or inferiority. Participants enthusiastically agreed that the papers could be the basis of an edited volume and discussed ways to organize such a work.

Susan L. Speaker (U. S. National Library of Medicine)