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advisory capacity for all phases of the study from approval of the study protocol through review and approval of final reports." He noted that he "attended several meetings and engaged in considerable correspondence in this study from that time through about 1982, when, for some reason, activities on this particular project ceased. Since our responsibilities in this project were never requested after 1982, nor did we see a draft of the final report, it seems that the carefully structured plan to ensure a proper conclusion to this study was breached."

The Center plans to submit the report to peer-reviewed journals for publication. Dr. Kaczmarek told *Newsline* that the patient with the two year latency has been removed from the study and that the authors are further reviewing the study. The SNM and ACNP Committees are concerned that if the paper is published with its current conclusions, it will be misleading. Says Dr. Becker, "The paper is dangerous because many people won't read it in its entirety but rather will just look at the abstract, title, and conclusions. Their conclusions may then be quoted without qualification and would eventually be accepted at face value."

According to Dr. Brill, the Committees would like the Center to remove the statement claiming that with more data an effect might be proved and to let stand the statement that the data fail to show a significant effect "until and unless a peer-reviewed study can prove otherwise."

Original Protocol Not Completed

Defending the study in his response to Dr. Saenger, Dr. Chiacchierini wrote, "... the study was designed to follow 6,500 exposed and 6,500 unexposed patients for an 80% chance of detecting a threefold increase in the risk of thyroid cancer at the 5% significance level. The CDRH report describes the entirety of the study to date.

According to Dr. Kaczmarek, the researchers calculated a relative risk of 2.86 from all the malignancies occurring at least five years after exposure.

Dr. Chiacchierini wrote to Dr. Saenger, "We feel the results are suggestive enough to warrant completion of the original protocol even if it cannot be done here at CDRH. As you and the other committee members stated, the results of the study, when completed, "are critical to the national health." He noted that "the findings are the result of the follow-up of only about one half of the planned study population." But, counters Dr. Becker, "if it's not an adequate follow-up, don't publish the study yet."

NCI Withdrew Support for Study

The diagnostic ^{131}I study, which Dr. Kaczmarek notes began over 30 years ago, was supported over the years through interagency agreements with the Nuclear Regulatory Commission and the NCI. However, according to Dr. Land, after the NCI provided some funding for the project, an outside review committee for the NCI's Radiation Epidemiology Branch "turned it down" because "there seemed to be a lot of difficulty in achieving the original goals... locating cases and controls." Dr. Land allowed that the process of following patients over the years in such a prospective study "is difficult to do" because people move and often women get married and change their names.

The major complaint with the study is that its data don't support its conclusions. Dr. Saenger summarizes, "They've suggested that we did a mountain of damage to those children, and I don't think the data that they've assembled has shown that." Says Dr. Brill, "They ran out of money, they ran out of time, they ran out of everything else, and they just threw what they had into a bag. It's a harmful document... Given the impact on legitimate societal activities involving the pro-

duction or use of ^{131}I , a great deal more care should have been taken on this study."

Sarah M. Tilyou

References

1. Hamilton PM, Chiacchierini RP, Kaczmarek RG. A follow-up study of persons who had iodine-131 and other diagnostic procedures during childhood and adolescence. HHS Publication FDA 89-8276.
2. Holm L-E, Wiklund KE, Lundell GE, et al. Thyroid cancer after diagnostic doses of iodine-131: a retrospective cohort study. *J Natl Cancer Inst* 1988; 80:1132.
3. Yalow R. Editorial: The contributions of ^{131}I to the understanding of radiation carcinogenesis. *Endocrinology* 1990; 126 (4):1787-1789.

PET Booklet Available

The Mallinckrodt Institute of Radiology at Washington University School of Medicine, in St. Louis, Missouri, has produced a color publication on PET, *Positron Emission Tomography: The Imaging of Function Rather than Form*. Commissioned and funded by the Department of Energy (DOE), the 15-page booklet describes PET's history, development, and up-to-date medical applications. The report was prepared by Michael J. Welch, PhD, professor of radiation chemistry and radiology at Washington University, and Michael R. Gold, director of public relations and marketing at Mallinckrodt. "The DOE had received numerous requests from VA hospitals and other institutions all over the country to produce a booklet that would introduce PET, since many of them were considering establishing a PET system," says Paul Cho, PhD, senior staff member of the DOE's Office of Health and Environmental Research.

The publications can be obtained at no cost by writing to Paul Cho, PhD, U.S. Department of Energy, Office of Health and Environmental Research, ER-73, Washington, DC 20545. ■