

12-4547-CV

United States Court of Appeals
for the
Second Circuit

THE AUTHORS GUILD, INC., THE AUSTRALIAN SOCIETY OF AUTHORS LIMITED, UNION DES ECRIVAINES ET DES ECRIVAINS QUEBECOIS, ANGELO LOUKAKIS, ROXANA ROBINSON, ANDRE ROY, JAMES SHAPIRO, DANIELE SIMPSON, T.J. STILES, FAY WELDON, THE AUTHORS LEAGUE FUND, INC., AUTHORS' LICENSING AND COLLECTING SOCIETY, SVERIGES FORFATTARFORBUND, NORSK FAGLITTERAER FORFATTERO OG OVERSETTERFORENING, THE WRITERS' UNION OF CANADA, PAT CUMMINGS, ERIK GRUNDSTROM, HELGE RONNING, JACK R. SALAMANCA,

Plaintiffs-Appellants,

(For Continuation of Caption See Inside Cover)

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

**BRIEF OF *AMICUS CURIAE* MEDICAL HISTORIANS IN SUPPORT
OF DEFENDANTS-APPELLEES AND URGING AFFIRMANCE**

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v.

HATHITRUST, CORNELL UNIVERSITY, MARY SUE COLEMAN, President,
University of Michigan, MARK G. YUDOF, President, The University of
California, KEVIN REILLY, President, The University of Wisconsin System,
MICHAEL MCROBBIE, President, Indiana University,

Defendants-Appellees,

NATIONAL FEDERATION OF THE BLIND, GEORGINA KLEEGER, BLAIR
SEIDLITZ, COURTNEY WHEELER,

Intervenor Defendants-Appellees.

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INTEREST OF *AMICUS CURIAE*

Amici are specialists in the history of medicine who hold teaching and research positions at prestigious research universities in the United States.¹ They respectfully submit this brief of *amicus curiae* in support of Appellees. *Amici*'s intent in writing the brief is not to address the legal issues involved in the case but rather to provide the Court with information about how a large group of people, namely scholars who use libraries to conduct their research, will be profoundly affected by the outcome of this appeal. *Amici*'s institutional affiliations are provided for identification purposes only, and imply no endorsement of the views expressed herein: Nancy Tomes, Ph.D. (Professor of History at Stony Brook University, President of the American Association for the History of Medicine); Rima D. Apple, Ph.D. (Professor Emerita at the University of Wisconsin-Madison); David Barnes, Ph.D. (Associate Professor of History and Sociology of Science and Director of the Health and Societies Program at the University of Pennsylvania); Jeremy Greene, M.D., Ph.D. (Elizabeth Treide and A. McGehee Harvey Chair in the History of Medicine at the Johns Hopkins University School of Medicine); David Jones, M.D., Ph.D. (A. Bernard Ackerman Professor of the

¹ Pursuant to Fed. R. App. P. 29(c)(5) and Local Rule 29.1(b) of the United States Court of Appeals for the Second Circuit, *Amici* hereby certify that no party's counsel authored this brief in whole or in part; no party or party's counsel contributed money intended to fund preparing or submitting the brief; and no person other than *Amici* contributed money intended to fund preparing or submitting the brief.

Culture of Medicine at Harvard University); Arleen Marcia Tuchman, Ph.D. (Professor of History and affiliated faculty member of the *Center for Medicine, Health and Society* and the *Center for Biomedical Ethics and Society* at Vanderbilt University.)

SUMMARY OF THE ARGUMENT

The ability to freely and easily identify and locate diverse research materials and existing medical research is essential not only to the integrity of medical historiography but to the medical and public health communities as a whole. An inability to access text-searchable databases whose scope reaches back decades, such as HathiTrust, would diminish researchers' ability to learn from and build upon past research, and would have a crippling effect on the medical community's capacity to adequately address the many challenges still unsolved in the modern medical world.

ARGUMENT

Historical researchers depend upon research libraries to do their work and thus have a vested interest in preserving the tradition of fair use that has long guided their use. Restrictions on research libraries' abilities to use new digital technologies to preserve sources and make them key word searchable would have a very negative impact on scholarship in the United States. In the case of the history of medicine, the kind of enhanced access to library collections provided by the

HathiTrust will facilitate researchers' ability to provide useful information and strategic advice about health issues of great importance. Thus the *Amici* write in support of the HathiTrust's appeal.

The Court may be surprised to learn how useful historical research is in the field of health research. As health policy experts are the first to admit, many important health problems have not yet yielded quickly or easily to the power of modern biomedicine. In some cases, the problem lies with unequal distribution of resources; new medical technologies and pharmaceutical discoveries are too expensive for widespread use, especially in developing nations. In other cases, available knowledge about the disease is hampered by ethical questions or social issues that limit its application. And last but not least, in a great many cases science has yet to develop a "magic bullet" capable of curing a specific disease.

For all these reasons, understanding how diseases and their management have evolved over time is a very important tool for health policy makers. By delving deeply into the original sources of the past, including newspapers, government reports, scientific journals and monographs, historians provide a wealth of insights into the political, social, and economic factors that shape both the expression and treatment of illness. Over the past decade, the growing availability of digitized sources and keyword searching has added new depth to the quality of this work. Agencies as diverse as the Centers for Disease Control, the

Department of Defense, the National Academy of Medicine, the National Institutes of Health, and the World Health Organization have all used information provided by historians to inform their strategies regarding major health problems as diverse as child and maternal health, disability policy, infectious disease management, industrial health and safety, and environmental risk management. Major health science journals such as the *Journal of the American Medical Association*, *The New England Journal of Medicine*, and the *American Journal of Public Health* regularly feature historical articles on these and other topics. Two examples that illustrate the utility of historical research are the management of pandemic infectious diseases and the evaluation of drug safety.

Public health authorities around the world today are concerned about how well they can manage pandemics involving viral diseases, either novel strains of existing diseases or completely new agents. As scientific understanding of viruses has grown since the 1980s, global health experts have come to better understand the likelihood of such threats. Viruses replicate so often that their chances of mutating into new and potentially more dangerous variants are very high. Viruses also have the capacity to swap genetic material with their counterparts that affect other species, such as birds and swine, creating even more unpredictable and possibly deadly new strains of disease. Outbreaks of SARS in 2002 and a novel strain of the H1NI influenza virus in 2009 caused worldwide concern. Just last

week came news of a death from SARS in France. There are no effective cures for these viral diseases; all health professionals can do is to provide supportive therapy to the ill and try to limit the disease's spread to others. Their best case scenario is to slow down the novel strain's spread long enough for scientists to develop an effective vaccine. The methods of slowing disease transmission in 2013 remain much as they were in 1918: isolation of the ill and other social distancing measures.

These facts help explain the intense interest among public health authorities in the history of the last great pandemic of the H1N1 influenza, which occurred in 1918-1919. Estimates of the world wide death rate range from 40 million to 100 million. (Poor record keeping makes the exact count unavailable.) In the United States alone, an estimated 675,000 people died, many of them young and healthy adults. The chaos of wartime, along with new forms of transportation and mass media, combined to make the influenza pandemic both very lethal and widely feared. Although much has changed since 1919, the ways in which modern media, easier transportation, and urban lifestyles contributed to the disease's spread have clear parallels to conditions today. Moreover, there remains no "cure" for influenza. Hence contemporary public health agencies have been interested in learning more about the impact of the 1918-1919 pandemic in the United States as part of strategic planning about how to manage a similar disease event in the early

21st century. To give but one example of this rich literature, *Public Health Reports* in 2010 dedicated a special issue to historical works on the influenza pandemic exploring the lessons to be learned from its successes and failures.²

The field of pharmaceutical research likewise illustrates the urgency for digitizing past medical periodicals and printed publications in text-searchable format. In the first years of the 21st century, researchers at Johns Hopkins University School of Medicine began to test a promising new inhaled medication for the treatment of asthma. The medication, hexamethonium, was an acetylcholine receptor ganglionic blocker initially used systemically for the treatment of high blood pressure, which had fallen out of favor in clinical use by the early 1970s. The Johns Hopkins team theorized, however, that an inhaled version of the drug might actually be useful for relaxing airway constriction in the treatment of asthma. To the best of their knowledge, hexamethonium had never been used as an inhaled agent and showed great promise. A few scattered papers in the medical literature from the 1970s suggested no evidence that inhaled hexamethonium was harmful. They initiated clinical trials in healthy human volunteers in the spring of 2001.

One of the healthy volunteers enrolled for this trial, Ellen Roche, received her first dose of inhaled hexamethonium on May 4, 2001. The next day she

² Influenza Pandemic in the United States, 125 *Public Health Reports* (2010).

developed a cough, and soon developed a fever as well. A CT scan conducted on May 12 showed extensive ground-glass opacities in both lungs, and two days later she required mechanical ventilation in an intensive care unit. Before the month was out she was dead.

It should be added that Ellen Roche did not have asthma and therefore did not stand to benefit materially in any way from her participation in the study. As her shocked family, colleagues, and journalists began to ask why a perfectly healthy volunteer had died from the administration of an experimental drug, more attention was paid to the back history of hexamethonium itself. Journalists from *The New York Times* turned up physical copies of undigitized medical articles published in the 1950s that clearly indicated hexamethonium was associated with lung toxicity. As the *New York Times* reported, “when [the lead researcher] applied to the Hopkins review board for approval to perform the experiment, his literature search apparently failed to turn up those papers.”³ Why? In part because they were not indexed as part of the most commonly-used online database of the clinical literature, *PubMed*, which has only systematically indexed articles from 1966 onwards.

The digitized collections of the HathiTrust, however, contain text-searchable clinical journals and texts which include nearly 20,000 digitally text-searchable

³ James Glanz, *Cues of Asthma Study Risks May Have Been Overlooked*, N.Y. Times, July 27, 2001.

entries regarding hexamethonium prior to 1966. A simple Boolean search pairing “hexamethonium” with “toxicity” and “lung” produces multiple references to prominent papers from the 1950s—including more than 100 explicit references to a condition known as “hexamethonium lung.” The condition was first described in 1954, and had already, by 1956, been widely discussed by pharmacologists, pulmonologists, and cardiologists as a cautionary tale in experimental pharmacotherapeutics. These reports were in prominent medical journals. “In recent years the use of hypotensive drugs has attracted increasing attention,” wrote two physicians in a review of “Hexamethonium Lung” in 1956. “The present case is reported to show that such therapy may not always be free of danger...and to draw attention to an unusual fibrosis occurring in the lungs of some cases under treatment with drugs of the hexamethonium series.”⁴ In short, the hazards of hexamethonium had been well-documented in the modern medical literature, just not in the medical literature indexed by conventional digital databases such as PubMed. Had the fulltext-searchable database of digitized historical documents of the Hathi trust been available to Johns Hopkins University medical researchers in 2001, the flawed study would quite likely never have taken place and Ellen Roche may very well not have died a senseless death.

⁴ Wallace Park and FJ Cockersole, ‘*Hexamethonium Lung*’: *Report of a Case Associated With Pregnancy*, 63(5) *British J. of Obstetrics and Gynecology* 728 (1956)

In response to Ellen Roche's death, in July of 2001, the United States Office for Human Research Protections (OHRP) placed the status of almost all federally-funded human subjects medical research at Johns Hopkins University in indefinite suspension. This was a heavy price for Hopkins to pay, but not nearly as heavy as that paid by Ellen Roche and her family. In the field of medical research, online accessibility of historical records can be a matter of life or death.

These examples could be multiplied many times over. Historians of medicine are actively involved in many important areas of research: the evolution of industrial health and safety issues; the control of infectious diseases such as tuberculosis, malaria, dengue fever, and polio; the changing ethics of human subject experimentation; the impact of new pharmaceutical agents on the diagnosis and treatment of disease; the impact of unequal access and discrimination on specific groups such as women, children, racial and ethnic minorities; the factors leading to increases and decreases in specific diseases such as lung cancer, cardiovascular disease, and type 2 diabetes; and the efficacy of public health measures such as mandatory vaccination and sex education.

In order to do our research, *amici* rely heavily on the books and journals available in research universities. While some universities have extensive collections, others do not. Researchers at newer institutions rely heavily on being able to borrow, through interlibrary loan, from the collections of older universities,

including those who are part of the HathiTrust project. By digitizing their holdings and allowing enhanced keyword searching of their contents, the HathiTrust project is making it easier for historians of medicine to find sources for their work. The project does not make the scanned book available to researchers; rather it lets them know that the book exists and can either be purchased or requested via interlibrary loan, just as the researcher would do had they located the material using a conventional subject heading supplied by World Cat or some other online database of library holdings. These benefits are especially important to scholars with disabilities whose physical access to libraries may be limited, or who may have limitations on their sight that make conventional reading practices difficult.

Amici, who as a group have authored twenty books, appreciate the importance of copyright and the protection of creative property. Although they profess no expertise on the legal issues involved in this case, what the HathiTrust is doing does not seem to threaten authors' rights to protect their work.


CONCLUSION

Libraries are under tremendous pressures right now due to new technologies, ever rising journal fees, storage difficulties, and the inevitable deterioration of print sources. As the United States struggles to compete in a global knowledge economy, it needs to protect the national treasures that its great research libraries represent so that they will still be available to our children and

our grandchildren. Historians' ability to provide useful perspectives on pressing health issues depends upon the good health of our research libraries. Thus, speaking on behalf of our fellow historians of medicine, *Amici* respectfully ask the court to consider the negative impact that overturning this decision on appeal would have on the production of useful knowledge.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This *amicus* brief complies with the type-volume limitations of Fed. R. App. P. 29(d) & 32(a)(7)(B), because this brief contains 2447 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii). This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14 point font.

Dated: New York, New York
June 4, 2013

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CERTIFICATE OF SERVICE

I hereby certify that on June 4, 2013, I electronically filed the foregoing *amicus* brief with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. The participants in the case who are registered CM/ECF users will be served by the appellate CM/ECF system.

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