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"Can You Handle the Truth?"

"Subjected to Science: Human Experimentation in America before the Second World War"

Susan E. Lederer, 1995, 208 pages, The Johns Hopkins University Press, \$19.95

Review by Norman M. Goldfarb

"Subjected to Science" is essential reading for anyone concerned with clinical research public policy and attitudes. It tells the story of how medical researchers largely succeeded in defending human and animal experimentation from attacks by the antivivisectionist movement between the U.S. Civil War and the Second World War.

Translated literally, vivisection refers to surgery. However, the objective of the antivivisectionist movement was to stop or reform medical experimentation on animals and vulnerable humans such as children. In the absence of effective antibiotics and today's scientific understanding of disease, many research studies carried significant risk to study subjects. In an era when human and animal experimentation was not regulated, ethical abuses – by today's standards (for the ethical relativists among us) – were common. There were frequent public debates about who had the authority to give consent for children in public orphanages to participate in research studies.

Medical researchers had strong arguments on their side as well. The only alternative to animal research was often human research. The only alternatives to human research were ad hoc experiments on patients or no research at all, neither approach conducive to medical progress. Ultimately, medical researchers won the battle for public support by saving democracy with medical marvels such as antibiotics and X-ray imaging in a wartime atmosphere of hyper-patriotism that acclaimed study subjects – "scientific heroes and martyrs" – for sacrificing their health and even their lives for the public welfare.

It was not until the assumed moral authority of medical research experts – and every other expert – dissipated in the 1960s that progress could be made towards a grand bargain: Human and animal research could proceed, but in an environment of evolving government regulation.

The major clinical research public policy issues of today include drug safety (i.e., zero risk) and clinical trial publication ("transparency"). The drug safety issue will likely evolve into much-needed improvements in post-marketing surveillance for adverse events. As the affordability of medical treatment continues to erode, economics are likely to play a larger role in clinical research, especially with the new generation of miraculously effective and expensive drugs. The globalization of clinical research is raising cross-cultural ethical issues, but will likely evolve naturally into a relatively uniform regulatory environment based on ICH guidelines and accommodations for local considerations.

Based on the history of the antivivisectionist movement, the perspectives of medical researchers are more likely to prevail if (a) they continue to deliver affordable health benefits to the public and (b) they do not dissipate their morale authority with (apparent) ethical abuses. The battle has been joined on both fronts, so the story of today's public policy issues remains to be told.

The book is available at bookstores.

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