The Federal Government and Academic Texts as Barriers to Informed Consent

Angela Lanfranchi, M.D.

ABSTRACT

Informed patient consent for medical treatment is required by both law and medical ethics. Yet, both federal agencies and academicians are participating in the suppression of information about the heightened risk of breast cancer posed by oral contraceptives and induced abortion. There is historical precedent in the long-delayed acknowledgment of the smoking/lung cancer link.

By law, a patient has the right to be fully informed of the nature of her medical condition and any proposed course of therapy. It is assumed that a patient will be given the complete and true scientific basis of her diagnosis and treatment, to ensure that her well-being and her autonomy in decision-making are protected.

Informed consent is the process by which a patient can participate in choices about medical treatment. It originates from the legal and ethical right of the patient to direct what is done to her body, and from the ethical duty of the physician to involve the patient in her medical care.

Our federal government has become a barrier to informed consent concerning oral contraceptive drugs and induced abortion.

NIH and NCI Violate Their Mission Statements

Both the National Institutes of Health (NIH) and the National Cancer Institute (NCI), a component of the NIH, have violated their mission statements.

The NIH has as its stated mission "science in pursuit of fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to extend health life and reduce the burdens of illness and disability." It included as its fourth goal to "exemplify and promote the highest level of scientific integrity, public accountability, and social responsibility in the conduct of science."[1] In pursuit of its goal of improving the nation's health, it conducts and supports research in the causes, diagnosis, prevention, and cure of human diseases.

The NIH has failed to perform its mission in very significant ways. There is evidence of widespread fraud in connection with NIH-funded research. In June 2005, a study of NIH grantees by three scientists, published in the prestigious British journal *Nature*, documented fraud. Anonymous questionnaires revealed that a statistically significant 15.5% of scientists admitted to "changing the design, methodology or results of a study in response to pressure from a funding source," i.e. the NIH itself. More alarmingly, NIH proved to be a corrupting influence, as 9.5% of early career scientists admitted this unethical behavior, and by mid-career 20.0% admitted to it.[2]

These significant problems with scientific integrity had come to light earlier through some 2003 investigative work done by a reporter, David Willman of the *Los Angeles Times*.[3] In February 2005, the Alliance for Human Research Protection applauded Dr. Elias Zerhouni, director of the NIH, for acknowledging the magnitude of financial conflicts and ethical violations, and organizing an ethics summit so as not to lose public trust in all research.[4]

The NCI has also flagrantly ignored one of its major missions of "new information dissemination mandates" as required by Congressional legislative amendments to its original National Cancer Program.[5]

Estrogen-Related Risks Denied or Minimized

Well-documented literature on the carcinogenic effects of oral contraceptives had been published for more than 20 years. But NCI largely ignored it until 2006 when, without fanfare, it put on its web site a page about the carcinogenic effects of oral contraceptives.[6]

Remarkably, 6 years earlier, the National Toxicology Advisory Committee had placed estrogen on its lists of carcinogens (but without the addition of oral contraceptives, which contain estrogen) as a risk factor for breast cancer.[7] In 2005, the World Health Organization's International Agency on Research of Cancer met in France to review the world's literature on estrogen-progestin combination drugs, which include oral contraceptives. They then classified oral contraceptives as class-1 carcinogens.[8] It was a full year before this information appeared on the NCI web site, without any large public awareness campaign for the millions of American women who were taking these drugs and unknowingly increasing their risk for breast cancer.

There is either an effort to obfuscate, for medical personnel, the increased breast cancer risk with oral contraceptives, or incompetence at NCI. The NCI web site has both patient and health professional versions of its breast cancer (PDQ) prevention sections. In July 2007, the patient version clearly listed oral contraceptives ("the pill") as increasing the risk of breast cancer.[9] The health professional version of the same prevention information concerning oral contraceptives was, however, placed under the heading "Factors of Unproven or Disproven Associations," and downplayed by stating that there was a *small* increased risk in current users that diminishes over time, and then giving the reference for a "well-conducted case-control study that did *not* observe any increased risk" [emphasis added].[10] This also

contradicted its own web page placed May 4, 2006, which gave information on oral contraceptives increasing the risk of breast, cervical, and liver cancer.[6]

As of January 2008, both NCI PDQs had been substantially revised. The patient version listed both abortion and oral contraceptives under the heading "The following have been proven not to be risk factors for breast cancer or their effects on breast cancer risk are not known." Elaborating, the PDQ stated that "there does not appear to be a link between abortion and breast cancer," and that "taking oral contraceptives...may slightly increase the risk of breast cancer in current users." The health professional version omitted mention of abortion or oral contraceptives. It listed pregnancy before age 20 as a risk-reducing factor, and hormone-replacement therapy as a risk-increasing factor.

The NCI changes its website information frequently—it was revised more than 20 times in the first 7 months of 2007. Readers might be interested in searching www.cancer.gov on www.archive.org to see how things change.

Also shocking is the blatantly incorrect information given to patients by the NCI web site. For example, under the section of protective factors and decreased exposure to estrogen, it is stated that the exposure to estrogen "is reduced in the following ways: Pregnancy: estrogen levels are lower during pregnancy."[9] This error was still present on the website as of January 2008; perhaps it will be corrected. In fact, pregnancy levels of estrogen *increase* by 2,000% by the end of the first trimester. Either the scientists at the NCI are unaware of this, or they are avoiding the biological explanation of why an early first full-term pregnancy reduces breast cancer risk. It is well established that breast maturation during pregnancy, which changes 85% of breast tissue to cancer-resistant Type 4 lobules, greatly reduces a woman's risk of breast cancer.[11] These same biological facts of breast maturation also account for the increased risk of breast cancer due to induced abortion or premature delivery before 32 weeks.

Another flagrant NCI deviation from its stated mission was its 2003 Workshop on Early Reproductive Events and Breast Cancer Risk.[12] The mission of the workshop was to have 100 scientists review the literature on such risk factors as spontaneous and induced abortion and premature delivery, and then come to a consensus about their importance. The consensus on induced abortion was that there was no association. Premature delivery was considered an "epidemiologic gap." However, the basic biological changes that occur during pregnancy account for the increase in breast cancer risk for both induced abortion and premature delivery shown in the preponderance of studies. [13,14]

Before a woman's first full-term pregnancy (FFTP), her breasts are composed of cancer-vulnerable Type 1 and Type 2 lobules, where ductal and lobular cancers, respectively, start. With increasing levels of the pregnancy hormones estrogen and progesterone, the numbers of these cancer-vulnerable lobules increase, thereby increasing the risk of breast cancer. By 32 weeks of pregnancy, however, early in the third trimester, the pheromones hCG and hPL (human chorionic gonadotropin and human placental lactogen) made by the fetal-placental unit have caused significant maturation of breast tissue. By the end of the third trimester, 85% of the breast consists of cancer-resistant Type 4 lobules containing colostrum. When a pregnancy is interrupted before 32 weeks gestation, either naturally through a live premature birth,[15] or through abortion with the resultant dead fetus, the breast has not significantly matured the increased numbers of cancer-vulnerable Type 1 and Type 2 lobules made during the first and second trimesters. Until maturation is well underway after 32 weeks gestation, the longer a woman is pregnant before premature delivery or induced abortion, the higher her risk of breast cancer because her breasts have greater numbers of lobules where breast cancers start.

Early spontaneous abortions in the first trimester are the result of pregnancies that have lower hormone levels, so that the breasts do not enlarge and create the additional lobules that are at risk for subsequent cancer formation. Either the mother's ovaries or the fetal-placental unit fails to produce enough hormones to sustain the pregnancy. Often women will remark that they miscarried, yet never "felt" pregnant because they didn't experience the normal hormonal changes of nausea or enlarging breasts. Thus, these early abortions do not increase breast cancer risk.

The NCI Workshop on Early Reproductive Events is reminiscent of an event that occurred in Nazi Germany in the 1930s. Hitler was displeased because "Jewish" science was coming to prominence. The government assembled 100 physicists, including two Nobel laureates, to each write an essay against Einstein's theory of relativity. The book was published as *100 Essays Against Einstein*. Einstein remarked to an inquiring reporter that were they correct, "it would have only taken one." In a similar way, our government has interfered with the scientific process of conducting studies and relaying the relevant information to the general public.

Evidence for this bias is plentiful. For example, Leslie Bernstein, an epidemiologist and workshop leader who was interviewed after the workshop, said that having a child was the surest, most effective way to reduce breast cancer risk. In an interview about the workshop she told a reporter: "The biggest bang for the buck is the first birth, and the younger you are the better off you are," followed by: "I would never be a proponent of going around and telling them that having babies is the way to reduce your risk." She also added, "I don't want the issue relating to induced abortion to breast cancer risk to be a part of mix of the discussion of induced abortion, its legality, its continued availability."[16]

That same bias is seen in academic breast cancer texts concerning prevention. In the 2000 edition of *Diseases of the Breast* by Jay Harris et al., early full-term pregnancy is not listed in its table of methods of prevention because, according to its accompanying text, "unplanned early pregnancy and an average of more than 2 completed pregnancies per woman have undesirable social and ecologic consequences."[17] The fact that it takes a fertility rate of 2.3 children per woman to maintain the population is disregarded. The book's recommendations appear to be influenced by the notion that humans are bad for the "ecology." Busy practicing clinicians may rely on tables for a quick answer, rather than reading the text.

Bias is also shown when a text acknowledges that oral contraceptives increase the risk of breast cancer 30%, but concludes that, "considering the benefits of the pill," a slightly increased risk is not considered clinically significant.[18] In my experience as a surgeon, I find that women consider all breast cancer significant, especially when it involves them or a loved one.

NCI leaders seem reluctant to acknowledge an increase in the incidence of breast cancer. In January 2002, Dr. Barnett Kramer, director of the Office of Disease Prevention at the NCI, stated to the *New York Times*: "In the end screening, far from preventing cancer, actually leads to more cancer patients…by finding both those whose cancers would have been deadly and those whose cancers would have remained small…or would have even disappeared…. People often talk about mammograms to prevent breast cancer when what it's done is to increase, not decrease, the incidence of breast cancer."[19] No studies have reported spontaneous regression or resolution of invasive breast cancers without treatment. In fact, it is largely the detection of many more early stage breast cancers that has led to the declining mortality rates of breast cancer, despite its increasing incidence.

There is other evidence, besides the "Workshop on Reproductive Risks," that the NCI has misled public officials. In 2002 New Jersey State Senator Martha Bark requested information from Dr. William Hait, director of the Cancer Institute of New Jersey, an NCI affiliate, about the abortion/breast cancer link (ABC). He responded that "prostitutes have a low incidence of breast cancer, (presumably due to multiple pregnancies)" and that nuns have higher rates due to lack of child bearing. When I asked for the data supporting his statement about prostitutes and breast cancer risk, he admitted there was none. He related none of the supporting evidence for the ABC Link to the senator.[20]

Like the preventive effects of child-bearing, the risk-increasing effect of induced abortion is misstated in major textbooks. In *The Breast: Comprehensive Management of Benign and Malignant Disorders*, oral contraceptives and induced abortion are listed in the table as having "no effect" on breast cancer risk, even though hormone replacement therapy is listed as an increased risk while its measured effect reported in the text is lower or only marginally higher than oral contraceptives or induced abortion. In the table, HRT, with a relative risk (RR) of 1.26 cited in the text, is listed as a "3+ association," while oral contraceptives (RR 1.24) and second trimester abortion (RR 1.38) are listed as having "no effect."[21]

At the San Antonio Breast Cancer Symposium in December 2001, I spoke with Jay Harris, M.D., editor of *Diseases of the Breast*, about the bias shown in the section of his text involving induced abortion. He first responded he was only the editor, but when pressed that he was responsible for all content, replied that a woman such as the head of the National Breast Cancer Coalition, a lay advocacy group, would be needed to bring the information to the public.

Large breast-cancer advocacy groups are now able to raise large sums of money for research and have political influence through lobbying. They also sponsor medical society meetings and give awards to academics. Often the leaders of these lay groups have ties to abortion-rights and abortion-providing organizations. For example, the founder of the Susan G. Komen Foundation, a breast-cancer advocacy and research group, was founded by a Nancy Brinker, who also was a board member for Planned Parenthood, this nation's largest abortion provider.[22] Brinker was also appointed as U.S. ambassador to Hungary. When our current First Lady Laura Bush visited Pope Benedict XVI, she also visited the Komen Foundation offices in Rome. Clearly, Nancy Brinker has direct ties to the executive branch of the government, which in turn makes political appointments to both the NIH and NCI.

Most academics are supported by grants. And most of the information used by practicing physicians—in textbooks or from teaching conferences—is provided by the givers or recipients of grants from the NIH, NCI, or private breast cancer advocacy groups. The bias in these materials is pervasive.

Historical Precedent

As stated in Ecclesiastes, there is nothing new under the sun. In 1860, Dr. Oliver Wendell Holmes, a physician, essayist, and father of the U.S. jurist, in an address to the Massachusetts Medical Society, stated, "Theoretically, medicine ought to go on its own straightforward inductive path without regard to changes of government or to fluctuations of public opinion.… The truth is that medicine, professionally founded on observation, is as sensitive to outside influences, societal, religious, philosophical, imaginative, as the barometer is to the changes of atmospheric pressure."[23]

I do not believe it was coincidence that on May 7, 2006, only four days after the NCI posted on its web site for the first time information that oral contraceptives were carcinogenic, there was a cover article in the Sunday *New York Times* magazine titled "The War on Contraception." Nor do I believe it was coincidence that the *New York Times* editorial *before* the Workshop on Early Reproductive Events in 2003 stated that the workshop would bring to an end the notion that abortion and breast cancer were linked, if all the experts agreed, and that the posted NCI web page would then change.[24] Before the workshop, the NCI's web page had stated that evidence supporting the abortion breast cancer link was "inconsistent."

The use of political pressure to influence the NCI at the expense of the health and well being of the nation it was charged to protect is hardly new. One only has to look at its history a short 50 years ago. The first study linking cigarettes to lung cancer was published in 1928.[25] After World War II, lung cancer, which had once been a rare cancer, was increasing to epidemic proportions. Soldiers had received cigarettes in their C-rations. Print ads showed physicians extolling the stress-reduction and relaxation benefits of cigarettes. One ad reported that "20,679 physicians say Luckies are less irritating to the throat" than other brands. Cigarette smoking had become very popular. Thoracic surgeons, such as Oschner in New Orleans, were calling out for more public awareness of the cancer risk. Yet 30 years after the first study had shown a link between cigarettes and lung cancer, the NCI was still making pronouncements about the need for more study, and the lack of certainty about the smoking/lung cancer link. Tobacco-state senators, protecting the economic interests of their states, influenced the NCI. This was fully documented in the book by former Federal Drug Administration director, Dr. David Kessler, *A Question of Intent: A Great American Battle with a Deadly Industry*.[26] When grassroots awareness campaigns were adversely affecting the popularity of cigarette smoking, the Tobacco Institute was born.

Finally, it was the surgeon general, as the head of the U.S. Public Health Service reporting to an assistant secretary for health in 1964,

who put out the first report that cigarettes were indeed a cause of lung cancer. He had lost the support of the American Medical Association (AMA) for his report after the AMA received several million dollars for continued study of the issue from the Tobacco Institute. However, he was supported by the use of the Bradford Hill epidemiologic criteria for causality in the first Advisory Committee to the Surgeon-General on the Health Consequences of Smoking. These nine criteria were elaborated upon by Sir Austin Bradford Hill in his 1965 presidential address to the Section of Occupational Medicine of the Royal Society.[27]

Hill's criteria, which are widely recognized as a basis for inferring causality, are used to determine whether an association (risk) found in epidemiologic studies is real or artefactual, and whether the association is secondary to a real (factual) cause, i.e. one based upon biological reality. The nine Bradford Hill criteria are: strength of association, consistency, specificity of the association, temporality, biological gradient, plausibility, coherence, experiment, and analogy. The epidemiologic studies showing the abortion/breast cancer link satisfy these nine criteria.[28]

Just as in the past, when the tobacco-state senators brought pressure to past NCI directors to be "cautious" in their public pronouncements about cigarettes as a cause of lung cancer, I do not believe it is coincidence that the states with the highest abortion rates have the senators who are most vocally pro-abortion, for example, those from New York and California.

In the December 2004 issue of *Ethics and Medics*, Dr. Edward Furton writes, "The unwillingness of scientists to speak out against the shoddy research being advanced by those who deny the abortion-breast cancer link is a very serious breach. The lives and health of millions of women are put at risk."[29]

Conclusion

Well-documented breast physiology accounts for the fact that oral contraceptives and abortion are risk factors for breast cancer. There is an effort to suppress this information by federal agencies and those in academic medicine. Without this information, women cannot make a fully informed choice about their method of fertility control or about whether to maintain an unplanned pregnancy. Medical ethics demands that they be informed.

Angela Lanfranchi, M.D., F.A.C.S., is a clinical assistant professor of surgery at the Robert Wood Johnson Medical School and a private practice specialist in breast surgery. Contact: angelabcpi@yahoo.com.

REFERENCES

1. NIH Mission Statement. Available at: www.nih.gov/about/index.html#mission. Accessed Jan 27, 2008.
2. Martinson BC, Anderson MS, deVries R. Scientists behaving badly. *Nature* 2005;435:737-738.
3. Willman D. Stealth merger: drug companies and governmental research. *Los Angeles Times*, Dec 12, 2003, p A1.
4. NIH chief calls for ethics summit to address conflicts of interest in medical research. *Los Angeles Times*, Feb 14, 2005. Available at: www.ahrp.org/infomail/05/02/14.php. Accessed Jan 27, 2008.
5. NCI Mission Statement. Available at: www.cancer.gov/aboutnci/overview/mission. Accessed Jan 27, 2008.
6. Oral Contraceptives and Cancer Risk: Questions and Answers. NCI Fact Sheet, revised May 4, 2006. Available at: http://www.cancer.gov/cancertopics/factsheet/Risk/oral-contraceptives. Accessed Jan 28, 2008.
7. Schmid RE. Scientists vote to list estrogen as carcinogen despite benefits. *Philadelphia Inquirer*, Dec 6, 2001.
8. Cogliano V, Grosse Y, Baan R, et al. Carcinogenicity of combined oestrogen progestagen contraceptives and menopausal treatment. *Lancet Oncol* 2005;6:552-553.
9. NCI. Breast Cancer Prevention (PDQ): patient version. Available at: www.cancer.gov/cancertopics/pdq/prevention/breast/. Accessed July 12, 2007.
10. NCI. Breast Cancer Prevention (PDQ): health professional version. Available at: www.cancer.gov/cancertopics/pdq/prevention/breast/. Accessed Sep 13, 2007.
11. Russo J, Hu YF, Silva ID, Russo IH. Cancer risk related to mammary gland structure and development. *Microsc Res Tech* 2001; 52:204-233.
12. NCI. Summary Report: Early Reproductive Events and Breast Cancer Workshop. Available at: www.cancer.gov/cancertopics/ere-workshop-report/print (posted Mar 4, 2003, updated Mar 25, 2003). Accessed Jan 28, 2008.
13. Lanfranchi A. The abortion breast cancer link: the studies and the science. In: Bachiochi E, ed. *The Cost of Choice*. San Francisco, Calif.: Encounter Books; 2004:72-86.
14. Breast Cancer Prevention Institute. Reproductive Breast Cancer Risks and Breast Lobule Maturation; 2007. Available at: www.bcpinstitute.org. Accessed Jan 28, 2008.
15. Melbye M, Wohlfahrt J, Andersen AM, Westergaard T, Andersen PK. Premature delivery and breast cancer risk. *Br J Cancer* 1999:80;609.
16. Lowe RM. NCI Scientific panel concludes abortion has no impact on breast cancer risk. *CancerPage.com*, Mar 3, 2003. Available at: http://www.cancerpage.com/news/article.asp?id=5601. Accessed Jan 28, 2008.
17. Harris J, Lippman ME, Morrow M, Osborne CK. *Diseases of the Breast,* 2nd ed. Baltimore, Md.: Lippincott, Williams & Wilkins; 2000:211-212.
18. Dixon JM, Sainsbury JR. *Handbook of Diseases of the Breast*. 2nd ed. Churchill Livingstone; 1998:93.
19. Kolata G. Cancer "prevention" is big seller, but medical experts are divided. *NY Times*, Jan 11, 2002, p A1.
20. Hait W. Letter to N.J. state senator Martha Bark, received May 3, 2002.
21. Bland KI, Copeland EM, eds. *The Breast: Comprehensive Management of Benign and Malignant Disease*. 3rd ed. Saunders; 2004:342-345.
22. Life Issues Institute. Susan G. Komen Breast Cancer Foundation and Planned Parenthood: the visible link. Report on Susan G. Komen Grants to Planned Parenthood; August 2005. Available at: www.lifeissues.org/AbortionBreastcancer/komen/grant_report.pdf. Accessed Jan 28, 2008.
23. Holmes OW. Address to annual meeting, Massachusetts Medical Society, May 30, 1860. In: *Currents and Counter-Currents in Medical Science with Other Addresses and Essays*. Boston, Mass: Ticknor and Fields; 1861.
24. Editorial. Abortion and Breast Cancer. *NY Times*, Jan 6, 2003, p. A20.
25. Borio G. The twentieth century: the rise of the cigarette. In: *Tobacco Timeline*. Available at: www.tobacco.org/resources/history/Tobacco_History20-1.html. Accessed Jan 28, 2008.
26. Kessler DA. *A Question of Intent: A Great American Battle with a Deadly Industry.* Cambridge, Mass.: Public Affairs Press; 2001.
27. Hill AB.1965 Presidential address*, Proc R Soc Med* 1965; 58: 295-300.
28. Lanfranchi, A. The breast: physiology and the epidemiology of the abortion breast cancer link. *Imago Hominis* 2005;3:228-236.
29. Furton EJ. The corrupution of science by ideology. *Ethics & Medics* 2004;12:1-2.