

STATE OF NORTH DAKOTA
COUNTY OF CASS

IN DISTRICT COURT
EAST CENTRAL JUDICIAL DISTRICT

Amy Jo Mattson,

Civil No. 99-3734

Plaintiff,

v.

MKB Management Corporation
d/b/a Red River Women's Clinic,

Defendant.

**AFFIDAVIT OF
POLLY A. NEWCOMB, Ph.D.**

POLLY A. NEWCOMB, Ph.D., deposes and says the following:

1. I am a full member of the Fred Hutchinson Cancer Research Center in Seattle. The Center is a non-profit organization that conducts cancer research in the basic and clinical sciences, and it is the largest recipient of National Cancer Institute awards in public health sciences. I am also a Professor of Epidemiology at the University of Washington School of Public Health and a Senior Scientist at the University of Wisconsin. I am an associate editor at two epidemiology journals and provide editorial service to 18 peer-review journals, including the *New England Journal of Medicine* and the *American Journal of Epidemiology*.

2. I received a bachelors of science degree in molecular biology from the Evergreen State College in 1978. I also received a masters in public health and a Ph.D. in epidemiology from the University of Washington in 1982 and 1986 respectively. I

completed a post-doctoral fellowship in cancer biology at the University of Wisconsin in 1988.

3. Since 1988, I have conducted epidemiological research on the causes of cancer, particularly breast cancer, in women. Epidemiology is a specialized biomedical discipline that studies the causes of diseases in populations. Epidemiologists receive advanced training in statistics and statistical analysis and in constructing valid research models for investigating the links between exposures and disease.

4. During my career, I have published 85 articles in peer-reviewed journals, including the *Journal of the American Medical Association*, *New England Journal of Medicine*, and *Journal of the National Cancer Institute*, some of the premier medical journals in the United States. I have also published 5 book chapters and 5 letters to the editor. Nearly all of my publications have been on the topic of cancer in women. Approximately half of these articles discussed breast cancer, and 2 specifically addressed the alleged link between abortion and breast cancer. I have received in excess of seven million dollars in grants as principal investigation from the National Institutes of Health and other agencies to fund this research. A complete list of my publications and presentations (68 national and international) can be found in my curriculum vitae. (See Exhibit A.)

5. From 1988 to 1991, I directed a large population case control study that evaluated the causes of breast cancer. A case control study is a research design in which individuals with a particular diseases (the “cases”) are compared to individuals without the disease (the “controls”) for differences in various life style or biological factors. In this study, we compared 7000 women from four states with breast cancer to 10,000

women without the disease and evaluated a number of potential risk factors, including abortion. At the time that the results were published in the Journal of the American Medical Association in 1996, this study was the largest, published case series to evaluate the potential link between breast cancer and abortion. Since that time, I have conducted 2 additional studies investigating breast cancer and abortion. One of these studies is currently in press and one is not yet published.

6. I have testified as an expert witness regarding the alleged link between induced abortion and breast cancer on one occasion and I have been engaged as an expert consultant regarding the alleged link on at least 3 occasions.

7. I submit this affidavit based upon my training in epidemiology, fourteen years of experience in conducting epidemiological research, including my original research on the alleged link between breast cancer and abortion, and my review of the relevant scientific literature.

Epidemiological Terminology Regarding Potential Risk Factors and Disease

8. Epidemiology is the study of distribution and causes of diseases in populations. Epidemiologists report statistical associations between risk factors and disease by using the summary statistic the “relative risk.” This is the ratio of the risk or incidence of disease in exposed and unexposed individuals.

9. A relative risk of 1 indicates that there is no relationship between the factor studied and the disease. A relative risk of 1.5 indicates that individuals with the risk factor studied are 50% more likely to develop the disease than similar individuals without the risk factor. A relative risk of 5 indicates a 500% increase in risk for developing the disease, compared to the baseline risk in unexposed individuals.

10. In epidemiological terms, a 1.5 relative risk is considered very modest and at the lower limits of meaningful interpretation. For instance, epidemiological studies of the link between smoking and lung cancer show a relative risk of 20 or more.

11. It is important to remember that any percentage increase in risk of developing a disease must always be considered in terms of the baseline risk for that age or profile. Thus, for a twenty year old who may have a very low likelihood of developing a disease, a fifty percent increase would still represent an extremely small risk—since double .00001 is only .00002.

12. An elevated relative risk does not mean that the risk factor studied *causes* the disease in question. Several requirements must be satisfied in order to conclude that epidemiological studies show a cause and effect relationship between a factor and a disease. First, the strength of the association must be considered because the stronger the association, the more confident I can be of the validity of the result. Second, multiple well-conducted studies of different designs, especially of cohort design, must show a similar relative risk observing the association in different populations. Third, biases that may be causing the results should be ruled out. Fourth, a biological mechanism linking the risk factor to the disease should be established. Fifth, alternative explanations for the association should be eliminated. None of these five criteria has been satisfied in studies considering the potential link between breast cancer and abortion.

The Scientific Evidence Does Not Support the Conclusion that Induced Abortion Increases the Risk of Developing Breast Cancer

13. The weight of epidemiological evidence indicates that induced abortion does not increase the risks of breast cancer.

14. The most methodologically sound studies (cohort designs) investigating the potential link between breast cancer and abortion have found relative risks consistent with 1, such as relative risks of 1.2 or 1.3. See Melbye, *et al.*, 1997 (Exhibit B); Lazovich, *et al.*, 2000 (Exhibit C). Other studies also do not indicate a meaningful increase in risk. My case-control study conducted between 1988 and 1991 showed an estimated relative risk of 1.23 between induced abortion and breast cancer. See Newcomb, *et al.*, 1996 (Exhibit D). My more recent record-based study, which is currently to be published in the forthcoming issue of the peer-reviewed journal, *Cancer Causes and Control*, reports that, compared to all women who had never had an induced abortion, the relative risk of breast cancer in women with an induced abortion was 0.9%, with a confidence interval of 0.5 – 1.6. Other well-conducted studies have found a relative risk of 1.2-1.5. See, e.g., Wingo, *et al.*, 1997 (Exhibit E).

15. The confidence interval indicates the degree of certitude which the relative risk estimate excludes chance as an explanation. Relative risk must always be discussed in light of an author's reported confidence interval. When considered in light of the reported confidence intervals, these relative risks indicate to me that there is no established connection between induced abortion and breast cancer.

16. The most methodologically sound studies in this area are “cohort” studies that track exposed individuals for the development of disease—in this case, women who did and did not have abortions—and follow them forward in time for any occurrence of breast cancer in each exposed group. The well-conducted studies include those that have complete follow up (*i.e.*, have outcome information on all subjects) for cohort studies or

high response rates that take into account “confounding” factors; that are large enough to produce precise estimates; and use appropriate statistical techniques for the analysis.

17. The well-conducted epidemiological studies do not support a conclusion that abortion is a risk factor for breast cancer for the following reasons:

- Epidemiological studies are extremely limited for the measurement of small relative risks. Instead, results showing relative risks as small as 1.5 often stem from distortions and biases of the study itself, rather than from a true association between the risk factor and the disease.
- The studies do not show a consistent association for all women between abortion and breast cancer. The studies not only report different relative risks, but they also report that different groups of women are most at risk. Thus, for example, some studies suggest that the highest risk is experienced by women who have abortions before full term pregnancies or at early ages, but other studies do not. Conclusions about risk factors for disease can be made only if a relative risk finding is replicated by many different studies of different designs.
- The best conducted and most valid of the studies shows a relative risk of 1.00, and thus shows no association between abortion and breast cancer. See Melbye, *et al.*, 1997 (Exhibit B).
- No study has established a biological mechanism in humans that could account for a link between breast cancer and abortion.

18. The soundest epidemiological study investigating the link between breast cancer and abortion completed to date is the Melbye study, conducted in Denmark. The results of this study were published in 1997 in the *New England Journal of Medicine*, one of the most respected general science journals in the United States.

19. The Melbye study found a relative risk of 1.00 between induced abortion and breast cancer. In other words, the study found no statistical association between abortion and breast cancer. The study’s methodology makes its results particularly reliable for a number of reasons.

20. First, the Melbye study does not suffer from reporting bias because medical history was obtained from national registries that record all induced abortions and breast cancer cases, rather than from personal interviews with the women. In Denmark, individuals are assigned identification numbers, thus permitting links to be made between the abortion and cancer registries. Reporting bias occurs in epidemiological studies that rely on personal interviews because individuals with the disease being studied may be more likely to report the existence of a potential risk factor than individuals who are healthy. If this occurs, it will appear that the risk factor is more prevalent among the diseased population than among the healthy population and an association will be found between the risk factor and the disease even when no such association exists.

21. Indirect evidence exists that women with breast cancer are in fact more likely to report previous abortions than are healthy women, thus leading to a false association between induced abortion and breast cancer. See, e.g., Rookus, *et al.*, 1996 (Exhibit F); Lindefors-Harris, *et al.* 1991 (Exhibit G). For instance, the results of my 1988 to 1991 study strongly support a conclusion that reporting bias was occurring. The data from this study showed that the relative risk for breast cancer varied depending on the time period in which the women reported that they had an induced abortion. Thus, for women having abortions prior to 1973, when abortion was legalized throughout the United States, the relative risk was 1.35 (with a confidence interval of 1.01-1.80), whereas the relative risk for women who had abortions after 1973 was 1.12 (with a confidence interval of 0.8-1.5). These results demonstrate that more healthy women were reporting abortions after 1973 than were reporting abortions prior to 1973. The most

reasonable explanation for this result is that healthy women, compared to women with breast cancer, were less willing to report that they had had an illegal induced abortion.

22. Studies support the existence of reporting bias. In one study, for example, the researcher interviewed healthy and diseased women and asked them about their abortion history. See Lindefors-Harris, *et al.*, 1991 (Exhibit G). The researcher then compared the interview results to the information in Sweden's national abortion registry and found that as many as 50% of the healthy women had underreported previous abortions. A Dutch study demonstrates similar evidence of bias. See Rookus, *et al.*, 1996 (Exhibit F).

23. The Melbye study is reliable because its results are based on considering the entire population of women born in Denmark over several decades. The study sampled over one million women; previous studies had relied on much smaller sample sizes.

24. Thus, the weight of scientific evidence does not support the conclusion that abortion is a risk factor for breast cancer. The studies demonstrate very small relative risks between abortion and breast cancer and inconsistent relative risks. Significantly, the Melbye study, which is the most methodologically sound study, shows no relative risk between abortion and breast cancer. Moreover, no study has established a biological mechanism linking abortion to breast cancer in humans.

25. I have reviewed Dr. Brind's affidavit in this case and believe that he has misunderstood the literature regarding the potential link between breast cancer and abortion for the following reasons.

26. First, Dr. Brind's affidavit evinces fundamental misunderstandings of epidemiological terminology. For instance, Dr. Brind refers on several occasions to the fact that his meta-analysis shows a "highly significant" 30% increase in risk in developing breast cancer for women who have had induced abortions. See, e.g., Brind Aff. ¶ 9. As an epidemiologist, however, I would not interpret the validity of a study based upon statistical significance alone. A finding can be *statistically significant* if there is more than a 95% probability that the finding is not due to chance. However, bias may still be present and this is especially likely when the estimated relative risks are so weak. Thus one cannot infer causation based solely upon statistically significant results.

27. Second, Dr. Brind relies heavily on his own meta-analysis, published in 1996, for the conclusion that there is an established 30% increase in risk for women who have had an abortion. But Dr. Brind's meta-analysis contains several crucial methodological flaws.

- A valid meta-analysis should always consider the quality of the primary studies. Dr. Brind's analysis fails to do that.
- Dr. Brind included all studies, regardless of quality, in performing his meta-analysis. For instance, he included the results of a 1957 study, Segi, et al., 1957, even though the statistical techniques to investigate risk factors for disease were only developed twenty-five years ago. No current epidemiologist would rely on the methods used in the Segi study.
- Moreover, Dr. Brind's results do not reflect the current epidemiologic literature on this topic. Dr. Brind's meta-analysis was published in 1996 and it did not include the largest and best conducted study published to date on the link between induced abortion and breast cancer. See Melbye, *et al.* 1997 (Exhibit B).
- A meta-analysis is an inappropriate technique for investigating the link between abortion and breast cancer. Many of the studies suffer from reporting bias, and this bias would simply be replicated in the single relative-risk estimate calculated by the meta-analysis.

- Dr. Brind included studies that were missing key data, such as the number of women who had abortions. *See, e.g., Segi, et al., 1957.* When such information was missing, Dr. Brind took information from other studies or relied on a simulation program to infer the abortion rates. After-the-fact manipulations of data are anathema in the field of epidemiology.

28. Dr. Brind's criticisms of the Melbye study as set forth in his affidavit are based on a misunderstanding of epidemiological methods. Dr. Brind criticizes Melbye for counting only abortions that occurred after 1973, when the abortion registry began in Denmark. Thus, he claims that a large number of older women were "misclassified" in the study as not having had abortions, and that if they had not been misclassified, the relative risk found by the study would have been much higher. However, Melbye treated *both* healthy and diseased women in this group as not having had abortions, and thus the data from these women did not likely affect his relative risk calculation. Dr. Brind's criticism on this point is based on the unjustified assumption that more of the diseased, as compared to the healthy women, in the "misclassified" group would have had abortions. It is just as likely that fewer of the diseased women, as compared to the healthy women, in the misclassified group had had abortions, and that therefore including the data from this group would have lowered the relative risk.

29. Indeed, Melbye considered in his study all women born between 1935 and 1978, and the abortion registry reflected all abortions obtained by the younger half of this population. For this very large sample of the population on which full information was available, the study showed no link between abortion and breast cancer.

30. Finally, Dr. Brind incorrectly relies on the Russo study to conclude that there is an established biological mechanism by which abortion can cause breast cancer

in humans. But, the Russo study was conducted on rats and the rat mammary gland has been shown to be limited as a model for the human breast. The Russo data on rats or other animal models cannot be directly extrapolated to humans.

31. In addition, the Russo study does not directly support the conclusion that abortion causes breast cancer in rats. The data from this study demonstrates that a pregnancy is protective against breast cancer because rats that experienced a full-term pregnancy were less likely to develop breast cancer than rats who either had an abortion or that were never pregnant at all. This data cannot be relied upon to support a causal effect between abortion itself and breast cancer.

**The Proposed Language Regarding Breast Cancer and Abortion
Misrepresents the Scientific Evidence Regarding Breast Cancer and
Abortion**

32. I have read the plaintiff's proposed language regarding breast cancer and abortion. In my opinion, the proposed language is patently untrue and misleading and misrepresents the scientific evidence.

Paragraph One

33. The first sentence of the language offered by plaintiffs is misleading. Research does support the existence of a long-term protective effect against breast cancer that is experienced by women who have a younger age of first birth. The sentence fails to make clear that, according to the epidemiologic evidence, a woman who has an abortion is in the same position as a woman who never becomes pregnant with regard to the loss of this protective effect.

34. Indeed, it is inaccurate to represent that an abortion *causes* breast cancer, when the abortion does no such thing. Representing that there is a cause and effect

relationship in this way is frankly deceptive. It would be like saying that using condoms causes breast cancer because it prevents pregnancy. Indeed, by this “logic,” encouraging young women to abstain from sex before marriage would cause breast cancer in all unmarried women to postpone pregnancy until later ages.

35. For example, a woman who has an abortion while she is in her teens or 20s may still bear a child. When this occurs, and particularly when the birth occurs within several years of the induced abortion, the woman will experience the same protective effect that she would have if she had carried her earlier pregnancy to term. If a woman who has had an abortion has a first full-term pregnancy, for example, before the age of 30, she is probably no differently situated than a woman who did not have an abortion but had a first full-term pregnancy at the same time in her life. The plaintiff’s proposed language fails to acknowledge that future full-term pregnancies, if at relatively early ages will confer protection, regardless of abortion history.

36. The plaintiff’s proposed language also ignores that many women who have abortions will already have had a first full-term pregnancy before seeking an abortion. Thus, for those women, they will already have gained the long-term protective effect of a full-term pregnancy.

37. In addition, the second sentence ignores the scientific evidence that indicates that a woman’s risk of breast cancer actually spikes in the years after she has a full term pregnancy. See Chie 2000, *et al.* (Exhibit H.) Thus, while having a first full-term pregnancy at a younger age provides a long-term protective effect against breast cancer, it actually increases the risk of breast cancer in the short term.

Paragraph Two

38. The second paragraph is also misleading. Again, the paragraph creates a cause and effect between induced abortion and breast cancer that is simply not supported by the weight of sound scientific research. The paragraph conveys this meaning by linking exposure to estrogen during pregnancy to an increase in the risk of developing breast cancer if the pregnancy is terminated. This is not supported by scientific evidence, however. Estrogen may promote undifferentiated breast cells, but estrogen's role itself is complicated and we do not fully understand its effects in long and short term

39. In addition, as discussed above, the claim that abortion is a risk factor for breast cancer is unfounded for several reasons. First, the most methodologically sound studies published to date show no association between abortion and breast cancer; second, the well-conducted epidemiological studies that do show a positive association show a only a very small increase in risk and the studies report inconsistent relative risks; third, the evidence indicates that the small risks in those studies may be caused by reporting bias rather than a real association between abortion and breast cancer; and, fourth, no study has established a biological mechanism linking abortion to breast cancer in humans.

40. As a whole, the second paragraph of the proposed language conveys the false message that abortion is a risk factor for breast cancer and therefore it is misleading.

Paragraph Three

41. The first sentence of paragraph three incorrectly states that "most" epidemiological studies on American women "have observed" that abortion increases a woman's risk of developing breast cancer. This is simply not correct. The consensus in

the epidemiological community is that induced abortion is not a risk factor for breast cancer.

42. The second sentence of paragraph three similarly suggests that abortion is a risk factor for breast cancer. For all of the reasons explained in this affidavit, the scientific evidence simply does not support this conclusion.

The Clinic's Brochure Correctly Represents That There is No Established Link Between Induced Abortion and Breast Cancer

43. I have read the language contained in the brochure presently being distributed by the defendant in this case and it is my opinion that it is a true statement and not misleading. For all of the reasons set forth in this affidavit, I believe that it is a true statement that “[a] substantial body of medical research indicates that there is no established link between abortion and breast cancer.” I also know to be true that some anti-abortion activists claim that there is a link and that the National Cancer Institute has stated that “[t]here is no evidence of a direct relationship between breast cancer and either induced or spontaneous abortion.”

44. In my opinion, the Clinic's statements are not rendered false or misleading on account of the word “established” in the second sentence. The medical community generally and epidemiologists use the term to describe established risk factors to breast cancer such as age at first birth and family history. The brochure correctly and appropriately states that the substantial weight of the evidence indicates that there is “no established link between abortion and breast cancer.”

