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Vol. 6, No. 11, November 2010 "Can You Handle the Truth?"

"Dark Medicine: Rationalizing Unethical Medical Research"

William R. LaFleur, Gernot Böhme & Susumu Shimazono, editors, 2007, 259 pages, American Public Health Association, $22.00

Review by Norman M. Goldfarb

"Dark Medicine: Rationalizing Unethical Medical Research" explores the mystery of how apparently upstanding citizens can engage in appalling human research experiments. Until we understand the failure mechanism, our attempts to prevent unethical research are likely to be ineffective and wasteful. The book's premise is that rationalization is at the heart of the problem.

Physicians and scientists did not participate in the Nazi atrocities because of incompetence, madness or coercion; they participated because they convinced themselves that it was the right thing to do. What is the harm in medical experiments that kill death camp prisoners a bit early, especially when the food and beds are so much better? Why waste precious bullets and manpower needed for the survival of the motherland when scientifically designed gas chambers are so much more efficient?

After the horrors of the war became public knowledge, numerous U.S. doctors still conducted grossly unethical human experiments because they did not see how the Nuremburg code could apply to morally upright American doctors. In 1965, Henry Beecher, a professor at Harvard Medical School, delivered a lecture describing articles published in scientific journals based on at least 50 ethically questionable research protocols. Dozens of physicians participated in the Tuskegee syphilis study, publishing a multitude of scientific papers over a 40-year period, before anyone noticed the ethical atrocity. Albert Kligman won prominent honors and awards for his medical research in dermatology long after his abhorrent experiments at Holmesburg Prison were well documented.

In other words, unethical research is not conducted by an evil cabal but by apparently normal people who have rationalized their conduct. Stanley Milgram's obedience experiment and Philip Zimbardo's simulated prison experiment demonstrated how easy it is to transform normal people into sadistic monsters. It was so easy, in fact, that their experiments are often cited as notably unethical.

The question is thus not how to keep evil people out of human research, but how to prevent normal people from rationalizing evil research. We have thus developed an elaborate system of regulations, guidelines, institutional policies, institutional review boards (ethics committees), training programs, monitoring, audits and inspections. Although this system may work to prevent problems due to rationalization, it is possible that the system could be streamlined and made more effective if the problem of rationalization were to be addressed directly.

Grossly unethical human research is mostly a thing of the past, but the ethics are not settled in some newer areas, e.g., genetic data, human embryos, and research in low-resource (developing) countries. Even violations of the basic principle of informed consent are rationalized on a daily basis, as demonstrated by indigestible informed consent forms that do not comply with the regulatory requirement: "The information that is given to the subject or the representative shall be in language understandable to the subject or the

representative." (21 CFR 50.20) In fact, we have managed to rationalize regulations that only require subjects to be "informed" in the sense that the information *is provided to them*, but not in the more important sense that they *understand that information*. The ICH E6 Guideline for Good Clinical Practice (1996) defines informed consent as a "process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, *after having been informed* of all aspects of the trial that are relevant to the subject's decision to participate." (ICH E6 1.28) (Italics added.) The guideline further states that "the language used in the oral and written information about the trial, including the written informed consent form, should be as non-technical as practical and should be understandable to the subject" (ICH E6 4.8.6). A narrow reading of the guideline does not require that the subject understand the language, but some effort should be required to confirm understanding.

The book consists of 16 essays:

- Rationalizing Unethical Medical Research: Taking Seriously the Case of Viktor von Weizsacker
- Medical Research, Morality, and History: The German Journal Ethik and the Limits of Human Experimentation
- Experimentation on Humans and Informed Consent: How We Arrived Where We Are
- The Silence of the Scholars
- The Ethics of Evil: The Challenge and the Lessons of Nazi Medical Experiments
- Unit 731 and the Human Skulls Discovered in 1989: Physicians Carrying Out Organized Crimes
- Biohazard: Unit 731 in Postwar Japanese Politics of National "Forgetfulness"
- Biological Weapons: The United States and the Korean War
- Experimental Injury: Wound Ballistics and Aviation Medicine in Mid-century America
- Stumbling Toward Bioethics: Human Experiments Policy and the Early Cold War
- Toward an Ethics of Iatrogenesis
- Strategies for Survival versus Accepting Impermanence: Rationalizing Brain Death and Organ Transplantation Today
- The Age of a "Revolutionized Human Body" and the Right to Die
- Why We Must Be Prudent in Research Using Human Embryos: Differing Views of Human Dignity
- Eugenics, Reproductive Technologies, and the Feminist Dilemma in Japan
- Refusing Utopia's Bait: Research, Rationalizations, and Hans Jonas

The book is available in bookstores.

Reviewer

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