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How Much Radiation Can An Astronaut Withstand? NASA Used Dwayne Sexton To Find Out.

INFORMED CONSENT

BY HOWARD L. ROSENBERG

The dimly lit hallway weaved left and right like a maze. Clutching Dwayne's small hand, Mary Sue Sexton fell in step behind the white-coated technician. They passed a control panel and walked through a wrought-iron gate into the chamber. The room was dark except for a brilliant halo over an empty, aluminum bed.

Dwayne climbed over the nylon net surrounding the bed and settled into the trough-shaped berth. Mary Sue exchanged reassuring smiles and a hesitant wave with her six-year-old son. Then she turned and stepped back out to wait in the hall.

Mary Sue could not see the eight cones pointing toward Dwayne from the shadows, but she could hear a slight hum as the shielding was removed and the teletherapy machines began bathing the young boy in what one of the doctors later called a "sea of radiation."

Unknown to Mary Sue Sexton, her son Dwayne was serving as part of a government experiment: He was helping to find the parameters of the radiation sickness syndrome—precisely how large a dose it would take to cause a person to lose his appetite, get nauseous and vomit.

At least 89 cancer patients, including Dwayne Sexton, were systematically exposed to large doses of radiation between 1960 and 1974 in two specially

designed chambers at the Institute of Nuclear Studies in Oak Ridge, Tennessee. Medical confidentiality has prevented identification of most of these patients. Information provided by medical personnel at the facility and a telephone canvassing of one area of Tennessee led to the unfolding story of Dwayne Sexton and how he was used to obtain data for the United States' space program. It is hoped that the publication of this account will spur other patients who went through these experiments or their families to come forward with more information about the controversial treatments.

Based on an 18-month *Mother Jones* investigation and a review of thousands of pages of documents obtained under the Freedom of Information Act (FOIA), it appears that the radiation treatments began as a legitimate attempt to improve cancer therapy techniques.

However, dozens of interviews, the Freedom of Information Act documents and consultations with leading medical and scientific authorities reveal that these treatments evolved into something quite different:

- The Oak Ridge Institute, where the treatments were conducted, was an Atomic Energy Commission (AEC) clinic used for simultaneous research experiments on animals and humans.

- Leading authorities on radiation protection, and even the AEC itself in its review of these experiments, judged that the treatments were of little, if any, benefit to the patients. The man who oversaw the experiments, how-



ever, is today one of the government's chief experts on the effects of radiation.

- The government doctors administering the treatments knew of other therapy techniques—using either different types of radiation exposure or chemotherapy—that were superior. At least in Dwayne Sexton's case, the government scientists at Oak Ridge initially withheld these better-established cancer treatments.

- The clinic facilities were "substandard" according to the government itself, and the AEC eventually forced its own clinic to close down.

- Patients did not offer their *fully informed* consent to be part of some experiments. And some patients, like Dwayne Sexton, were subjected to several different types of experiments.

- Though the treatments were administered as cancer therapy, one primary purpose was to obtain data for the United States' space program on human reactions to radiation.

HOW IT BEGAN

NASA, the National Aeronautics and Space Administration, urgently needed data on human sensitivity to radiation, and the cancer patients who came through the doors of the Oak Ridge Institute of Nuclear Studies became the human guinea pigs who provided this information.

Animals had been the first to breach the boundaries of space. Dogs and chimpanzees and monkeys were metamorphosed into avian creatures, hurtling through the stratosphere atop rockets. Down below, scientists were wrestling with unanswered questions about how human beings would stand up to the effects of radiation. Nausea and vomiting caused by radiation sickness were possibly manageable ailments on the ground. But to an astronaut wearing an oxygen mask, they could prove fatal.

Hard data on human radiosensitivity was vital to NASA. But who would volunteer to be exposed to potentially lethal doses of radiation? In Oak Ridge, Tennessee, a pathologist at the AEC's clinic, Clarence Lushbaugh, agreed to search for some of the answers NASA wanted.

ATOMIC CITY, USA

Oak Ridge is called the "Energy Capital of the World" nowadays. It used to be known as the "Atomic City." This was the town created by Uncle Sam to produce fuel for the Manhattan Project's A-bombs during World War II. Hidden in hollows amid rolling hills of black oak, massive factories for producing bomb-grade uranium rose up within a perimeter of total military security. The limestone ridges along the snaking Clinch River offered natural protection from air attack. Power from the Tennessee Valley Authority was in plentiful supply.

Today Oak Ridge's broad, main avenues are still lined with Army barracks, converted and refurbished as apartment buildings. The "downtown" area is a modern shopping center. The denizens of the "Energy Capital" are a curious mix of rural-bred hill people and scientists and technicians from around the world. One out of every 35 Oak Ridgers holds a Ph.D. degree—one of the highest per capita ratios in the nation.

Clarence Lushbaugh arrived in 1963 to head the AEC clinic's ominously titled "Applied Radiation Biology Division." A short, balding man with a combative personality, Lushbaugh likes to say he "grew up in the gutters" of Cincinnati, Ohio, where his name, Clarence, "was a fighting name—you had to protect a name like Clarence." Most of his friends now call him "Lush," but the feisty attitude of his youth has not mellowed much in 65 years.

The nameplate behind Lushbaugh's desk informs visitors that he is the HSOBIC—Head-Son-Of-a-Bitch-In-Charge.

Educated at the University of Chicago, where he received his bachelor's degree, a Ph.D. in pathology and an M.D. in medicine, Lushbaugh began his career in 1949 as a pathologist in Los Alamos, New Mexico—another "atomic city." He doubled as the government town's coroner. In

1963, Lushbaugh moved to rural Tennessee and became a member of the staff of the Oak Ridge Institute.

"In Los Alamos," he explains, "we had plenty of radioisotopes and plenty of machinery, but we didn't have a whole lot of sick people because it was a rather young population." Oak Ridge offered the same access to radioisotopes plus a large group of Tennesseans who were grateful for free medical attention at the AEC clinic.

The Oak Ridge Institute had a mandate from the Atomic Energy Commission—which was then the government agency charged with promoting nuclear energy—to conduct research into the "beneficial applications of radiation." Some significant achievements did come out of Oak Ridge's clinic, including the development of a cobalt 60 (C-60) teletherapy machine, which served as a prototype for others now used in cancer therapy at hospitals across the country.

Lushbaugh was teamed with eminent hematologist Gould Andrews. Lushbaugh's star was rising. Andrews "was probably the world-renowned expert in taking care of persons with radiation injuries," Lushbaugh says modestly, "and I was the world-renowned expert at trying to figure out what went wrong at the autopsy table."

If someone was acutely irradiated in an accident, no matter when or where, Andrews was called in to give medical attention. His hunched figure was unmistakable—he was afflicted with extreme curvature of the spine. Andrews was a compas-

Patients did not offer their fully informed consent, and facilities were criticized as "substandard."

sionate and competent attendant to his patients, but whenever his medical ministrations failed, it was Lushbaugh's turn. Lushbaugh did the autopsies.

Shortly after his arrival in Oak Ridge, Lushbaugh won a NASA contract to conduct a retrospective analysis of the effects of radiation: a hunt for the point at which the syndrome symptoms appear. He looked for clues in the medical charts of cancer patients who had been treated with radiotherapy. By the end of 1964, Lushbaugh had compiled data on more than 3,000 patients at 43 different hospitals.

But the retrospective analysis had its limitations. The patients had received varying doses of radiation, and their doctors had not kept detailed notes on reactions in the systematic manner of a research scientist. A "prospective" study was needed. Oak Ridge was the ideal place for the study and Lushbaugh was the ideal choice to conduct it. By carefully monitoring patients during and after radiotherapy at the clinic, Lushbaugh and his associates could be on the lookout for syndrome symptoms and could correlate them with the exact dose of radiation received.

"BENEFICIAL" USES?

In 1960, the Oak Ridge clinic had begun operating a therapy chamber known as METBI—the Medium-Exposure-Rate Total-Body Irradiator. Built in a special wing of the tiny clinic, METBI was designed for experiments testing spray irradiation as a treatment for blood cancers. It was part of the Atomic Energy Commission's effort to use its nuclear wares to find those "beneficial applications of radiation."

Prior to World War II, researchers at the Memorial Sloan-Kettering Cancer Center in New York discovered that by spraying a leukemia victim's total body with X-rays, the radiation could be used to depress the bone marrow and kill cancerous blood cells forming there. Then, during the war, scientists found that injections of radiophosphorus and several nitrogen mustards could achieve essentially the same results at only a fraction of the cost. "In essence," said one of the AEC's consulting physicians, "spray irradiation techniques were superseded by simpler and better techniques."

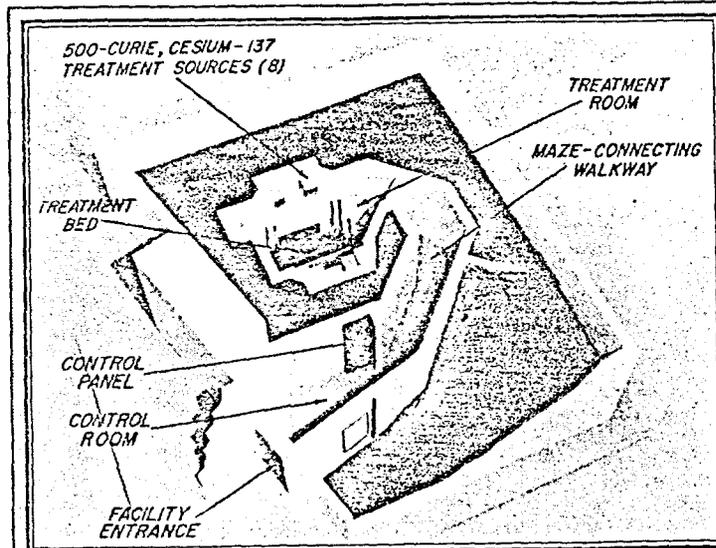
Lushbaugh agrees. "The hematologists began using these nitrogen mustards," he says, "and so they began hogging all these patients with leukemia. . . . Well, obviously, the radiotherapists and the whole damn field of radiologists were not going to put up with that. So they came along with a system for doing the same things as the nitrogen mustards, [the difference being that] you don't have to hold the guy down and stick needles in him."

What they came along with at Oak Ridge was METBI—and a new twist in the technique of spray irradiation. Doctors

at Sloan-Kettering used an X-ray machine to spray their patients, but the Oak Ridge doctors thought that radiation-emitting isotopes like C-60 and cesium 137 (Ce-137) would be more flexible than a bulky machine.

Lushbaugh explains it this way: "See, with an X-ray tube, you would put the person on the floor in the fetal position, with his knees drawn up, and you'd zap him from the right side with an X-ray machine and then you'd flip him over and irradiate him from the other side." The METBI facility was a quantum improvement.

The doctors could zap their patients in a specially designed room with doses ranging from 1.8 rads per hour (1.8r) to 300



This is a model of the METBI facility at Oak Ridge. Here and in another chamber 89 cancer patients were treated with high levels of radiation. The project apparently began as an attempt to improve cancer therapy. Ultimately, the experiments benefited NASA.

rads per hour (300r). These are extremely high doses—an ordinary chest X-ray is about one-tenth of a rad—but the exposures were and are considered therapeutic in treating some cancers. But as we will see in Dwayne Sexton's case and those of the other 88 patients in these experiments, the massive radiation doses were not only part of a treatment plan, but also a way of gathering data for the space program.

The treatment of leukemia patients in METBI began as soon as the facility was operational. Gould Andrews directed the clinical hematology staff. Lushbaugh monitored the cancer patients for signs of the

syndrome. Many aspects of the syndrome were already known even then. The government's handbook for the holocaust, *The Effects of Nuclear Weapons*, reports that "for doses between 200 and 1,000 rads the probability of survival is good at the lower end of the range, but poor at the upper end. The initial symptoms are similar to those common in radiation sickness . . . the larger the dose, the sooner will these symptoms develop."

As part of the federally funded Oak Ridge Associated Universities—a consortium of 50 colleges and universities throughout the South—the AEC clinic had a ready-made network from which to draw patients. Doctors in the rural South regularly referred cancer patients to Oak Ridge. Among them were people suffering from Hodgkin's disease, chronic lymphocytic leukemia, chronic granulocytic leukemia, polycythemia rubra vera, idiopathic thrombocytopenia and lymphosarcoma cell leukemia.

The Oak Ridge researchers began their study by exposing patients to 50 or 100 rads at a time in the METBI chamber at a rate of 1.5 rads per minute. According to an internal progress report written in 1970, doctors involved in the experiments apparently never really thought these large doses would benefit the patients much, but since the cancer victims would probably require radiotherapy anyway, the scientists at Oak Ridge hoped to obtain some of the syndrome data NASA wanted. "It was not our plan to evaluate the long-

Diagram courtesy of Oak Ridge Associated Universities

transferred into four syringes and injected into each of Mary Sue's hips and arms.

For Mary Sue, the injections were merely a painful irritant, but she was stoic about her discomfort. After all, her pain might help save Dwayne's life. But her eyes welled with tears when she pulled back the sheet covering her son's unconscious body and began counting the puncture wounds in his legs and chest.

On August 16 there was more surgery. A small incision was made in Mary Sue's left thoracic duct just above the collarbone, and a tube was inserted. For five days fluid drained through the tube into a plastic vacuum bag. This "serum" was filtered and then injected into Dwayne.

The doctors had hoped that Mary Sue's healthy body would build up antibodies, which would destroy the leukemic cells injected into her. Then, the antibodies in her blood serum could be used to fight the leukemic cells produced in Dwayne's bone marrow. But by mid-November of 1965, it was clear that this experiment had failed. Dwayne Sexton's condition was worsening.

"It was a superb idea," says the Baltimore Cancer Center's Peter Wiernick. "But you just cannot do those things in humans first thing." Medical authorities contacted by *Mother Jones*

agreed that it is simply unethical to inject cancer cells into a healthy human being, unless it is clearly a last resort. In Dwayne's case, it was not. Other therapies, whose worth was already proven, were readily available at the time. Today, research into cancer therapies using antibodies is still under way at several facilities, including the National Cancer Institute. Yet even now, 16 years after Dwayne's treatment, the experiments are conducted largely on laboratory animals and on human cancer cells in laboratory dishes.

After the failure of the bone marrow transfer, the Oak Ridge Institute doctors belatedly began treating Dwayne Sexton with chemotherapy.

A NEW GIMMICK

The Oak Ridge researchers were collecting syndrome data in earnest at that time, but the METBI facility had its problems and limitations. In addition, the Oak Ridgers had a new theory they wanted to test: Could they alleviate some of the side effects of the therapy by using lower doses of radiation over days or even weeks of continuous exposure?

By 1967, the AEC had financed the construction of a second facility at Oak Ridge: LETBI—the Low-Exposure-Rate Total-Body Irradiator. The difference between it and METBI was like the difference between the Ritz and a fleabag hotel. In fact, the paneled LETBI chamber was specifically designed and furnished to look like an ordinary hotel room where patients undergoing therapy could relax

and feel like they were on vacation. Except the LETBI chamber had no windows.

LETBI was really two rooms, one built within the other. The outer chamber was concrete. Inside, a smaller, wooden box was centrally positioned. Between the walls were eight cobalt 60 teletherapy machines, which created a radiation field that could administer doses as low as 1.5 rads per hour.

The radiation machines were operated and monitored remotely from an instrument console located in an adjacent control room. The panel also contained closed-circuit TV monitors, a communications system linked to the chamber and a read-out for the syndrome cord—an umbilical specifically developed to study the vital functions of patients as they underwent these new radiation treatments. The 65-foot umbilical was used to search for syndrome symptoms.

By monitoring read-outs, technicians could watch for subtle changes in respiration that would indicate nausea. The syndrome study had advanced to the point where the doctors knew a patient was about to get sick and vomit before the patient did.

The patients "would really run the whole thing," Lushbaugh explains. "Just by [the patient] opening the door [to leave the chamber], the whole thing would turn off, and he'd go out

and take a leak and go back in, and somebody would bring him his meals."

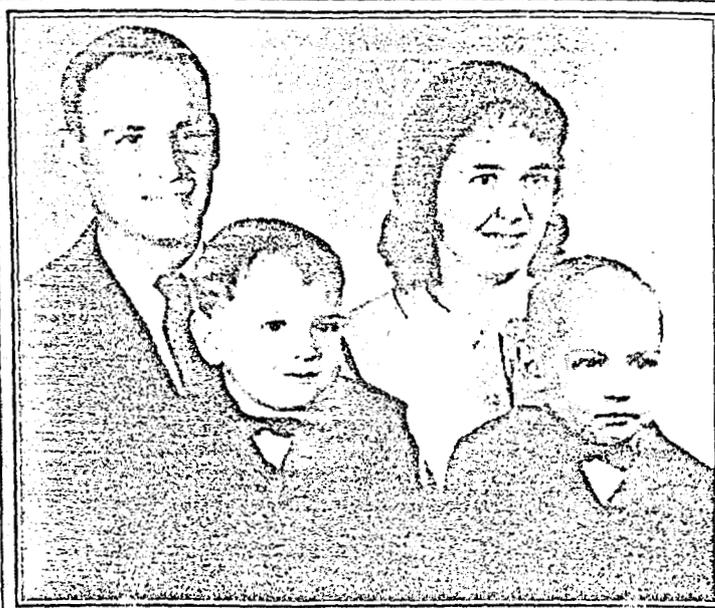
Lushbaugh was successful in coming up with data that helped determine how much radiation it took to induce the syndrome. But NASA still wanted to know whether milder symptoms of radiation sickness might reduce an astronaut's ability to perform routine tasks in space.

DWAYNE'S LAST CRISIS

A series of strategically placed mirrors enabled Mary Sue to watch Dwayne in the METBI chamber. He thumbed a well-worn comic book contentedly while the machines were turned on. Just four months shy of his seventh birthday, Dwayne had become all-too-familiar with the routine of hospital life. Over three and a half years, he had spent countless days at the Oak Ridge clinic. Despite the failure of the bone marrow transfer, chemical therapies had kept his leukemic cells in remission—until this new crisis.

Mary Sue silently mumbled a prayer. On Thanksgiving Eve 1968, blood had begun trickling from Dwayne's nostrils and oozing from the back of his throat. Mary Sue could not stop the hemorrhaging. The Sextons sped the 70-mile drive from their home in Robbins, Tennessee.

Now she watched anxiously as Dwayne began to fidget on the aluminum bed. The only hope for prolonging his life, the doctors said, was to depress Dwayne's bone marrow with a



This picture of the Sexton family was taken in September 1967, about a year before Dwayne, on the right, died at the Oak Ridge clinic.

range effectiveness of these relatively large individual doses," Andrews, Lushbaugh and their colleagues explained in the report. "This would have required establishing a total treatment plan with this technique, which we were not prepared to do."

The scientists wanted to "be able to add or substitute other forms of treatment," which is not surprising, in light of the fact that the doctors virtually admitted that the METBI exposures were *not even the best method of treating the cancer patients with radiation*. "One should not infer from this study," they wrote in a candid assessment of the experiment, "that we expected these individual or infrequently given

exposures to produce better clinical results . . . at present, we feel that some pattern of fractionated exposure [small doses of radiation in several treatments] probably offers a preferable approach for total-body radiotherapy."

What these large, single exposures in the METBI chamber *did* offer was the best opportunity to monitor for the radiation sickness syndrome. According to a report of the experiment provided to NASA, at least two patients at Oak Ridge received doses of 500 rads prior to a treatment called "bone marrow transplantation." Obviously, these two people were ideal subjects for the doctors involved in the NASA study to monitor for the syndrome.

ENTER, DWAYNE SEXTON

It was June of 1965 and the humid air was just hinting at the oppressive Tennessee summer ahead when three-year-old Dwayne Sexton first took sick. The auburn-haired boy just wasn't his usual self. First-born child of Talmon and Mary Sue Sexton, Dwayne had his daddy's dimpled chin, his mother's wide, brown eyes and enough energy to keep them both busy. That summer he changed. "Dwayne just wanted to sit or lay down," his mother remembers. "He was tired, run-down."

They visited the family doctor, who diagnosed Dwayne as anemic and prescribed liquid iron and vitamin B-12. The treatment didn't help much. Dwayne's normally rosy cheeks remained pale and waxy. Mary Sue insisted the doctor hospitalize him and find out what was wrong. Blood transfusions began in an attempt to counter the anemia. Finally, Mary Sue asked the doctor point-blank: "Does Dwayne have leukemia?" The physician said no, and then suggested that maybe the cause and cure of Dwayne's illness could be found at Oak Ridge. The arrangements had already been made. Mary Sue began keeping detailed notes in a journal.

On July 27, Dwayne checked into the Oak Ridge clinic for the first time. A chest X-ray was taken and bone marrow was withdrawn from his hip for a test. Mary Sue just happened by a room where one of the doctors was confiding the bad news

to Talmon: Dwayne had acute lymphatic leukemia.

Two days later Mary Sue wrote in her journal: "The medical staff discussed a type of treatment they would like to try on Dwayne. It was stated it could possibly be a cure for him. We know there is no hope at all for Dwayne except for a short life for him of from six weeks or maybe up to a year and a half, and he would be so sick so much of the time."

Mary Sue and Talmon agonized over the decision. "We decided it was worth the risk we would have to take for a chance at a cure for Dwayne," she noted in the journal. "We were reassured that the experiment was promising enough to take a chance with."

Mary Sue asked the doctor, "Does Dwayne have leukemia?" He suggested a cure might be found at Oak Ridge.

The doctors told the Sextons that Dwayne's case was virtually hopeless. They mentioned that there were various possible treatments but pointed out that, at best, all the treatments might do is provide a temporary reprieve. The Oak Ridge researchers then explained that they were interested in "bone marrow transfers," Mary Sue recalls. "They said it was experimental and would kill the leukemia cells. They offered that as an alternative. We took it as a desperate move for the health of our child."

THE CONSENT FORM

Both Dwayne's parents signed a consent form drafted by the Oak Ridge doctors. It reads, in part, "We understand and agree to a special experimental procedure designed to try to help our child who has acute leukemia. This will consist of removing bone marrow from the child, subjecting the marrow to radiation designed to kill the leukemic cells and subsequently injecting these cells into the mother . . . there are some risks involved for both mother and child. The nature of these has been explained to us, and we are willing to accept them."

In fact, the signing of the form by the Sextons did not really constitute "informed consent." Dwayne's parents were apparently misled into believing that the experimental bone marrow transfer was his best and only hope for survival. However, that treatment was clearly untried, and several better alternatives for treating acute lymphatic leukemia were widely known and available. According to Dr. Peter Wiernik, director of the Baltimore (Maryland) Cancer Research Center and a former official of the National Cancer Institute, a therapy protocol consisting of several chemical agents was the "common treatment at that time."

Instead of chemotherapy, eight days after his arrival at Oak Ridge, Dwayne was wheeled into the clinic's surgical arena and sedated. Bone marrow was carefully extracted through *seventeen* punctures in his legs, hips and breastbone. The marrow was then irradiated—probably in the METBI chamber. That afternoon, the irradiated bone marrow was

large enough dose of radiation to kill the cancer cells growing there. It was risky. The amount of radiation would also kill other cells and effectively knock out his body's immunity to bacteria. Dwayne would have to be closely guarded against deadly infection.

From METBI, Dwayne was wheeled into the nearby LETBI chamber, which the Oak Ridge doctors were using as a germ-free isolation ward. The umbilical monitor was strapped around his waist. The doctors told Mary Sue they needed to watch his vital signs carefully. They *didn't* tell her they were using the umbilical to collect data for their NASA study. Dwayne Sexton accepted this latest radiation therapy without a whimper.

"That radiation dose they gave Dwayne may have done the job," Mary Sue says now of the attempt to arrest the growth of the cancer cells, "but I think it done it a bit too much, possibly." In the following weeks, Dwayne's weight dropped by half to less than 30 pounds.

He barely had the strength to lift his head off the pillow, but he enjoyed picking through a flood of letters and Christmas cards, which poured in from relatives and friends. Mary Sue slept beside Dwayne in an empty bed, keeping a constant vigil. "Dwayne didn't care what they did to him," she says, "as long as his Mommy was there. It was like a fairy tale. He was such a brave little boy."

Dwayne knew intuitively his life was ending. "Don't cry, Mommy," he told Mary Sue as she stroked his forehead. "I'm going to be with Jesus."

OF MICE & MEN

Medical science has its own system of judging advances in treatment and therapy. Teams of doctors with expertise in the particular area of research carefully consider and evaluate their fellow doctors' projects.

On several occasions during the LETBI and METBI experiments, inspectors from the AEC visited the Oak Ridge clinic. Judging by the documentary records available, most of the so-called peer reviews by doctors who scrutinized the facility were less than laudatory. One reviewer charged "the directors weren't paying enough attention to what was going on. There had been a previous site visit a couple of years before mine, and their report was ignored."

The report of the review team dispatched to Oak Ridge in March 1974 could not be ignored. They called the clinical facilities "substandard" and recommended the facility be shut down or the program be moved elsewhere. Dr. William Bibb, now the Energy Department's director of research in Oak Ridge, argues that the clinic was closed because "it was giving exquisite care to the people it was taking care of, but it was not providing any research results at all."

On the contrary, the evidence indicates that patients were not receiving "exquisite care." The physicians' judgments of which therapy might be most beneficial to the patients may have been clouded by their desire to come up with "beneficial applications of radiation" for the AEC and syndrome data for NASA. The cancer patients who came to the clinic for help became, in effect, laboratory animals.

In a confidential report, members of the AEC review team that visited the clinic in 1974 expressed their uneasiness with the low quality of the facility and the poor patient care. They characterized the nuclear medicine program as "very pedestrian" and gave the clinical hematology division "an unfavorable rating." But more importantly, the reviewers discovered that some patients at the clinic may have had their lives jeopardized: just beneath the wooden floor of the LETBI chamber, the Oak Ridge researchers had suspended on plastic cords approximately 50 cages of laboratory mice.

Leukemia patients, especially those undergoing radiotherapy like Dwayne Sexton, are virtually defenseless against infection. In hospitals they are carefully isolated from any source of harmful bacteria. Yet, at Oak Ridge, the clinicians were experimenting by irradiating mice and men simultaneously and thus, according to the AEC re-

port, exposing the patients to potentially deadly infection from the animal cages hung directly below the LETBI treatment chamber.

Twice a week, animal caretakers crawled between the inner and outer shells of the LETBI facility to provide fresh food and water for the mice. They carried the dirty cages "through the patient area to an elevator and down to the cage washer," noted the AEC review report. "This entire arrangement seems to be questionable because of the necessity of transporting the animals, animal wastes and equipment through areas used by patients who frequently have compromised host defense mechanisms." In other words, patients whose bodies are incapable of fighting off infection. "This area," the reviewers wrote, "would appear to be highly prone to severe infestations of vermin."

Human guinea pigs are essential to every discovery designed to prolong life, relieve suffering or improve the quality of the human condition. Sooner or later, someone has to submit to new therapies to determine whether they are effective or useless. Doctors routinely comb the professional journals of their various disciplines, searching for clues of discovery provided by their peers' successes and failures.

The 14 years of experiments by the Oak Ridge researchers provided few of those clues. Clarence Lushbaugh did produce a 224-page report on the LETBI and METBI studies for NASA, but he did not publish a single scientific paper on the

Morgan believes he was "misled" about the clinic. "My hope & trust were misplaced," he says now.

experiments in any recognized journal because "we never considered them to be of enough scientific quality." In his report's summary, Lushbaugh cautioned that the studies should "not be considered definitive." In fact, the experiments raised more questions than they answered.

WERE PATIENTS HELPED?

In their confidential report, the AEC reviewers lambasted the researchers for their work, which they labeled "dismal." The report explicitly says the METBI and LETBI programs evolved "without adequate planning, criticism or objectives." The bone marrow transplant experiments received especially harsh criticism. "In view of accepted therapeutic modalities, ethical questions were raised with respect to the protocols employed in these studies," the confidential AEC report read.

The chamber experiments didn't even result in any appreciable improvement in radiotherapy techniques. "There is little if any clinically useful data on the METBI and LETBI programs," one of the AEC reviewers wrote in his confidential report four years later. "LETBI has been used long enough to establish (if I understand Dr. Lushbaugh correctly) that a very low dose rate does not offer any advantage over the administration of the dose at a higher rate in small, daily fractions."

Was the purpose of the experiments primarily to provide data for the space program?

In the beginning, Lushbaugh and Andrews wrote in 1970, a principal objective of the experiments "was to seek information that might lead to improved radiation therapy." However, that noble search for the light of knowledge was soon corrupted. "During the course of the study," they noted in their progress report, "the urgent need arose for information on hematologic effects in man, since the National Aeronautics and Space Administration was faced with potentially high levels of radiation exposures in space exploration."

In short, the syndrome search took precedence. It is not surprising that the METBI and LETBI experiments—with respect to cancer therapy—would get a lower priority: Lushbaugh and Andrews admitted in their 1970 progress report that they did not expect "these individual or infrequently given exposures to produce better clinical results" and that a different radiation treatment "probably offers a preferable approach for total-body radiotherapy."

Despite the documentary evidence, Lushbaugh denies emphatically the suggestion that the experiments were conducted principally for NASA's benefit. He claims his monitoring program was simply "piggybacked" onto the LETBI and METBI cancer therapy treatments. The Energy Department's William Bibb also denies that the search for the

Photograph by Howard Rosenberg

syndrome motivated the experiments. "It was the AEC that financed that," Bibb says. "With or without the NASA study, that program would have gone on." Yet, Lushbaugh's 1975 report to NASA clearly states that "the radiobiologic studies" were "carried out with joint AEC and NASA support during the years 1964 to 1974." NASA's support was financially crucial, especially in the experiments' final years.

According to Allen Webb, chemist at the clinic during the experiments, "In the early 1970s, Lushbaugh had to kick asses and pull strings to get enough money to keep LETBI running. NASA provided the monies."

Lushbaugh himself estimates that during the ten years

NASA sponsored his research, the space agency provided "three or four million dollars." The records available are limited to the period between 1969 and 1976 and account for payments by NASA of only \$799,766 of the total amount. Lushbaugh's colleague, R.C. Ricks—who coauthored the report for NASA—says that with the exception of about \$5,000 he spent for bicycle ergometry equipment, NASA paid his salary and Lushbaugh's salary, and the rest of "the funds were spent primarily for salaries for people to be at LETBI."

Clearly, the paper trail of evidence leads directly to the space agency. An attachment to NASA purchase orders (signed by AEC officials and authorizing funds for the project) notes that "the 'Prospective' Human Radiation Sensitivity studies will be continued and will be increased in number in both LETBI and METBI as more patients appropriate to this type of therapy are referred to us." Without NASA money, there would not have been enough cash to continue.

Did the LETBI and METBI radiation experiments actually benefit the patients?

The AEC's reviewers answered that question with an unequivocal and emphatic no. "There has been little thought," they wrote in a disturbing assessment of the experiments, "as to therapeutic utility or potential long-range consequences." In any medical facility, what is best for the patient should always be of paramount importance; and yet, the AEC reviewers accused the Oak Ridge researchers of ignoring whether the therapy they employed was doing any good. Unfortunately, at least 89 cancer patients—including Dwayne Sexton—passed through the LETBI and METBI chambers before the government came to that belated conclusion and itself ordered a halt to the experiments.

Gould Andrews left the Oak Ridge clinic after the AEC ordered the facility closed and joined the faculty of the University of Maryland. Lushbaugh asserts that it was

THE AFTERMATH

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Clarence Lushbaugh, who has testified about exposing Oak Ridge patients to radiation, now says his role was not significant.

INFORMED CONSENT

CONTINUED FROM PAGE 37

Andrews who determined which patients should be irradiated in the chambers and how big a dose they should get. However, a number of those involved in the experiments remembered that a committee of the clinic's staff—including Lushbaugh—made the determinations collectively. Andrews cannot speak for himself. He died in the summer of 1980.

Dr. Karl Z. Morgan was the director of the Oak Ridge National Laboratory's Health Physics Division during the LETBI and METBI experiments. Morgan is known throughout the world as the "father of health physics," a science dedicated to the prevention of radiation damage. He is probably the leading figure on radiation protection in the United States and, as such, could hardly be called "antinuclear." Currently a professor of physics at the Georgia Institute of Technology, Morgan believes that during his tenure at the Oak Ridge national laboratory, he was sadly confused about the purpose and results of the LETBI and METBI radiation experiments.

"I naively thought that the purpose of this nearby center [the clinic] was to use ionizing radiation in the treatment of cancer in a manner that had been proven to offer justifiable hope of remission and, in some cases, a cure," Morgan says today. "I believe I was misled, and my hope and trust in this program were badly misplaced."

As it turns out, one of Morgan's lifetime friends, his childhood Sunday school teacher, was one of the 89 patients who went to the Oak Ridge clinic for help and became a subject for the radiation syndrome study. Information about the nature of this clinic has, for Morgan, a special pain.

"The evidence strongly suggests," Morgan continues carefully, "that the purpose of this program was not what we were led to believe." Though Morgan trained dozens of medical doctors himself in methods of using radiation for human benefit, he says he is "appalled, overcome with consternation and filled with a deep sense of indignation" by the news that the cancer patients treated at the Oak Ridge clinic really became guinea pigs for the space program. "It causes one to wonder," Morgan concludes, "whether the members of the medical profession who were responsible could have been sincere the day they took the Hippocratic oath."

Clarence Lushbaugh still has his offices at the clinic itself, but now he is the director of the Oak Ridge Associated Universities' Medical and Health Sciences Division and brags that "only God can retire me." Just months after the review team concluded its damaging report on the clinic, Lushbaugh was awarded another ongoing contract, this one by the Energy Department to conduct an epidemiological analysis of possible health risks to nuclear workers at the Energy Department's Oak Ridge plants.

Lushbaugh's new research project could be another potential bombshell if it confirms the results of a previous study of nuclear workers. That study, by University of Pittsburgh professor Thomas Mancuso, revealed—after 12 years of work—that nuclear workers at the Energy Department's Hanford, Washington, atomic works suffered a significant increase in the incidence of certain types of cancer at radia-

tion exposure levels *well below* "safe" limits.

While Lushbaugh has no experience in conducting epidemiological analyses, as in this new study, he does have experience in coming up with the sort of data the government likes. In his final report to NASA on the LETBI and METBI experiments, Lushbaugh explained that one of his objectives in undertaking the project was that "these unbiased clinical observations were sorely needed to defend existing environmental and occupational radiation exposure constraints from attack by well-meaning, but impractical, theorists."

In the past, when the government faced troubles because nuclear workers or atom bomb test victims were suing Uncle Sam for injuries they sustained, Lushbaugh was counted on to offer "expert testimony" against them. That was exactly what took place in U.S. District Court in Las Vegas, Nevada, on May 16, 1977.

Seven years earlier an underground nuclear bomb test at the nearby Nevada Test Site went awry. Scientists had miscalculated the power of the so-called Baneberry bomb, and a mushroom cloud broke through the earth's crust and rose some 10,000 feet into the sky. The cloud began drifting toward an AEC base camp. Setting aside their own safety, 13 guards frantically evacuated the camp. Three of the 13 later died of leukemia, apparently because of their exposure to unsafe amounts of radiation. Two of the widows sued the federal government. Clarence Lushbaugh testified against one of the women.

Lushbaugh now denies he had any significant role in the actual operation of METBI and LETBI. Yet, to prove his own expertise on radiation effects during his testimony at the Baneberry widow's trial, Lushbaugh described the LETBI and METBI experiments. He testified that "we ourselves exposed persons to various total-body doses of radiation, and this was an ongoing study that I worked in and subsequently I became the leader of it, and we radiated persons with various kinds of leukemias in a specially designed room where they actually lived in a sea of radiation with their daily dose."

Dwayne Sexton died at the Oak Ridge clinic on December 29, 1968, a month after his last therapy session in METBI. A limited autopsy was performed. The cause of death was determined to be acute strep and staph infection.

*It seems we only miss you more
As each passing day goes by
Yes, our hearts have all been broken
Yet we try hard not to cry*

*You were such a bright spot in our lives
Since the first day you came
There's an empty place in our home
That will never be the same*

—from a poem dedicated to Dwayne, by Mary Sue Sexton, written three months after his death

In the entire history of the United States Manned Spaceflight Program, not a single astronaut ever received a high-enough dose of radiation to suffer from the syndrome. Dwayne Sexton did.

Howard L. Rosenberg is the author of Atomic Soldiers (Beacon Press, 1980). He also describes himself as "a writer and rider" on the staff of Jack Anderson's "Washington Merry-Go-Round." Supplementary research for this article was contributed by the Environmental Policy Center.

File - Sexton / Mother Jones

ASSISTANT TO MANAGER FOR PUBLIC INFORMATION

MANAGER'S STAFF MEETING REPORT

August 24, 1981

1. By Friday afternoon news media interest had perceptibly decreased on the Mother Jones magazine article concerning irradiation of patients at the former AEC/ORINS Hospital in Oak Ridge. Following a vigorous promotion effort by the magazine (reportedly with the assistance of a public relations firm), Washington based media began coverage of the event on Wednesday prior to the Mother Jones press conference in Washington on Thursday. Regional and local news media interest increased to such an extent on Wednesday afternoon and Thursday morning that we arranged a local news conference late Thursday morning. Coverage by national media has varied but has generally tilted toward highlighting the accusations. Regional/local media has been far more balanced and fair. The subject should stay on the back burner until Congressional hearings are held in September.
2. Senator Howard Metzenbaum plans to visit GCEP on August 29 for a briefing and tour. He is visiting the plant while in the area for a "fund raiser" at Haverly. Will Walker and Sandy Perkins will handle the visit. DOE Headquarters' Congressional Affairs has been advised of the visit.
3. Congresswoman Marilyn Bouquard has requested a visit to the Y-12 Plant for tours and briefings on the weapons program. Arrangements have been made for her to visit the plant on August 28. The Office of Military Application, Headquarters, has been informed of the visit and will authorize access as required.

Jim Alexander for
Wayne Range, Assistant to Manager for
Public Information

102228b

STATEMENT USED BY NASA IN ANSWER TO INQUIRY:

The facts are that NASA learned of the studies being conducted and in 1964 requested that the agency be supplied with data in a form that would be usable to it to study what astronauts might expect when and if exposed to radiation in space. NASA funding went mainly to obtain this data in proper form. Some \$65,000* funds did help to pay for some patient monitoring equipment. The Oak Ridge people categorically deny that the studies of cancer patients were in any way changed or extended to satisfy NASA requests nor were any such requests made by NASA.

*estimate to be verified

8/20/81

1022287

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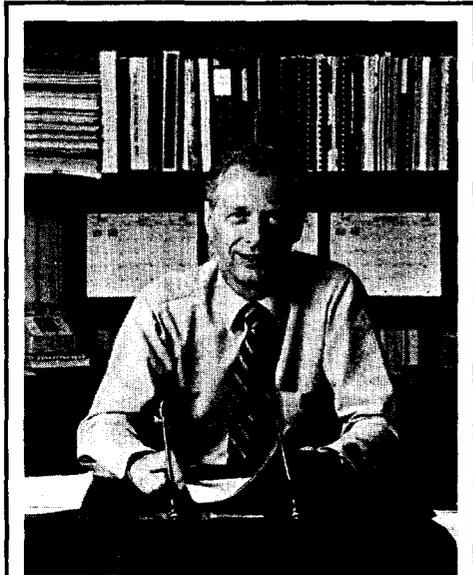
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1022289

ORAU United Way Campaign 'Kicks Off' This Month

ORAU's United Way drive team is off and running toward three major goals for the 1981-82 fund drive.

- To strive for 100 percent participation throughout all of ORAU's divisions and offices
- To raise at least \$11,500 and work further toward a greater goal of \$14,000
- To make all ORAU employees more aware of the United Way and why it deserves our help and support.



"IMPORTANT FOR ALL OF US." ORAU Executive Director Phillip L. Johnson asks all ORAU employees to make a special effort to support the United Way. The services provided are "important to all of us," he said. "That's why ORAU strongly supports this unique, once-a-year fund-raising effort among our employees. We know of no better way to help those in need in a more efficient way."

Heading ORAU's campaign is *John Haffey* (OIS), a former Anderson County United Way board president, drive chairman, and current board member. "Major keys to a successful drive are communication and commitment," he says.

"The more our people know about how the United Way helps our community—the young, the aging, those with special needs—the higher our chances of doing a good job."

Other ORAU drive leaders are equally enthusiastic. In fact, Executive Director *Phillip Johnson* asked that only those volunteers who strongly support the United Way be appointed to represent each division, office, and program.

Leaders named to date include: *Carole Byrd* and *Bobbie Schwarz*, CARL; *Joyce Cagle*, *Sandra Plant*, and *Diane Reed*, OIS; *Rac Cox*, MERT; *Carla Green*, OPS; *Beth Jenkerson*, OTS; *Vivian Joyce*, IEA; *Marvin Peyton*, EED; *Phyllis Reed*, OFMS; *Bill Roach*, OSH; *Don Robie*, MHSD, and *Gene Spejewski*, UNISOR.

Campaign plans call for a kickoff in mid-September with special programs being scheduled in each division and unit thereafter.

The minimal goal has been set at \$11,500, about 8 percent more than last year's total for ORAU and a percentage in line with

continued, page 2

ORAU and DOE Set Record Straight on Magazine's Charges



Lushbaugh and Bibb speaking at press conference at EED conference room.

Dr. C. C. Lushbaugh, chairman of MHSD, and *Dr. William Bibb*, DOE's contract administrator for ORAU, responded quickly in a press conference August 20 to refute claims printed in *Mother Jones* magazine that cancer patients in ORAU's former medical clinic were subjected to massive amounts of radiation for the purpose of gathering data for the National Aeronautics and Space Administration (NASA).

The magazine specifically cites the case of *Dwayne Sexton*, a child with terminal leukemia when referred to ORAU's medical clinic in July 1965. He died in December 1968 after various treatments

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After 31 Years, Museum Transfers to New Contractor, Science Applications, Inc.

More than four million visitors have learned about energy at the American Museum of Science & Energy during the 31 years that ORAU has operated the Museum for the Department of Energy. After September 30, a new contractor, Science Applications, Inc. will be operating the Museum.

Dr. Phillip L. Johnson, ORAU's executive director, offered "congratulations to Science Applications, Inc., best wishes to ORAU's transferring employees who will work for the new contractor, and a pledge to help as much as possible during the transition. . . These have been good years for our organization, our employees, and our community; and we are pleased to have had a part in it all."

Three longtime employees of the Museum Division are among those who will be making the transition. *Tallie Holt*, maintenance mechanic, joined ORAU (then Oak Ridge Institute of Nuclear Studies) in September 1955. "I think you'd have to hunt a long time to find an organization as good as this one," says Tallie."

Phil Lamm, a senior exhibits manager, started to work for ORAU in July 1957 with the traveling exhibits program. "I've seen a lot of changes like the transition from This Atomic World to large circulating exhibits and from strictly nuclear to all types of energy.

continued, page 4



Museum veterans with a total of 72 years of service to ORAU—from left are Tallie Holt, Marion Marsee, and Phil Lamm.

UW Campaign Kickoff

continued from page 1

other average 1981-82 goals. Anderson County, for example, is working toward an overall increase of about 8 percent.

"But we want to be better than average," drive leaders report. Thus, team leaders have set additional objectives of getting as close to \$14,000 overall and to 100 percent participation as possible.

The two goals—one essential, and the other the "quest"—are not the only unusual parts of this year's campaign.

"You won't hear many of us talking about a fair share, for example," John said. "The individual is the only one who knows what's fair. For some, \$50 may be far more generous than \$100 for another. We do hope everyone gives according to ability. But our real objective is to communicate the need, and then we know our fellow employees will respond."



Eager to get the United Way campaign started, Carla Green, left, and Beth Jenkerson, right, sign pledge cards as others on the United Way team watch. From left, are Sandra Plant, Joyce Cagle, John Haffey, Marvin Peyton, Bobbie Schwarz, and Diane Reed.

Walburg Is New Director of Marmoset Program

Dr. H. E. (Pete) Walburg is the new director of the marmoset research and breeding program which will be reporting directly to the Executive Office. He is also director of CARL which will become part of ORAU October 1.



Walburg

The marmoset breeding program began in 1961 with a colony of wild marmosets and tamarins. Currently, the inventory is about 450 marmosets, comprised mostly of cotton-topped and white-lipped tamarins and the common marmoset. "Reproduction in the ORAU marmoset colony has improved steadily since its inception due largely to the effort of Drs. Nazareth Gengozian and Conrad Richter working with MHSD staff," he said.

Why is the marmoset program important? Pete explains, "Marmosets are becoming increasingly important as models for human metabolism and disease, not only because they are phylogenetically related to man as primates, but because they are able to breed in captivity."

Also, he said, "The cost of marmoset production and maintenance is much less than for the more commonly utilized rhesus and other macaque monkeys. An increase in marmoset usage can be expected as budgets continue to be restricted."

Others on the marmoset staff are Isaiah Caldwell, Robert Carson, William Arndt, and Roy Rice.



IEA Has New Home in Washington D.C.

The IEA Washington office now has a new address. Actually it has just moved around to the other side of Dupont Circle.

"We are right on top of the Dupont Circle Metro Stop at 1346 Connecticut Avenue, Suite 530," says Sue Kincade, administrative manager.

The Carnegie Endowment for International Peace Foundation which has sublet to the Washington office for the last five years needed the space for its own programs. IEA is now leasing from the Dupont Circle Building. The phone number is still the same, 202-653-3290.

DOE To Extend Contract

The Department of Energy has announced it would extend its contract with ORAU to conduct a broad range of energy-related research, education, and training programs for an additional five-year period.

R. J. Hart, manager of DOE's Oak Ridge Operations, said negotiation of terms and conditions between DOE and ORAU would begin shortly to extend the current contract through September 30, 1987. The present contract expires June 30, 1982.

ORAU's operating budget for FY 1981 is estimated at about \$21 million, with \$15 million from DOE as the largest funding source. The balance comes from grants and contracts from other federal agencies such as the National Institutes of Health, the Environmental Protection Agency, the Nuclear Regulatory Commission, and private sources.

Fred Snyder Teaches At UTM and UNC

Fred Snyder, MHSD assistant director, has been reappointed a professor in the Department of Biochemistry of the College of Medicine at the University of Tennessee Center for Health Sciences in Memphis.

Since 1964, Fred has been a volunteer faculty member and spent a few days each quarter at the college teaching biochemistry. And several graduate students have come to ORAU and done doctoral research under Fred.

The University of North Carolina at Chapel Hill also shares this same arrangement with ORAU and Fred. UT and UNC are both ORAU member institutions.

Judy Statzer Knows How United Way Can Help

For a family in the cove north of Oliver Springs, *Judy Statzer* is a name they won't soon forget. Judy and a few others spent many days seeing to it that a family in need got furniture, clothes, and food when their home completely burned last summer.



Statzer

Judy, information officer for the Museum, spends extra hours with the Children's Welfare and Distressed Families, an agency which helps families in emergency situations.

She has also volunteered time and written articles for the Home Aide Service, an agency which helps families that have difficulties financially or otherwise.

"Both the Children's Welfare and Distressed Families and Home Aide Service are really good agencies," says Judy, "but they are on very low budgets. The United Way supports them each year, but I wish more people would get involved. There are little things they can do that can really make a difference."



United Way

Thanks to you... it works... for ALL OF US

Crowells Active in YWCA

To *Mayme Crowell*, the Young Women's Christian Association (YWCA) is obviously an organization she feels strongly about—she's worked with them for nearly 20 years.



Crowell

Mayme is on YWCA's board of directors and serves as chairman of the Financial Development Committee. She is a research associate for MERT's Assessment and Field Support program. Mayme says, "over the years, the YWCA has been a big part of my family's life. My two daughters have taken sewing classes, German, and aerobics," just a few activities the YWCA has to offer.

TD's Graduate, Head for Schools All Over United States and Puerto Rico

After a tough ten-week training period, 14 more teacher-demonstrators (TD) left with their props, speeches, and enthusiasm to spread the energy word across the nation. "And believe me, they are ready," claims EED's *Marvin Peyton*, director of training.

EED took a new approach to training TD's this summer with more emphasis on academics. "In the past we've presented a summary of the basics," explains Marvin. "This year, the TD's received a good, solid foundation with an intensive review of physics, chemistry, biology, and geology. We were not trying to make TD's energy experts, just good teachers and resource persons."

During training, TD's were expected to learn three training manuals from cover-to-cover, write their own script for their traveling programs, and maintain their equipment and van. Each TD also presented programs in the Museum auditorium for daily visitors.

"The cooperation with other divisions during the TD training is tremendous," says Marvin. "Also several on the EED staff gave presentations in their fields and it's a great way for the TD's to learn."

The team of 31 TD's consists of 14 new members and 17 who returned from last year. TD's are sponsored either by ORAU, a public utility, or a university and are assigned to a particular area. Four TD's will be taking out EED's newest traveling program, *Gas Works*, the story of natural gas. They are *Dean Keith*, assigned to New York; *Jim Sexton*, Indiana; *Sue Stone*, northwest United States; and *Dave Warner*, Connecticut.

Fifteen TD's are assigned to *Energy Today and Tomorrow*, a program on all forms of energy. *Donald Baker* will cover

the Washington area; *Fran Capaldi*, Arizona; *Mike Clayton*, Ohio; *John Guyton*, Mississippi; *Karin Hokkanen*, Michigan; *Ken Klapp*, New York; *Ed McCleary*, Oklahoma, Illinois, North Carolina, and Virginia; *Janet Michel*, Louisiana; *Jim Noey*, Ohio; *Kan O'Keefe*, New York; *Miguel Morel* and *Myriam Perez*, Puerto Rico; *Jim Puckett*, New Jersey; *Joe Sprigg*, Alabama; *Paul Viggiano*, Florida; and *Sue Wood*, Texas.



Before heading out in five different directions, TD's *Sue Stone* (standing left), *Dave Warner* (kneeling left), *Don Kilgore* (seated left), *Jim Sexton* (kneeling right), and *Paul Viggiano* (standing right) pose with *Daphne*, the eight-and-a-half-foot inflatable dinosaur, a major prop in the *Gas Works* program.

Energy Adventure, a program on petroleum, will be spread across the United States by 11 TD's. *John Bouffard* will cover Kentucky; *Tim Handler*, New York; *Joe Haubenreich*, Illinois; *Mary Huffman*, Michigan; *Don Kilgore*, Colorado; *Kevin Mart*, Washington; *Ty McKinnie*, California; *Cathy Price*, Ohio; *Chris Salmon*, Georgia; *Rita Schalk*, Louisiana; and *Jack Valentine*, New York.

Jim Anderson and *Chuck Spets* will rove the United States with the Breeder Reactor Corporation's program, *Energy for the Future*.

Ladies Night Out

Where: Ridge Inn Restaurant
 Date: September 17, 1981
 Time: 5:30 p.m.
 Price: \$6.00
 (includes tax and tip)

Deadline for Reservations: September 14, 1981

Please contact *Dale Jones* at 576-3034.

ORNL Physicists Hear Summer Researcher

Mary Ann Heck, a student research participant at UNISOR, made a presentation on developing rare-earth oxide targets and catchers for ion sources to ORNL's Physics Division last month. She is working on this experiment with UNISOR's *Ron Mlekodaj*.

A chemistry major at Clarke College in Dubuque, Iowa, *Mary Ann* was inadvertently left out of last month's *Express* article on the summer researchers.

ORAU and DOE Set Record Straight on Charges

continued from page 1

including chemotherapy and whole-body irradiation.

Dr. Lushbaugh told Oak Ridge-Knoxville area news media that "The primary focus of the program at the medical clinic was the beneficial application of nuclear medicine in the treatment of cancer. The patient's needs always came first." Data analysis of existing patient records for NASA had nothing to do with the medical decisions, he said.

Dr. Lushbaugh said that the Sexton boy was given the best possible care. "His parents brought him to the hospital because his own doctor had done everything that could be done. . . We treated him and kept him alive for three years." The average lifespan for such victims was about a year at that time with virtually 100 percent mortality. Today the lives of about half can be saved.

On August 21, after completing a review of the records on the care and treatment of the Sexton youngster, Dr. Bibb said that the records indicate that Dwayne Sexton was not involved in the NASA study at all. In fact, the primary report to NASA on high-level radiation was published the year *before* the Sexton boy died.

In a letter dated August 25 to the ORAU board and the biomedical advisory committee, ORAU's Executive Director *Dr. Philip L. Johnson* pointed out a number of factual inaccuracies in the *Mother Jones* article.

Said Dr. Johnson, "It is clear that:

Consent forms indicating the nature of treatments were signed by all patients including Mrs. Sexton.

The NASA study was a retrospective study of some 3000 patient re-

ords. NASA work did not affect the treatment protocol.

Patients had excellent care. In fact, part of the limits on the research value was because care of patients came first. . ."

Albert Gore, Jr., U.S. Representative of Tennessee's Fourth District, has stated a Congressional hearing may be held in September.

New Contractor for Museum

continued from page 1

But, I sure have enjoyed it," adds Phil, "otherwise I wouldn't have been here so long."

Marion Marsee, also a senior exhibits manager, joined ORAU in July 1959. "It's a great opportunity to travel and meet people," says Marion. "I haven't gotten into any humdrum at the Museum. It's all been challenging and exciting."

ORAU Employees' Club

West Side Dinner Theater
"Oklahoma"

October 15, 1981

\$10 Per Couple - Club Members
\$12 Per Couple - Museum Employees
\$17 Additional Guests

Memoriam

ORINS Staffer Dies

Elizabeth Rona, a pioneer in the field of radioisotope techniques, died July 27. She was an esteemed member of the scientific staff of the former Oak Ridge Institute of Nuclear Studies (now ORAU) from 1950 until her retirement in 1965.



Rona

Following her second retirement from the University of Miami's Institute of Marine Sciences, she returned to Oak Ridge and wrote a short history of radioactivity, nuclear physics, and atomic energy from the vantage point of having known and worked with the great pioneers of nuclear science. "How It Came About" was published by ORAU in 1978.

Roger Cloutier, program director of Professional Training and a long-time admirer of Dr. Rona, pointed out that she will be remembered for her research in geochronology of ocean sediments and for her teaching skills. "For over sixty years she taught other scientists how to measure radioactivity. Although she felt her students' work was always more important than her own, none have yet matched her contribution to science," he said.

A native of Hungary, Elizabeth Rona received her Ph.D. at the age of 21 from the University of Budapest around 1912. Already a noted scientist when she emigrated to the United States in 1941, she became a naturalized citizen and continued her distinguished career for almost 40 more years.

ORAU Oak Ridge Associated Universities
Post Office Box 117
Oak Ridge, Tennessee 37830

express

Address Correction Requested

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The Express is a monthly publication for ORAU employees and family members. Please call us if you have story ideas and suggestions.

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1022293

Report on Congressional Hearing by
House Science and Technology Subcommittee on Investigations and Oversight
Chaired by Rep. Albert Gore, Jr. (D-Tennessee, Fourth District)
Regarding the Mother Jones Controversy

In mid-August, 1981, promoters of an article scheduled for the September-October edition of an antinuclear publication entitled Mother Jones charged that the Oak Ridge Institute of Nuclear Studies (as ORAU was known before 1966) had used patients as "human guinea pigs" without their consent in experiments to provide data for the National Aeronautics and Space Administration.

National television and other news media had been contacted to detail charges in the article, "Informed Consent," with subheads "How Much Radiation Can An Astronaut Withstand? NASA Used Dwayne Sexton to Find Out." Specifically the article charged that ORAU's Medical Division had experimented unethically to find beneficial applications of nuclear energy and help NASA without regard to the best interests of patients. As a focused example, the author Howard L. Rosenberg alleged that medical assistance to one young patient (Sexton) had been inadequate and improper (e.g., that radiation levels were too high). Rosenberg also claimed that clinical facilities were substandard and produced little of research value. As a result of the charges, Congressman Albert Gore, Jr. (D-Tennessee, Fourth District) scheduled hearings subsequently held September 23 in Washington before the House Science and Technology Subcommittee on Investigations and Oversight.

The response of U.S. Department of Energy and Oak Ridge Associated Universities officials was prompt and effective:

1. On August 20, 1981, the same day that promoters of the magazine article had a Washington press conference, a DOE-ORAU press conference was held at ORAU in which DOE's Dr. William Bibb and ORAU's Dr. C. C. Lushbaugh countered the magazine charges and outlined the true background and purposes of the program. The weight of the evidence was clearly against Mother Jones. Local newspaper and TV coverage was overwhelmingly supportive of ORAU. Specifically, DOE/ORAU efforts communicated:
 - A. Patients were never "used as human guinea pigs" in the sense conveyed by the Mother Jones article; i.e., as unknowing victims of experiments for purposes without regard to their best interests. The patients' needs always came first.
 - B. Dwayne Sexton, the child exploited in the Mother Jones article, did not receive high levels of radiation "to test man's tolerance of radiation in space," but in a last-ditch effort to save his life. Conventional chemotherapy and other treatments had failed. The child was dying after more than three years of various therapies in the ORAU hospital and clinic; his doctors concluded that the high levels of radiation were essentially the only means left to extend his life. In fact, he had lived 3.5 years after first entering our clinic with acute lymphocytic leukemia.

- C. It is true that patients did receive experimental treatments with total body irradiation and that some of the data was used as part of a retrospective study to determine levels of human radiation tolerance. However, the treatment protocols were not influenced or biased in any way to enhance these evaluations. This study also examined 3000 patient records from 45 other hospitals that used total body irradiation in leukemia therapy. Ironically, the Sexton boy's irradiation therapy actually occurred after ORAU had completed the report to NASA and the National Academy of Sciences on high-level radiation in 1967--the year before the Sexton boy died. In 1968 the primary clinical research interest was in protracted and fractionated low-level radiation and not in single-dose exposures.
 - D. The child's parents were fully informed about the treatment--both verbally and in explanations written in lay language and signed by Mr. and Mrs. Sexton. The parents clearly gave ORAU their informed consent.
 - E. Although some program reviewers questioned the research value of some of the work of the clinic and the quality of the general facilities, the fact is that patient requirements always came before experimental needs for data, and good equipment was more important than high-quality buildings per se. The research clinic operated as well as possible within available government funds, making substantial contributions to the development of nuclear medicine over the past 30 years.
2. At the Gore subcommittee hearings, the points outlined above and many others were effectively presented by both DOE, ORAU, and former clinic employees and patients. Immediately following the hearings, Rep. Gore was quoted as saying the Mother Jones charges had been "essentially refuted." A report from the House subcommittee is expected late this fall.

* * * *

1022295

How Much Radiation Can An Astronaut Withstand? NASA Used Dwayne Sexton To Find Out.

INFORMED CONSENT

BY HOWARD L. ROSENBERG

The dimly lit hallway weaved left and right like a maze. Clutching Dwayne's small hand, Mary Sue Sexton fell in step behind the white-coated technician. They passed a control panel and walked through a wrought-iron gate into the chamber. The room was dark except for a brilliant halo over an empty, aluminum bed.

Dwayne climbed over the nylon net surrounding the bed and settled into the trough-shaped berth. Mary Sue exchanged reassuring smiles and a hesitant wave with her six-year-old son. Then she turned and stepped back out to wait in the hall.

Mary Sue could not see the eight cones pointing toward Dwayne from the shadows, but she could hear a slight hum as the shielding was removed and the teletherapy machines began bathing the young boy in what one of the doctors later called a "sea of radiation."

Unknown to Mary Sue Sexton, her son Dwayne was serving as part of a government experiment: He was helping to find the parameters of the radiation sickness syndrome—precisely how large a dose it would take to cause a person to lose his appetite, get nauseous and vomit.

At least 89 cancer patients, including Dwayne Sexton, were systematically exposed to large doses of radiation between 1960 and 1974 in two specially

designed chambers at the Institute of Nuclear Studies in Oak Ridge, Tennessee. Medical confidentiality has prevented identification of most of these patients. Information provided by medical personnel at the facility and a telephone canvassing of one area of Tennessee led to the unfolding story of Dwayne Sexton and how he was used to obtain data for the United States' space program. It is hoped that the publication of this account will spur other patients who went through these experiments or their families to come forward with more information about the controversial treatments.

Based on an 18-month *Mother Jones* investigation and a review of thousands of pages of documents obtained under the Freedom of Information Act (FOIA), it appears that the radiation treatments began as a legitimate attempt to improve cancer therapy techniques. However, dozens of interviews, the Freedom of Information Act documents and consultations with leading medical and scientific authorities reveal that these treatments evolved into something quite different:

- The Oak Ridge Institute, where the treatments were conducted, was an Atomic Energy Commission (AEC) clinic used for simultaneous research experiments on animals and humans.

- Leading authorities on radiation protection, and even the AEC itself in its review of these experiments, judged that the treatments were of little, if any, benefit to the patients. The man who oversaw the experiments, how-



ever, is today one of the government's chief experts on the effects of radiation.

- The government doctors administering the treatments knew of other therapy techniques—using either different types of radiation exposure or chemotherapy—that were superior. At least in Dwayne Sexton's case, the government scientists at Oak Ridge initially withheld these better-established cancer treatments.

- The clinic facilities were "substandard" according to the government itself, and the AEC eventually forced its own clinic to close down.

- Patients did not offer their fully informed consent to be part of some experiments. And some patients, like Dwayne Sexton, were subjected to several different types of experiments.

- Though the treatments were administered as cancer therapy, one primary purpose was to obtain data for the United States' space program on human reactions to radiation.

HOW IT BEGAN

NASA, the National Aeronautics and Space Administration, urgently needed data on human sensitivity to radiation, and the cancer patients who came through the doors of the Oak Ridge Institute of Nuclear Studies became the human guinea pigs who provided this information.

Animals had been the first to breach the boundaries of space. Dogs and chimpanzees and monkeys were metamorphosed into avian creatures, hurtling through the stratosphere atop rockets. Down below, scientists were wrestling with unanswered questions about how human beings would stand up to the effects of radiation. Nausea and vomiting caused by radiation sickness were possibly manageable ailments on the ground. But to an astronaut wearing an oxygen mask, they could prove fatal.

Hard data on human radiosensitivity was vital to NASA. But who would volunteer to be exposed to potentially lethal doses of radiation? In Oak Ridge, Tennessee, a pathologist at the AEC's clinic, Clarence Lushbaugh, agreed to search for some of the answers NASA wanted.

ATOMIC CITY, USA

Oak Ridge is called the "Energy Capital of the World" nowadays. It used to be known as the "Atomic City." This was the town created by Uncle Sam to produce fuel for the Manhattan Project's A-bombs during World War II. Hidden in hollows amid rolling hills of black oak, massive factories for producing bomb-grade uranium rose up within a perimeter of total military security. The limestone ridges along the snaking Clinch River offered natural protection from air attack. Power from the Tennessee Valley Authority was in plentiful supply.

Today Oak Ridge's broad, main avenues are still lined with Army barracks, converted and refurbished as apartment buildings. The "downtown" area is a modern shopping center. The denizens of the "Energy Capital" are a curious mix of rural-bred hill people and scientists and technicians from around the world. One out of every 35 Oak Ridgers holds a Ph.D. degree—one of the highest per capita ratios in the nation.

Clarence Lushbaugh arrived in 1963 to head the AEC clinic's ominously titled "Applied Radiation Biology Division." A short, balding man with a combative personality, Lushbaugh likes to say he "grew up in the gutters" of Cincinnati, Ohio, where his name, Clarence, "was a fighting name—you had to protect a name like Clarence." Most of his friends now call him "Lush," but the feisty attitude of his youth has not mellowed much in 65 years.

The nameplate behind Lushbaugh's desk informs visitors that he is the HSOBIC—Head-Son-Of-a-Bitch-In-Charge.

Educated at the University of Chicago, where he received his bachelor's degree, a Ph.D. in pathology and an M.D. in medicine, Lushbaugh began his career in 1949 as a pathologist in Los Alamos, New Mexico—another "atomic city." He doubled as the government town's coroner. In

1963, Lushbaugh moved to rural Tennessee and became a member of the staff of the Oak Ridge Institute.

"In Los Alamos," he explains, "we had plenty of radioisotopes and plenty of machinery, but we didn't have a whole lot of sick people because it was a rather young population." Oak Ridge offered the same access to radioisotopes plus a large group of Tennesseans who were grateful for free medical attention at the AEC clinic.

The Oak Ridge Institute had a mandate from the Atomic Energy Commission—which was then the government agency charged with promoting nuclear energy—to conduct research into the "beneficial applications of radiation." Some significant achievements did come out of Oak Ridge's clinic, including the development of a cobalt 60 (C-60) teletherapy machine, which served as a prototype for others now used in cancer therapy at hospitals across the country.

Lushbaugh was teamed with eminent hematologist Gould Andrews. Lushbaugh's star was rising. Andrews "was probably the world-renowned expert in taking care of persons with radiation injuries," Lushbaugh says modestly, "and I was the world-renowned expert at trying to figure out what went wrong at the autopsy table."

If someone was acutely irradiated in an accident, no matter when or where, Andrews was called in to give medical attention. His hunched figure was unmistakable—he was afflicted with extreme curvature of the spine. Andrews was a compas-

Patients did not offer their fully informed consent, and facilities were criticized as "substandard."

sionate and competent attendant to his patients, but whenever his medical ministrations failed, it was Lushbaugh's turn. Lushbaugh did the autopsies.

Shortly after his arrival in Oak Ridge, Lushbaugh won a NASA contract to conduct a retrospective analysis of the effects of radiation: a hunt for the point at which the syndrome symptoms appear. He looked for clues in the medical charts of cancer patients who had been treated with radiotherapy. By the end of 1964, Lushbaugh had compiled data on more than 3,000 patients at 43 different hospitals.

But the retrospective analysis had its limitations. The patients had received varying doses of radiation, and their doctors had not kept detailed notes on reactions in the systematic manner of a research scientist. A "prospective" study was needed. Oak Ridge was the ideal place for the study and Lushbaugh was the ideal choice to conduct it. By carefully monitoring patients during and after radiotherapy at the clinic, Lushbaugh and his associates could be on the lookout for syndrome symptoms and could correlate them with the exact dose of radiation received.

"BENEFICIAL" USES?

In 1960, the Oak Ridge clinic had begun operating a therapy chamber known as METBI—the Medium-Exposure-Rate Total-Body Irradiator. Built in a special wing of the tiny clinic, METBI was designed for experiments testing spray irradiation as a treatment for blood cancers. It was part of the Atomic Energy Commission's effort to use its nuclear wares to find those "beneficial applications of radiation."

Prior to World War II, researchers at the Memorial Sloan-Kettering Cancer Center in New York discovered that by spraying a leukemia victim's total body with X-rays, the radiation could be used to depress the bone marrow and kill cancerous blood cells forming there. Then, during the war, scientists found that injections of radiophosphorus and several nitrogen mustards could achieve essentially the same results at only a fraction of the cost. "In essence," said one of the AEC's consulting physicians, "spray irradiation techniques were superseded by simpler and better techniques."

Lushbaugh agrees. "The hematologists began using these nitrogen mustards," he says, "and so they began hogging all these patients with leukemia. . . . Well, obviously, the radiotherapists and the whole damn field of radiologists were not going to put up with that. So they came along with a system for doing the same things as the nitrogen mustards, [the difference being that] you don't have to hold the guy down and stick needles in him."

What they came along with at Oak Ridge was METBI—and a new twist in the technique of spray irradiation. Doctors

at Sloan-Kettering used an X-ray machine to spray their patients, but the Oak Ridgers thought that radiation-emitting isotopes like C-60 and cesium 137 (Ce-137) would be more flexible than a bulky machine.

Lushbaugh explains it this way: "See, with an X-ray tube, you would put the person on the floor in the fetal position, with his knees drawn up, and you'd zap him from the right side with an X-ray machine and then you'd flip him over and irradiate him from the other side." The METBI facility was a quantum improvement.

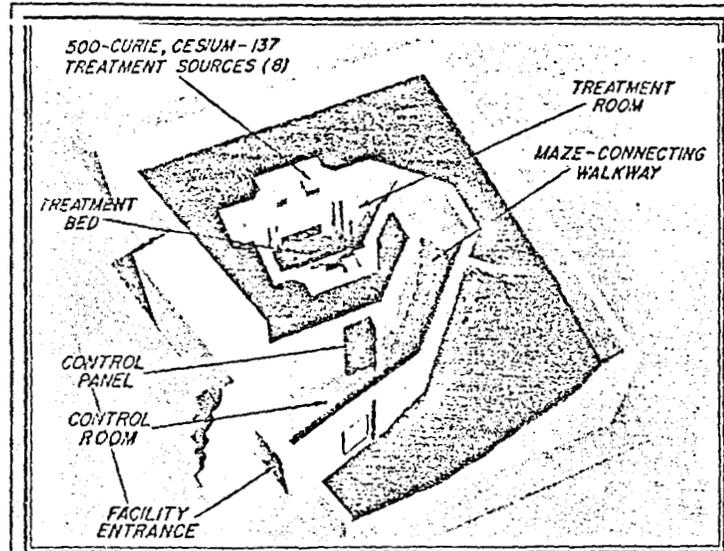
The doctors could zap their patients in a specially designed room with doses ranging from 1.8 rads per hour (1.8r) to 300 rads per hour (300r). These are extremely high doses—an ordinary chest X-ray is about one-tenth of a rad—but the exposures were and are considered therapeutic in treating some cancers. But as we will see in Dwayne Sexton's case and those of the other 88 patients in these experiments, the massive radiation doses were not only part of a treatment plan, but also a way of gathering data for the space program.

The treatment of leukemia patients in METBI began as soon as the facility was operational. Gould Andrews directed the clinical hematology staff. Lushbaugh monitored the cancer patients for signs of the

syndrome. Many aspects of the syndrome were already known even then. The government's handbook for the holocaust, *The Effects of Nuclear Weapons*, reports that "for doses between 200 and 1,000 rads the probability of survival is good at the lower end of the range, but poor at the upper end. The initial symptoms are similar to those common in radiation sickness . . . the larger the dose, the sooner will these symptoms develop."

As part of the federally funded Oak Ridge Associated Universities—a consortium of 50 colleges and universities throughout the South—the AEC clinic had a ready-made network from which to draw patients. Doctors in the rural South regularly referred cancer patients to Oak Ridge. Among them were people suffering from Hodgkin's disease, chronic lymphocytic leukemia, chronic granulocytic leukemia, polycythemia rubra vera, idiopathic thrombocytopenia and lymphosarcoma cell leukemia.

The Oak Ridge researchers began their study by exposing patients to 50 or 100 rads at a time in the METBI chamber at a rate of 1.5 rads per minute. According to an internal progress report written in 1970, doctors involved in the experiments apparently never really thought these large doses would benefit the patients much, but since the cancer victims would probably require radiotherapy anyway, the scientists at Oak Ridge hoped to obtain some of the syndrome data NASA wanted. "It was not our plan to evaluate the long-



This is a model of the METBI facility at Oak Ridge. Here and in another chamber 89 cancer patients were treated with high levels of radiation. The project apparently began as an attempt to improve cancer therapy. Ultimately, the experiments benefited NASA.

Courtesy of Oak Ridge Associated Universities

range effectiveness of these relatively large individual doses." Andrews, Lushbaugh and their colleagues explained in the report. "This would have required establishing a total treatment plan with this technique, which we were not prepared to do."

The scientists wanted to "be able to add or substitute other forms of treatment," which is not surprising, in light of the fact that the doctors virtually admitted that the METBI exposures were *not even the best method of treating the cancer patients with radiation*. "One should not infer from this study," they wrote in a candid assessment of the experiment, "that we expected these individual or infrequently given exposures to produce better clinical results . . . at present, we feel that some pattern of fractionated exposure [small doses of radiation in several treatments] probably offers a preferable approach for total-body radiotherapy."

What these large, single exposures in the METBI chamber *did* offer was the best opportunity to monitor for the radiation sickness syndrome. According to a report of the experiment provided to NASA, at least two patients at Oak Ridge received doses of 500 rads prior to a treatment called "bone marrow transplantation." Obviously, these two people were ideal subjects for the doctors involved in the NASA study to monitor for the syndrome.

ENTER, DWAYNE SEXTON

It was June of 1965 and the humid air was just hinting at the oppressive Tennessee summer ahead when three-year-old Dwayne Sexton first took sick. The auburn-haired boy just wasn't his usual self. First-born child of Talmon and Mary Sue Sexton, Dwayne had his daddy's dimpled chin, his mother's wide, brown eyes and enough energy to keep them both busy. That summer he changed. "Dwayne just wanted to sit or lay down," his mother remembers. "He was tired, run-down."

They visited the family doctor, who diagnosed Dwayne as anemic and prescribed liquid iron and vitamin B-12. The treatment didn't help much. Dwayne's normally rosy cheeks remained pale and waxy. Mary Sue insisted the doctor hospitalize him and find out what was wrong. Blood transfusions began in an attempt to counter the anemia. Finally, Mary Sue asked the doctor point-blank: "Does Dwayne have leukemia?" The physician said no, and then suggested that maybe the cause and cure of Dwayne's illness could be found at Oak Ridge. The arrangements had already been made. Mary Sue began keeping detailed notes in a journal.

On July 27, Dwayne checked into the Oak Ridge clinic for the first time. A chest X-ray was taken and bone marrow was withdrawn from his hip for a test. Mary Sue just happened by a room where one of the doctors was confiding the bad news

to Talmon: Dwayne had acute lymphatic leukemia.

Two days later Mary Sue wrote in her journal: "The medical staff discussed a type of treatment they would like to try on Dwayne. It was stated it could possibly be a cure for him. We know there is no hope at all for Dwayne except for a short life for him of from six weeks or maybe up to a year and a half, and he would be so sick so much of the time."

Mary Sue and Talmon agonized over the decision. "We decided it was worth the risk we would have to take for a chance at a cure for Dwayne," she noted in the journal. "We were reassured that the experiment was promising enough to take a chance with."

Mary Sue asked the doctor, "Does Dwayne have leukemia?" He suggested a cure might be found at Oak Ridge.

The doctors told the Sextons that Dwayne's case was virtually hopeless. They mentioned that there were various possible treatments but pointed out that, at best, all the treatments might do is provide a temporary reprieve. The Oak Ridge researchers then explained that they were interested in "bone marrow transfers," Mary Sue recalls. "They said it was experimental and would kill the leukemia cells. They offered that as an alternative. We took it as a desperation move for the health of our child."

THE CONSENT FORM

Both Dwayne's parents signed a consent form drafted by the Oak Ridge doctors. It reads, in part, "We understand and agree to a special experimental procedure designed to try to help our child who has acute leukemia. This will consist of removing bone marrow from the child, subjecting the marrow to radiation designed to kill the leukemic cells and subsequently injecting these cells into the mother . . . there are some risks involved for both mother and child. The nature of these has been explained to us, and we are willing to accept them."

In fact, the signing of the form by the Sextons did not really constitute "informed consent." Dwayne's parents were apparently misled into believing that the experimental bone marrow transfer was his best and only hope for survival. However, that treatment was clearly untried, and several better alternatives for treating acute lymphatic leukemia were widely known and available. According to Dr. Peter Wiernik, director of the Baltimore (Maryland) Cancer Research Center and a former official of the National Cancer Institute, a therapy protocol consisting of several chemical agents was the "common treatment at that time."

Instead of chemotherapy, eight days after his arrival at Oak Ridge, Dwayne was wheeled into the clinic's surgical arena and sedated. Bone marrow was carefully extracted through *seventeen* punctures in his legs, hips and breastbone. The marrow was then irradiated—probably in the METBI chamber. That afternoon, the irradiated bone marrow was

transferred into four syringes and injected into each of Mary Sue's hips and arms.

For Mary Sue, the injections were merely a painful irritant, but she was stoic about her discomfort. After all, her pain might help save Dwayne's life. But her eyes welled with tears when she pulled back the sheet covering her son's unconscious body and began counting the puncture wounds in his legs and chest.

On August 16 there was more surgery. A small incision was made in Mary Sue's left thoracic duct just above the collarbone, and a tube was inserted. For five days fluid drained through the tube into a plastic vacuum bag. This "serum" was filtered and then injected into Dwayne.

The doctors had hoped that Mary Sue's healthy body would build up antibodies, which would destroy the leukemic cells injected into her. Then, the antibodies in her blood serum could be used to fight the leukemic cells produced in Dwayne's bone marrow. But by mid-November of 1965, it was clear that this experiment had failed. Dwayne Sexton's condition was worsening.

"It was a superb idea," says the Baltimore Cancer Center's Peter Wiernick. "But you just cannot do those things in humans first thing." Medical authorities contacted by Mother Jones

agreed that it is simply unethical to inject cancer cells into a healthy human being, unless it is clearly a last resort. In Dwayne's case, it was not. Other therapies, whose worth was already proven, were readily available at the time. Today, research into cancer therapies using antibodies is still under way at several facilities, including the National Cancer Institute. Yet even now, 16 years after Dwayne's treatment, the experiments are conducted largely on laboratory animals and on human cancer cells in laboratory dishes.

After the failure of the bone marrow transfer, the Oak Ridge Institute doctors belatedly began treating Dwayne Sexton with chemotherapy.

A NEW GIMMICK

The Oak Ridge researchers were collecting syndrome data in earnest at that time, but the METBI facility had its problems and limitations. In addition, the Oak Ridgers had a new theory they wanted to test: Could they alleviate some of the side effects of the therapy by using lower doses of radiation over days or even weeks of continuous exposure?

By 1967, the AEC had financed the construction of a second facility at Oak Ridge: LETBI—the Low-Exposure-Rate Total-Body Irradiator. The difference between it and METBI was like the difference between the Ritz and a fleabag hotel. In fact, the paneled LETBI chamber was specifically designed and furnished to look like an ordinary hotel room where patients undergoing therapy could relax

and feel like they were on vacation. Except the LETBI chamber had no windows.

LETBI was really two rooms, one built within the other. The outer chamber was concrete. Inside, a smaller, wooden box was centrally positioned. Between the walls were eight cobalt 60 teletherapy machines, which created a radiation field that could administer doses as low as 1.5 rads per hour.

The radiation machines were operated and monitored remotely from an instrument console located in an adjacent control room. The panel also contained closed-circuit TV monitors, a communications system linked to the chamber and a read-out for the syndrome cord—an umbilical specifically

developed to study the vital functions of patients as they underwent these new radiation treatments. The 65-foot umbilical was used to search for syndrome symptoms.

By monitoring read-outs, technicians could watch for subtle changes in respiration that would indicate nausea. The syndrome study had advanced to the point where the doctors knew a patient was about to get sick and vomit before the patient did.

The patients "would really run the whole thing," Lushbaugh explains. "Just by [the patient] opening the door [to leave the chamber], the whole thing would turn off, and he'd go out

and take a leak and go back in, and somebody would bring him his meals."

Lushbaugh was successful in coming up with data that helped determine how much radiation it took to induce the syndrome. But NASA still wanted to know whether milder symptoms of radiation sickness might reduce an astronaut's ability to perform routine tasks in space.

DWAYNE'S LAST CRISIS

A series of strategically placed mirrors enabled Mary Sue to watch Dwayne in the METBI chamber. He thumbed a well-worn comic book contentedly while the machines were turned on. Just four months shy of his seventh birthday, Dwayne had become all-too-familiar with the routine of hospital life. Over three and a half years, he had spent countless days at the Oak Ridge clinic. Despite the failure of the bone marrow transfer, chemical therapies had kept his leukemic cells in remission—until this new crisis.

Mary Sue silently mumbled a prayer. On Thanksgiving Eve 1968, blood had begun trickling from Dwayne's nostrils and oozing from the back of his throat. Mary Sue could not stop the hemorrhaging. The Sextons sped the 70-mile drive from their home in Robbins, Tennessee.

Now she watched anxiously as Dwayne began to fidget on the aluminum bed. The only hope for prolonging his life, the doctors said, was to depress Dwayne's bone marrow with a



This picture of the Sexton family was taken in September 1967, about a year before Dwayne, on the right, died at the Oak Ridge clinic.

large enough dose of radiation to kill the cancer cells growing there. It was risky. The amount of radiation would also kill other cells and effectively knock out his body's immunity to bacteria. Dwayne would have to be closely guarded against deadly infection.

From METBI, Dwayne was wheeled into the nearby LETBI chamber, which the Oak Ridge doctors were using as a germ-free isolation ward. The umbilical monitor was strapped around his waist. The doctors told Mary Sue they needed to watch his vital signs carefully. They *didn't* tell her they were using the umbilical to collect data for their NASA study. Dwayne Sexton accepted this latest radiation therapy without a whimper.

"That radiation dose they gave Dwayne may have done the job," Mary Sue says now of the attempt to arrest the growth of the cancer cells, "but I think it done it a bit too much, possibly." In the following weeks, Dwayne's weight dropped by half to less than 30 pounds.

He barely had the strength to lift his head off the pillow, but he enjoyed picking through a flood of letters and Christmas cards, which poured in from relatives and friends. Mary Sue slept beside Dwayne in an empty bed, keeping a constant vigil. "Dwayne didn't care what they did to him," she says, "as long as his Mommy was there. It was like a fairy tale. He was such a brave little boy."

Dwayne knew intuitively his life was ending. "Don't cry, Mommy," he told Mary Sue as she stroked his forehead. "I'm going to be with Jesus."

OF MICE & MEN

Medical science has its own system of judging advances in treatment and therapy. Teams of doctors with expertise in the particular area of research carefully consider and evaluate their fellow doctors' projects.

On several occasions during the LETBI and METBI experiments, inspectors from the AEC visited the Oak Ridge clinic. Judging by the documentary records available, most of the so-called peer reviews by doctors who scrutinized the facility were less than laudatory. One reviewer charged "the directors weren't paying enough attention to what was going on. There had been a previous site visit a couple of years before mine, and their report was ignored."

The report of the review team dispatched to Oak Ridge in March 1974 could not be ignored. They called the clinical facilities "substandard" and recommended the facility be shut down or the program be moved elsewhere. Dr. William Bibb, now the Energy Department's director of research in Oak Ridge, argues that the clinic was closed because "it was giving exquisite care to the people it was taking care of, but it was not providing any research results at all."

On the contrary, the evidence indicates that patients were not receiving "exquisite care." The physicians' judgments of which therapy might be most beneficial to the patients may have been clouded by their desire to come up with "beneficial applications of radiation" for the AEC and syndrome data for NASA. The cancer patients who came to the clinic for help became, in effect, laboratory animals.

In a confidential report, members of the AEC review team that visited the clinic in 1974 expressed their uneasiness with the low quality of the facility and the poor patient care. They characterized the nuclear medicine program as "very pedestrian" and gave the clinical hematology division "an unfavorable rating." But more importantly, the reviewers discovered that some patients at the clinic may have had their lives jeopardized: just beneath the wooden floor of the LETBI chamber, the Oak Ridge researchers had suspended on plastic cords approximately 50 cages of laboratory mice.

Leukemia patients, especially those undergoing radiotherapy like Dwayne Sexton, are virtually defenseless against infection. In hospitals they are carefully isolated from any source of harmful bacteria. Yet, at Oak Ridge, the clinicians were experimenting by irradiating mice and men simultaneously and thus, according to the AEC report,

exposing the patients to potentially deadly infection from the animal cages hung directly below the LETBI treatment chamber.

Twice a week, animal caretakers crawled between the inner and outer shells of the LETBI facility to provide fresh food and water for the mice. They carried the dirty cages "through the patient area to an elevator and down to the cage washer," noted the AEC review report. "This entire arrangement seems to be questionable because of the necessity of transporting the animals, animal wastes and equipment through areas used by patients who frequently have compromised host defense mechanisms." In other words, patients whose bodies are incapable of fighting off infection. "This area," the reviewers wrote, "would appear to be highly prone to severe infestations of vermin."

Human guinea pigs are essential to every discovery designed to prolong life, relieve suffering or improve the quality of the human condition. Sooner or later, someone has to submit to new therapies to determine whether they are effective or useless. Doctors routinely comb the professional journals of their various disciplines, searching for clues of discovery provided by their peers' successes and failures.

The 14 years of experiments by the Oak Ridge researchers provided few of those clues. Clarence Lushbaugh did produce a 224-page report on the LETBI and METBI studies for NASA, but he did not publish a single scientific paper on the

Morgan believes he was "misled" about the clinic. "My hope & trust were misplaced," he says now.

experiments in any recognized journal because "we never considered them to be of enough scientific quality." In his report's summary, Lushbaugh cautioned that the studies should "not be considered definitive." In fact, the experiments raised more questions than they answered.

WERE PATIENTS HELPED?

In their confidential report, the AEC reviewers lambasted the researchers for their work, which they labeled "dismal." The report explicitly says the METBI and LETBI programs evolved "without adequate planning, criticism or objectives." The bone marrow transplant experiments received especially harsh criticism. "In view of accepted therapeutic modalities, ethical questions were raised with respect to the protocols employed in these studies," the confidential AEC report read.

The chamber experiments didn't even result in any appreciable improvement in radiotherapy techniques. "There is little if any clinically useful data on the METBI and LETBI programs," one of the AEC reviewers wrote in his confidential report four years later. "LETBI has been used long enough to establish (if I understand Dr. Lushbaugh correctly) that a very low dose rate does not offer any advantage over the administration of the dose at a higher rate in small, daily fractions."

Was the purpose of the experiments primarily to provide data for the space program?

In the beginning, Lushbaugh and Andrews wrote in 1970, a principal objective of the experiments "was to seek information that might lead to improved radiation therapy." However, that noble search for the light of knowledge was soon corrupted. "During the course of the study," they noted in their progress report, "the urgent need arose for information on hematologic effects in man, since the National Aeronautics and Space Administration was faced with potentially high levels of radiation exposures in space exploration."

In short, the syndrome search took precedence. It is not surprising that the METBI and LETBI experiments—with respect to cancer therapy—would get a lower priority: Lushbaugh and Andrews admitted in their 1970 progress report that they did not expect "these individual or infrequently given exposures to produce better clinical results" and that a different radiation treatment "probably offers a preferable approach for total-body radiotherapy."

Despite the documentary evidence, Lushbaugh denies emphatically the suggestion that the experiments were conducted principally for NASA's benefit. He claims his monitoring program was simply "piggybacked" onto the LETBI and METBI cancer therapy treatments. The Energy Department's William Bibb also denies that the search for the

Photograph by Howard Rosenberg



Clarence Lushbaugh, who has testified about exposing Oak Ridge patients to radiation, now says his role was not significant.

syndrome motivated the experiments. "It was the AEC that financed that," Bibb says. "With or without the NASA study, that program would have gone on." Yet, Lushbaugh's 1975 report to NASA clearly states that "the radiobiologic studies" were "carried out with joint AEC and NASA support during the years 1964 to 1974." NASA's support was financially crucial, especially in the experiments' final years.

According to Allen Webb, chemist at the clinic during the experiments, "In the early 1970s, Lushbaugh had to kick asses and pull strings to get enough money to keep LETBI running. NASA provided the monies."

Lushbaugh himself estimates that during the ten years NASA sponsored his research, the space agency provided "three or four million dollars." The records available are limited to the period between 1969 and 1976 and account for payments by NASA of only \$799,766 of the total amount. Lushbaugh's colleague, R.C. Ricks—who coauthored the report for NASA—says that with the exception of about \$5,000 he spent for bicycle ergometry equipment, NASA paid his salary and Lushbaugh's salary, and the rest of "the funds were spent primarily for salaries for people to be at LETBI."

Clearly, the paper trail of evidence leads directly to the space agency. An at-

tachment to NASA purchase orders (signed by AEC officials and authorizing funds for the project) notes that "the 'Prospective' Human Radiation Sensitivity studies will be continued and will be increased in number in both LETBI and METBI as more patients appropriate to this type of therapy are referred to us." Without NASA money, there would not have been enough cash to continue.

Did the LETBI and METBI radiation experiments actually benefit the patients?

The AEC's reviewers answered that question with an unequivocal and emphatic no. "There has been little thought," they wrote in a disturbing assessment of the experiments, "as to therapeutic utility or potential long-range consequences." In any medical facility, what is best for the patient should always be of paramount importance; and yet, the AEC reviewers accused the Oak Ridge researchers of ignoring whether the therapy they employed was doing any good. Unfortunately, at least 89 cancer patients—including Dwayne Sexton—passed through the LETBI and METBI chambers before the government came to that belated conclusion and itself ordered a halt to the experiments.

THE AFTERMATH

Gould Andrews left the Oak Ridge clinic after the AEC ordered the facility closed and joined the faculty of the University of Maryland. Lushbaugh asserts that it was

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INFORMED CONSENT

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Andrews who determined which patients should be irradiated in the chambers and how big a dose they should get. However, a number of those involved in the experiments remembered that a committee of the clinic's staff—including Lushbaugh—made the determinations collectively. Andrews cannot speak for himself. He died in the summer of 1980.

Dr. Karl Z. Morgan was the director of the Oak Ridge National Laboratory's Health Physics Division during the LETBI and METBI experiments. Morgan is known throughout the world as the "father of health physics," a science dedicated to the prevention of radiation damage. He is probably the leading figure on radiation protection in the United States and, as such, could hardly be called "antinuclear." Currently a professor of physics at the Georgia Institute of Technology, Morgan believes that during his tenure at the Oak Ridge national laboratory, he was sadly confused about the purpose and results of the LETBI and METBI radiation experiments.

"I naively thought that the purpose of this nearby center [the clinic] was to use ionizing radiation in the treatment of cancer in a manner that had been proven to offer justifiable hope of remission and, in some cases, a cure," Morgan says today. "I believe I was misled, and my hope and trust in this program were badly misplaced."

As it turns out, one of Morgan's lifetime friends, his childhood Sunday school teacher, was one of the 89 patients who went to the Oak Ridge clinic for help and became a subject for the radiation syndrome study. Information about the nature of this clinic has, for Morgan, a special pain.

"The evidence strongly suggests," Morgan continues carefully, "that the purpose of this program was not what we were led to believe." Though Morgan trained dozens of medical doctors himself in methods of using radiation for human benefit, he says he is "appalled, overcome with consternation and filled with a deep sense of indignation" by the news that the cancer patients treated at the Oak Ridge clinic really became guinea pigs for the space program. "It causes one to wonder," Morgan concludes, "whether the members of the medical profession who were responsible could have been sincere the day they took the Hippocratic oath."

Clarence Lushbaugh still has his offices at the clinic itself, but now he is the director of the Oak Ridge Associated Universities' Medical and Health Sciences Division and brags that "only God can retire me." Just months after the review team concluded its damaging report on the clinic, Lushbaugh was awarded another ongoing contract, this one by the Energy Department to conduct an epidemiological analysis of possible health risks to nuclear workers at the Energy Department's Oak Ridge plants.

Lushbaugh's new research project could be another potential bombshell if it confirms the results of a previous study of nuclear workers. That study, by University of Pittsburgh professor Thomas Mancuso, revealed—after 12 years of work—that nuclear workers at the Energy Department's Hanford, Washington, atomic works suffered a significant increase in the incidence of certain types of cancer at radia-

tion exposure levels *well below* "safe" limits.

While Lushbaugh has no experience in conducting epidemiological analyses, as in this new study, he does have experience in coming up with the sort of data the government likes. In his final report to NASA on the LETBI and METBI experiments, Lushbaugh explained that one of his objectives in undertaking the project was that "these unbiased clinical observations were sorely needed to defend existing environmental and occupational radiation exposure constraints from attack by well-meaning, but impractical, theorists."

In the past, when the government faced troubles because nuclear workers or atom bomb test victims were suing Uncle Sam for injuries they sustained, Lushbaugh was counted on to offer "expert testimony" against them. That was exactly what took place in U.S. District Court in Las Vegas, Nevada, on May 16, 1977.

Seven years earlier an underground nuclear bomb test at the nearby Nevada Test Site went awry. Scientists had miscalculated the power of the so-called Baneberry bomb, and a mushroom cloud broke through the earth's crust and rose some 10,000 feet into the sky. The cloud began drifting toward an AEC base camp. Setting aside their own safety, 13 guards frantically evacuated the camp. Three of the 13 later died of leukemia, apparently because of their exposure to unsafe amounts of radiation. Two of the widows sued the federal government. Clarence Lushbaugh testified against one of the women.

Lushbaugh now denies he had any significant role in the actual operation of METBI and LETBI. Yet, to prove his own expertise on radiation effects during his testimony at the Baneberry widow's trial, Lushbaugh described the LETBI and METBI experiments. He testified that "we ourselves exposed persons to various total-body doses of radiation, and this was an ongoing study that I worked in and subsequently I became the leader of it, and we radiated persons with various kinds of leukemias in a specially designed room where they actually lived in a sea of radiation with their daily dose."

Dwayne Sexton died at the Oak Ridge clinic on December 29, 1968, a month after his last therapy session in METBI. A limited autopsy was performed. The cause of death was determined to be acute strep and staph infection.

*It seems we only miss you more
As each passing day goes by
Yes, our hearts have all been broken
Yet we try hard not to cry*

*You were such a bright spot in our lives
Since the first day you came
There's an empty place in our home
That will never be the same*

—from a poem dedicated to Dwayne, by Mary Sue Sexton, written three months after his death

In the entire history of the United States Manned Spaceflight Program, not a single astronaut ever received a high-enough dose of radiation to suffer from the syndrome. Dwayne Sexton did.

Howard L. Rosenberg is the author of Atomic Soldiers (Beacon Press, 1980). He also describes himself as "a writer and rider" on the staff of Jack Anderson's "Washington Merry-Go-Round." Supplementary research for this article was contributed by the Environmental Policy Center.

Wesch Post - Karen Barker
Kerlyn

Federal Tort Claims action filed in

1983 - I have been working case
administratively since that time

Filed complaint 5/26/85 - in U.S. District
Court Inc. have not read complaint

From: J.SHERWOOD (DOE1604) Posted: Tue 28-May-85 11:03 EDT Sys 64
Subject: DEPARTMENT OF ENERGY :department of energy mrs sexton in a tele
* UPI NATIONAL Wire

Acknowledgment Sent

From: NEWS Posted: Tue 28-May-85 3:44 Sys 97
To: J.SHERWOOD
Subject: DEPARTMENT OF ENERGY :department of energy mrs sexton in a tele
* UPI NATIONAL Wire

adv 6:30 am edt

Parents sue government over son's leukemia death

WASHINGTON (UPI) — The parents of a 6-year-old boy who died of leukemia accused the federal government today of treating him as "a human guinea pig" by using experimental radiation on him instead of conventional chemotherapy.

Lawyers for Mary Sue and Talmon Sexton of Kingsport, Tenn., said they would file a \$10 million lawsuit against the federal government today charging it with "unethical and improper" experiments that led to the death of their son, Dwayne, in 1968.

The suit, to be filed in U.S. District Court for the District of Columbia, said Dwayne "was deprived of his best chance of survival" and his family suffered emotional and psychological damage because of medical care he received at an Oak Ridge, Tenn., clinic run by the Atomic Energy Commission.

"As a direct and proximate result of the government's negligent and unlawful conduct, Dwayne Sexton was unwittingly treated as a human guinea pig," the suit said.

Dwayne was diagnosed as having acute lymphatic leukemia in July 1965 after his parents took him to the clinic on the recommendation of a family doctor.

After discussion with clinic staff, the Sextons agreed to the use of an experimental radiation treatment on their son.

The treatment, which court documents said never had been tried on animals, involved removing bone marrow from Dwayne's body and subjecting it to radiation before injecting it back into him.

About two weeks after the treatment, Dwayne's leukemia went into remission. But 13 weeks later, Dwayne suffered a relapse and began chemotherapy. When he failed to respond, the Sextons agreed to another experimental treatment in which Dwayne's entire body was exposed to radiation for 3 1/2 hours.

The boy died Dec. 29, 1968.

The Oak Ridge clinic was one of several research facilities set up by the Atomic Energy Commission to explore medical use of radiation. The clinic was closed in the 1970s, and, since then, the AEC has been replaced by the Department of Energy.

Mrs. Sexton, in a telephone interview, said she and her husband, who have three sons, did not file the suit earlier because they were unaware the government's treatment had been negligent. She said they began to question the treatment in 1981 when an investigative reporter interviewed them for a story.

"We want to make sure it definitely will not happen to someone else," she said. "It'll never make up for Dwayne's death."

Arthur Bryant, an attorney representing the Sextons on behalf of Trial Lawyers for Public Justice, said the case is unusual because it accuses the government of negligence in implementing its experimental medical program.

"It's a lot more than a simple wrongful death suit," he said.

"This was a little boy who had a chance of surviving and they destroyed his only chance of surviving."

adv 6:30 am edt

upi 65-28-85 03:43 aed

Disposition:
End of Mail.

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1022305

8/15

Cyp to: Alexander
Wyatt - info.
Jones - info.

7/15 Given to Jameson @ 5:15p
and also fax to Maddox
and discussed. DF

United States Government

Department of Energy

Oak Ridge Operations

memorandum

DATE: August 15, 1990

REPLY TO: M-4:Alexander
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TO: M. J. Jameson, PA-1, Press Secretary, DOE/Headquarters

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The couple's charges served as the foundation for an article carried in a national magazine, Mother Jones, in the fall of 1981. The magazine called a Washington press conference to launch the edition and heavy news media attention followed. A press conference was held in Oak Ridge at that time. In September of that year, then Congressman Albert Gore of Tennessee, Chairman of the House Science and Technology Committee, held a Washington hearing to investigate the charges. A copy of a Science magazine article on the hearing and a hearing summary prepared at the time are attached as a

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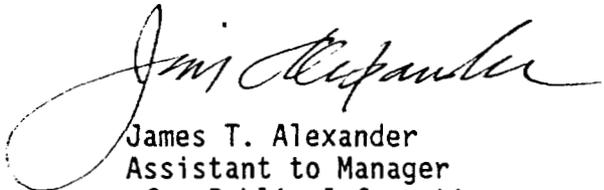
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James T. Alexander
Assistant to Manager
for Public Information

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Jeff Sherwood

1022308

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Ashton concedes that the problem is "many faceted and, therefore, difficult to get across." More organizations are showing interest—USDA and AID, for example, as well as nongovernmental organizations such as the World Wildlife Fund and International Union for the Conservation of Nature, says Ashton. But "there is a lack of communication. Nobody is running the show." More-

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The hearing was held on 23 September before the House science and technology subcommittee on investigations, chaired by Representative Albert Gore, Jr. (D-Tenn.). Gore picked his way carefully through the evidence, laying out a record that essentially faults the clinic for operating at less than the highest medical standards in the 1960's and 1970's, but fails to support the charge that patients were used in a callous fashion to generate data on space hazards.

Much of the testimony focused on the case of Dwayne Sexton, a child with acute leukemia who was treated at the Institute of Nuclear Studies (INS) in Oak Ridge, Tennessee, from 1966 to 1969. He

died there in 1969 at the age of 6½. Early press accounts suggested that Sexton was needlessly given radiotherapy as part of a program to collect data for the National Aeronautics and Space Administration (NASA). The evidence did not support this allegation. Indeed, the hearing produced little new information on the NASA-sponsored research.

Witnesses did raise questions about the quality of care Sexton received, however. One physician said that it may have been wrong to involve the child in an immunologic experiment at INS before he had been given a standard course of chemotherapy. Gore questioned some of the former INS researchers about the wisdom of conducting experiments in which people were exposed to radiation at low dose rates for prolonged periods. But medical witnesses said the experiments seemed reasonably well run, given the state of knowledge about radiotherapy in the late 1960's.

The inquiry was limited because there were many gaps in the record. Andrew Stofan, a NASA official, disclosed that all of NASA's documents on the INS

research, which ran from 1964 to 1974, had been thrown out in the course of routine housecleaning. Gould Andrews, INS' chief medical investigator, whose testimony would have been valuable, died last year.

The INS clinic was closed in 1974 after a review committee decided that it would cost too much to bring the facilities into compliance with the health and cleanliness standards enforced at that time by the big insurance companies. The staff and facilities were incorporated into the Oak Ridge Associated Universities.

As the hearings revealed, INS had several goals, which at times may have been in conflict. First, the clinic sought to help cancer patients by giving them a variety of treatments, including chemotherapy, which one INS staffer referred to as a "competitor" with the clinic's specialty: radiotherapy. A second goal was to develop new techniques for treating cancer with radiation. Third, some of the researchers were being paid by NASA to collect information on the effects of small doses of radiation on man. NASA wanted to know, for example,

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whether the radiation emitted by solar flares would fatigue or sicken astronauts in space.

The fundamental questions Gore asked were: Did the Institute's desire to collect experimental data affect choices of therapy, and did the therapy harm the patients? The hearing demonstrated that some of the research was closely coordinated with the effort to collect data for NASA. It did not show that patients were harmed or deprived of good medical care because they participated in experiments. In fact, many were given conventional therapy and benefited from it. Those who volunteered for experi-

ment forms used did not meet the highest standards.

The Sexton case did not cast light on the controversy involving low-level radiation studies of interest to NASA. Sexton, after all, was exposed to a high level of radiation. Officials who were at INS argue that the Sexton case would not have been included in NASA's data bank under any circumstances, because NASA was interested only in adults.

Nevertheless, Gore did produce evidence showing that INS researchers felt pressure to find data for NASA. In the example that Gore cited, the INS' medical director Andrews—to his credit—

Andrews—to his credit—refused to participate in what he considered unethical experiments involving prisoners in California

mentation had failed to respond to standard treatment. That, at least, was how the system was supposed to work. Whether or not it did in every case is not as clear.

Mary Sue Sexton, mother of Dwayne, told the subcommittee that she felt she had been "betrayed . . . lied to, and misled" by the physicians at the INS clinic. She had not felt that way at first, she explained, but only after she learned recently from a journalist that her son might have lived if he had been given a course of standard maintenance chemotherapy. Instead, he was given a partial course of chemotherapy and then an untried form of immunologic therapy. The treatment failed. The child was then given "maintenance chemotherapy," and, when all else had failed, a single large dose of gamma radiation.

Although Mrs. Sexton said that she was not fully informed of the risks that she and her son were taking, she did sign a consent form that described the proposed experiment in simple terms and noted that conventional treatment had been freely offered as an alternative. The Sextons clearly volunteered.

The subcommittee called on two scientists as independent commentators: Robert Wiernik, director of the Baltimore Cancer Research Center, and Eli Glatstein, chief of the radiation oncology branch of the National Cancer Institute. Neither found any evidence in the material produced for the hearing that patient care at the INS clinic had been altered to suit NASA's needs. At the same time, they said, the research protocols and

refused to participate in what he considered unethical experiments involving prisoners in California, as had been proposed with "enthusiasm" by a NASA official.

Gore also quoted from an INS budget report to NASA on low-dose radiation experiments planned for 1970 which said: "An active canvassing program for increasing our utilization of these facilities has been developed. . . . We anticipate that this program will produce a greater influx of patients than we have experienced in the last 2 years." The same memo informed NASA that "We now believe we are ready to use regularly spaced, carefully selected, repeated small exposures over a small period of many months in an effort to maintain more uniform control of disease. . . . We will use therapeutic irradiation scenarios derived in part from 'space radiation profiles.' . . . These may be based either on intelligent conjectures or actual experience measured in space. . . ." However, Gore did not cite evidence showing that this desire to please NASA had any detrimental impact on care at the INS clinic.

Gore said that he had called the hearing to find out "whether the people involved in this program were treated in the best possible way for their welfare or whether they were in any way dehumanized in the search for some other social good." Neither he nor the committee staff has passed judgment on that question yet, but they promise to do just that in a written report now being prepared.—ELIOT MARSHALL

Arms Control Teach-ins Planned by Scientists

The subject is Armageddon, but people meeting to learn about it on college campuses this fall will not be gathering to hear revivalist preaching. On the contrary, they will hear given by some profound materialists: nuclear physicists, computer scientists, and electrical engineers from America's best universities.

The occasion, scheduled for Veterans Day, 11 November, is being called the "Convocation on the Threat of Nuclear War." The prime sponsor is the Union of Concerned Scientists (UCS), an independent group with strong ties to the Massachusetts Institute of Technology (MIT).

The purpose of the campaign, according to a draft statement circulated by UCS, is to educate Americans about the "threat of nuclear weapons and the growing possibility of nuclear war and the urgent need to reduce nuclear risks. . . . If properly organized, the events will identify a group of individuals who might participate in a "help" organize future arms control efforts.

To insure that the message goes beyond the confines of academe, UCS has budgeted for expenses of about \$50,000 and secured the help of some skilled political advisers. Two of these are Carl Wagner, a former field campaign manager for Senator Edward Kennedy (D-Mass.), and David Brunell, a longtime activist in congressional reform movements.

The person who conceived the campaign is Henry Kendall, chairman of the board of UCS and a professor of physics at MIT. In January he commissioned an in-house study of the technological and political factors inhibiting arms control. By June he had become so concerned about the chaotic state of U.S. weapons policy that he felt some emergency action was called for. Until recently, the UCS has focused chiefly on the commercial nuclear sector. Suddenly, arms control has been made the first priority. Kendall insists, however, that older projects will not be neglected as a result.

Kendall and UCS' executive director, Eric Van Loon, say they have been surprised by the strength of the response they have received. They

1022310

Report on Congressional Hearing by
House Science and Technology Subcommittee on Investigations and Oversight
Chaired by Rep. Albert Gore, Jr. (D-Tennessee, Fourth District)
Regarding the Mother Jones Controversy

In mid-August, 1981, promoters of an article scheduled for the September-October edition of an antinuclear publication entitled Mother Jones charged that the Oak Ridge Institute of Nuclear Studies (as ORAU was known before 1966) had used patients as "human guinea pigs" without their consent in experiments to provide data for the National Aeronautics and Space Administration.

National television and other news media had been contacted to detail charges in the article, "Informed Consent," with subheads "How Much Radiation Can An Astronaut Withstand? NASA Used Dwayne Sexton to Find Out." Specifically the article charged that ORAU's Medical Division had experimented unethically to find beneficial applications of nuclear energy and help NASA without regard to the best interests of patients. As a focused example, the author Howard L. Rosenberg alleged that medical assistance to one young patient (Sexton) had been inadequate and improper (e.g., that radiation levels were too high). Rosenberg also claimed that clinical facilities were substandard and produced little of research value. As a result of the charges, Congressman Albert Gore, Jr. (D-Tennessee, Fourth District) scheduled hearings subsequently held September 23 in Washington before the House Science and Technology Subcommittee on Investigations and Oversight.

The response of U.S. Department of Energy and Oak Ridge Associated Universities officials was prompt and effective:

1. On August 20, 1981, the same day that promoters of the magazine article had a Washington press conference, a DOE-ORAU press conference was held at ORAU in which DOE's Dr. William Bibb and ORAU's Dr. C. C. Lushbaugh countered the magazine charges and outlined the true background and purposes of the program. The weight of the evidence was clearly against Mother Jones. Local newspaper and TV coverage was overwhelmingly supportive of ORAU. Specifically, DOE/ORAU efforts communicated:
 - A. Patients were never "used as human guinea pigs" in the sense conveyed by the Mother Jones article; i.e., as unknowing victims of experiments for purposes without regard to their best interests. The patients' needs always came first.
 - B. Dwayne Sexton, the child exploited in the Mother Jones article, did not receive high levels of radiation "to test man's tolerance of radiation in space," but in a last-ditch effort to save his life. Conventional chemotherapy and other treatments had failed. The child was dying after more than three years of various therapies in the ORAU hospital and clinic; his doctors concluded that the high levels of radiation were essentially the only means left to extend his life. In fact, he had lived 3.5 years after first entering our clinic with acute lymphocytic leukemia.

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- C. It is true that patients did receive experimental treatments with total body irradiation and that some of the data was used as part of a retrospective study to determine levels of human radiation tolerance. However, the treatment protocols were not influenced or biased in any way to enhance these evaluations. This study also examined 3000 patient records from 45 other hospitals that used total body irradiation in leukemia therapy. Ironically, the Sexton boy's irradiation therapy actually occurred after ORAU had completed the report to NASA and the National Academy of Sciences on high-level radiation in 1967--the year before the Sexton boy died. In 1968 the primary clinical research interest was in protracted and fractionated low-level radiation and not in single-dose exposures.
- D. The child's parents were fully informed about the treatment--both verbally and in explanations written in lay language and signed by Mr. and Mrs. Sexton. The parents clearly gave ORAU their informed consent.
- E. Although some program reviewers questioned the research value of some of the work of the clinic and the quality of the general facilities, the fact is that patient requirements always came before experimental needs for data, and good equipment was more important than high-quality buildings per se. The research clinic operated as well as possible within available government funds, making substantial contributions to the development of nuclear medicine over the past 30 years.
2. At the Gore subcommittee hearings, the points outlined above and many others were effectively presented by both DOE, ORAU, and former clinic employees and patients. Immediately following the hearings, Rep. Gore was quoted as saying the Mother Jones charges had been "essentially refuted." A report from the House subcommittee is expected late this fall.

* * * *

8/15

Cup to: Alexander
Wyatt - info.
Jones - info.

115
and also tied to Maddox
and discussed. DF

United States Government

Department of Energy

Oak Ridge Operations

memorandum

DATE: August 15, 1990

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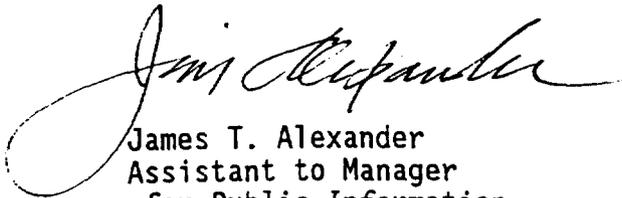
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As the hearings revealed, INS had several goals, which at times may have been in conflict. First, the clinic sought to help cancer patients by giving them a variety of treatments, including chemotherapy, which one INS staffer referred to as a "competitor" with the clinic's specialty: radiotherapy. A second goal was to develop new techniques for treating cancer with radiation. Third, some of the researchers were being paid by NASA to collect information on the effects of small doses of radiation on man. NASA wanted to know, for exam-

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whether the radiation emitted by solar flares would fatigue or sicken astronauts in space.

The fundamental questions Gore asked were: Did the Institute's desire to collect experimental data affect choices of therapy, and did the therapy harm the patients? The hearing demonstrated that some of the research was closely coordinated with the effort to collect data for NASA. It did not show that patients were harmed or deprived of good medical care because they participated in experiments. In fact, many were given conventional therapy and benefited from it. Those who volunteered for experi-

ment forms used did not meet the highest standards.

The Sexton case did not cast light on the controversy involving low-level radiation studies of interest to NASA. Sexton, after all, was exposed to a high level of radiation. Officials who were at INS argue that the Sexton case would not have been included in NASA's data bank under any circumstances, because NASA was interested only in adults.

Nevertheless, Gore did produce evidence showing that INS researchers felt pressure to find data for NASA. In the example that Gore cited, the INS' medical director Andrews—to his credit—

Andrews—to his credit—refused to participate in what he considered unethical experiments involving prisoners in California

mentation had failed to respond to standard treatment. That, at least, was how the system was supposed to work. Whether or not it did in every case is not as clear.

Mary Sue Sexton, mother of Dwayne, told the subcommittee that she felt she had been "betrayed . . . lied to, and misled" by the physicians at the INS clinic. She had not felt that way at first, she explained, but only after she learned recently from a journalist that her son might have lived if he had been given a course of standard maintenance chemotherapy. Instead, he was given a partial course of chemotherapy and then an untried form of immunologic therapy. The treatment failed. The child was then given "maintenance chemotherapy," and, when all else had failed, a single large dose of gamma radiation.

Although Mrs. Sexton said that she was not fully informed of the risks that she and her son were taking, she did sign a consent form that described the proposed experiment in simple terms and noted that conventional treatment had been freely offered as an alternative. The Sextons clearly volunteered.

The subcommittee called on two scientists as independent commentators: Robert Wiernik, director of the Baltimore Cancer Research Center, and Eli Glatstein, chief of the radiation oncology branch of the National Cancer Institute. Neither found any evidence in the material produced for the hearing that patient care at the INS clinic had been altered to suit NASA's needs. At the same time, they said, the research protocols and

refused to participate in what he considered unethical experiments involving prisoners in California, as had been proposed with "enthusiasm" by a NASA official.

Gore also quoted from an INS budget report to NASA on low-dose radiation experiments planned for 1970 which said: "An active canvassing program for increasing our utilization of these facilities has been developed. . . . We anticipate that this program will produce a greater influx of patients than we have experienced in the last 2 years." The same memo informed NASA that "We now believe we are ready to use regularly spaced, carefully selected, repeated small exposures over a small period of many months in an effort to maintain more uniform control of disease. . . . We will use therapeutic irradiation scenarios derived in part from 'space radiation profiles.' . . . These may be based either on intelligent conjectures or actual experience measured in space. . . ." However, Gore did not cite evidence showing that this desire to please NASA had any detrimental impact on care at the INS clinic.

Gore said that he had called the hearing to find out "whether the people involved in this program were treated in the best possible way for their welfare or whether they were in any way dehumanized in the search for some other social good." Neither he nor the committee staff has passed judgment on that question yet, but they promise to do just that in a written report now being prepared.—ELIOT MARSHALL

Arms Control Teaching Planned by Scientists

The subject is Armageddon: people meeting to learn about college campuses this fall will be gathering to hear revivalist preaching. On the contrary, they will be given by some profound mathematicians, nuclear physicists, computer scientists and electrical engineers from America's best universities.

The occasion, scheduled for next Monday, 11 November, is called the "Convocation on the Threat of Nuclear War." The prime sponsor is the Union of Concerned Scientists (UCS), an independent group with strong ties to the Massachusetts Institute of Technology (MIT).

The purpose of the campaign, according to a draft statement prepared by UCS, is to educate Americans about the "threat of nuclear war and the growing possibility of nuclear annihilation and the urgent need to reduce the risks. . . . If properly organized, these events will identify a group of individuals who might participate in a 'help' organize future arms control efforts.

To insure that the message goes beyond the confines of academia, UCS has budgeted for expenses of about \$50,000 and secured the aid of some skilled political advisers of these are Carl Wagner, a field campaign manager for Senator Edward Kennedy (D-Mass.), and David Brunell, a longtime activist in congressional reform movements.

The person who conceived the campaign is Henry Kendall, chairman of the board of UCS and a professor of physics at MIT. In January he commissioned an in-house study of technological and political factors inhibiting arms control. By June he had become so concerned about the chaotic state of U.S. weapons politics that he felt some emergency action should be called for. Until recently, the UCS had focused chiefly on the commercial nuclear sector. Suddenly, arms control has been made the first priority. Kendall insists, however, that older projects will not be neglected as a result.

Kendall and UCS' executive director, Eric Van Loon, say they have been surprised by the strength of the response they have received.

1022317

Report on Congressional Hearing by
House Science and Technology Subcommittee on Investigations and Oversight
Chaired by Rep. Albert Gore, Jr. (D-Tennessee, Fourth District)
Regarding the Mother Jones Controversy

In mid-August, 1981, promoters of an article scheduled for the September-October edition of an antinuclear publication entitled Mother Jones charged that the Oak Ridge Institute of Nuclear Studies (as ORAU was known before 1966) had used patients as "human guinea pigs" without their consent in experiments to provide data for the National Aeronautics and Space Administration.

National television and other news media had been contacted to detail charges in the article, "Informed Consent," with subheads "How Much Radiation Can An Astronaut Withstand? NASA Used Dwayne Sexton to Find Out." Specifically the article charged that ORAU's Medical Division had experimented unethically to find beneficial applications of nuclear energy and help NASA without regard to the best interests of patients. As a focused example, the author Howard L. Rosenberg alleged that medical assistance to one young patient (Sexton) had been inadequate and improper (e.g., that radiation levels were too high). Rosenberg also claimed that clinical facilities were substandard and produced little of research value. As a result of the charges, Congressman Albert Gore, Jr. (D-Tennessee, Fourth District) scheduled hearings subsequently held September 23 in Washington before the House Science and Technology Subcommittee on Investigations and Oversight.

The response of U.S. Department of Energy and Oak Ridge Associated Universities officials was prompt and effective:

1. On August 20, 1981, the same day that promoters of the magazine article had a Washington press conference, a DOE-ORAU press conference was held at ORAU in which DOE's Dr. William Bibb and ORAU's Dr. C. C. Lushbaugh countered the magazine charges and outlined the true background and purposes of the program. The weight of the evidence was clearly against Mother Jones. Local newspaper and TV coverage was overwhelmingly supportive of ORAU. Specifically, DOE/ORAU efforts communicated:
 - A. Patients were never "used as human guinea pigs" in the sense conveyed by the Mother Jones article; i.e., as unknowing victims of experiments for purposes without regard to their best interests. The patients' needs always came first.
 - B. Dwayne Sexton, the child exploited in the Mother Jones article, did not receive high levels of radiation "to test man's tolerance of radiation in space," but in a last-ditch effort to save his life. Conventional chemotherapy and other treatments had failed. The child was dying after more than three years of various therapies in the ORAU hospital and clinic; his doctors concluded that the high levels of radiation were essentially the only means left to extend his life. In fact, he had lived 3.5 years after first entering our clinic with acute lymphocytic leukemia.

1022318

- C. It is true that patients did receive experimental treatments with total body irradiation and that some of the data was used as part of a retrospective study to determine levels of human radiation tolerance. However, the treatment protocols were not influenced or biased in any way to enhance these evaluations. This study also examined 3000 patient records from 45 other hospitals that used total body irradiation in leukemia therapy. Ironically, the Sexton boy's irradiation therapy actually occurred after ORAU had completed the report to NASA and the National Academy of Sciences on high-level radiation in 1967--the year before the Sexton boy died. In 1968 the primary clinical research interest was in protracted and fractionated low-level radiation and not in single-dose exposures.
- D. The child's parents were fully informed about the treatment--both verbally and in explanations written in lay language and signed by Mr. and Mrs. Sexton. The parents clearly gave ORAU their informed consent.
- E. Although some program reviewers questioned the research value of some of the work of the clinic and the quality of the general facilities, the fact is that patient requirements always came before experimental needs for data, and good equipment was more important than high-quality buildings per se. The research clinic operated as well as possible within available government funds, making substantial contributions to the development of nuclear medicine over the past 30 years.
2. At the Gore subcommittee hearings, the points outlined above and many others were effectively presented by both DOE, ORAU, and former clinic employees and patients. Immediately following the hearings, Rep. Gore was quoted as saying the Mother Jones charges had been "essentially refuted." A report from the House subcommittee is expected late this fall.

* * * *

1022319

Human Guinea Pigs at Oak Ridge

Scientists respond to a report that they used cancer patients to test man's tolerance of radiation in space

The investigations subcommittee of the House Committee on Science and Technology is planning to hold hearings later this month on a report that got a lot of attention on 20 August: a charge that during the 1960's cancer patients at a small clinic linked with the Oak Ridge National Laboratory in Tennessee may have received unnecessary doses of gamma rays in an experiment aimed at learning just how much radiation astronauts could tolerate before becoming sick and choking in their oxygen masks. The hearings will be chaired by a Tennessee, Representative Albert Gore, Jr. (D).

Oak Ridge officials were caught somewhat unprepared when the author and publisher of the report, Howard Rosen-

interviewing officials, and reading "thousands of pages" of government documents.

The 20 August press conference made a splash on the national evening news. Among those who spoke before the cameras were Mary Sue Sexton, distraught mother of Dwayne, the 6-year-old Tennessee who died at the hospital in 1968; Karl Morgan, former chief health physicist at Oak Ridge, who said he felt "sorrow and dismay" that he had once sent a friend to the Oak Ridge clinic; and Peter Wiernick, a physician from the Baltimore Cancer Center, who said that he thought the clinic made a mistake in not telling patients about the uses to be made of the radiation research. He also thought the Sexton child might not have

until 1969, the year after Sexton's death. The animals had a separate air supply system. Cages and debris were moved through hallways where patients walked, but laboratory officials say there was no risk of contamination because the trash was kept in airtight plastic bags.

Rosenberg released other documents, including the summary of an unfavorable review given the clinic by the parent agency, the old Atomic Energy Commission (AEC), in 1974. According to the AEC summary, the clinic's facilities were "substandard with respect to licensing and accreditation guidelines," the entire medical division was "essentially isolated from the critical climate of academic clinical investigation," the main laboratories were inadequate, and the hematology program was particularly deficient. The irradiation programs were declared to be "without adequate planning, criticism, or objectives." The bone marrow immunology program was cited for "severe criticism" because "ethical questions were raised with respect to the protocols employed. . . ."

In addition, Rosenberg cited the fact that NASA financed some of the clinic's equipment and paid the salaries of some researchers. He claimed that the cancer program was "corrupted" by the desire to find data for NASA, and that patients were given nontherapeutic doses of radiation.

A team led by Oak Ridge pathologist Clarence Lushbaugh, now chairman of Oak Ridge's entire medical division, was recruited to study the nausea-inducing effects of radiation. Lushbaugh analyzed the records of 3000 patients in 46 hospitals to learn about the dangers that would confront the astronauts. Oak Ridge was not the primary source of Lushbaugh's information, for it gave radiotherapy to no more than 186 patients.

The man who was then chairman of Oak Ridge's medical division and designer of the treatment protocols, Gould Andrews, died in 1980. Speaking in his place, Lushbaugh now claims that Andrews made all decisions on therapy and was in no way influenced by NASA's concerns. Karl Hübner, a member of the hematology staff, said that the therapy offered at Oak Ridge in the 1960's and early 1970's was perfectly in keeping with standard approaches of the day.

Rosenberg claimed that the cancer program was "corrupted" by the desire to find data for NASA, and that patients were given nontherapeutic doses of radiation.

berg and *Mother Jones* magazine, held a press conference before network television cameras in Washington, D.C. A spokesman for the medical division at Oak Ridge, Wayne Range, essentially denied the thrust of the article, but challenged few of the facts. (The hospital itself has been closed since 1974.) Although the National Aeronautics and Space Administration (NASA) did pay for some of the research, Range said, its involvement was passive. Cancer therapy given at the hospital, he claimed, was a standard variety for 1965, and all that NASA gained was an opportunity to examine some patients' records.

Rosenberg's report focused on the case of Dwayne Sexton, a child with acute leukemia who was treated at the Oak Ridge Institute of Nuclear Studies between 1965 and 1968. The author explained that Sexton was the only one of "at least 89 cancer patients . . . systematically exposed to large doses of radiation between 1960 and 1974 in two specially designed chambers" whose record he was able to reconstruct. Rosenberg said he had spent 18 months canvassing Tennessee for information on patients,

received normal care in that he was not given a standard course of chemotherapy before other, untested therapies were used.

According to Rosenberg, doctors at the Oak Ridge Institute of Nuclear Studies who treated Sexton between 1965 and 1968 "belatedly began treating Dwayne Sexton with chemotherapy" only after they tried and failed to help him with an unusual experiment in immunology. Rosenberg also stressed that Sexton was later given a large dose of total-body radiation and sent to recover in a radiation chamber (not in operation) used to treat other patients. Beneath the chamber was an area where animals were kept. When the room was in use, they were exposed to gamma rays along with patients. Rosenberg suggested that people like Sexton, highly susceptible to infection, could have been exposed to dangerous bacteria. Sexton did, in fact, die of strep and staph infections, a common pattern for acute leukemia patients. Oak Ridge officials insist that bacteria from animals were not a problem, since the chamber was the cleanest area in the hospital, and no animals were present

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Range said, "We are quite proud our record. At a time when patients with acute leukemia had a survival outlook of about 6 months to a year, our patients were surviving on the average something like 4.5 years." The record compares well with those of other clinical centers in the 1960's, Range said.

William Bibb, the former AEC official in charge of funding the program, said that the Oak Ridge clinic was opened in 1950 "to take advantage of some of the technology coming out of the atomic energy business before it was generally available." The clinic was closed in 1974 for two reasons: other centers nearby with broader skills were giving comparable medical care, and the meager research output from Oak Ridge no longer justified the cost. Bibb said that in the final years, the clinic had only about seven patients at any given time.

Bibb described NASA's involvement as minimal. NASA came to him in the early 1960's because it was worried about the possible effects of solar flares, encounters with the Van Allen belt, and other radiation hazards in space. In 1964, 14 years after the Oak Ridge clinic had opened, the AEC agreed to run a retrospective study to collect the data NASA wanted from its own records and from other places. Later on, Bibb said, NASA agreed that in addition to paying the salaries of those doing the paper analysis, it would also provide some state-of-the-art monitoring equipment to record changes in the vital signs of patients undergoing whole-body irradiation at Oak Ridge. Patients sometimes stayed 3 days in the specially designed whole-body irradiation room, a chamber suspended in a concrete cell and flooded with gamma radiation at a level of about 1.6 roentgens* per hour. With the aid of NASA's equipment, nurses could monitor a patient's pulse and temperature without entering the room. The data were examined by the physicians and then turned over to Lushbaugh's staff. NASA also paid for a computer to help sort through the voluminous files.

"It would have been as stupid as hell," Bibb said, for NASA to try to get significant data from the Oak Ridge clinic alone, because it treated only 186 patients. Any conclusion based on data, he said, "wouldn't have been worth the paper it was written on because there wouldn't be enough data points to mean a damn thing."

Bibb pointed out that much of the research done for NASA was incorporated in the book, *Radiobiological Factors*

in *Manned Spaceflight*, published by the National Academy of Sciences in 1967. Nevertheless, he conceded that Oak Ridge did perform some NASA-financed prospective studies with cancer patients between 1969 and 1974. The purpose, he said, was to use the new monitoring system to try to find physiological signals indicating that a patient was about to become nauseous before the patient sensed nausea himself. No warning signals were found. Although the research was funded by NASA, Bibb insisted that the space agency had no influence over clinical procedures.

Hübner specifically denied the charge that Dwayne Sexton was given improper treatment. According to the medical records, Hübner said, the doctors first extracted a sample of bone marrow from the child in July 1965. Then they immediately started him on a course of chemotherapy lasting 17 days. The chemotherapy was stopped while they attempted an immunologic experiment. They irradiated the child's leukemic marrow cells, injected them into his mother, and then reinjected fluid from the mother back into the boy. The hope was that the mother would produce antibodies to fight the leukemia. Meanwhile, the leukemia was judged to be in remission, probably as a result of the first dose of chemotherapy. For 15 weeks the child received no chemotherapy. Then the disease reasserted itself, proving that the immunologic experiment had failed. The child was given chemotherapy again. The remission-relapse-chemotherapy routine was repeated for five more cycles, until December 1968.

Then the physicians decided that the drugs were failing. On 3 December 1968, the child was given his first and only radiation: a whole-body dose of 353 roentgens (or 265 rads) over a period of 3 hours and 38 minutes. The hospital record states: "Definite relapse from the acute leukemia had occurred. . . . It was decided to try to induce another remission by giving total-body irradiation. . . . The patient received 353 roentgens of exposure. . . . The patient experienced no adverse effects during the time of the irradiation and amazingly did not have any nausea nor vomiting during the time of exposure or immediately thereafter. The patient was then kept in as sterile an environment as possible. . . . It became quite apparent that the leukemic process was still not under control." He began to bleed internally and developed infections which could not be controlled by antibiotics. On 29 December, a little more than three weeks after irradiation, he died.

Radiologists at Harvard's Joint Center

Radiotherapy, at the National Cancer Institute (NCI), and at St. Jude's Hospital in Memphis, Tennessee (which has a renowned childhood leukemia program), agreed that the treatment given Sexton sounded reasonable in its context, that of an experimental center in the mid-1960's. Samuel Hellman of Harvard added, however, that the record "doesn't sound to me like anything that approaches conventional therapy." Yet he said, "One could make a rationale for its efficacy, and there are people who believe in whole-body irradiation." Today, whole-body doses are given only to prepare a patient for a bone marrow transplant, a procedure quite different from the one tried at Oak Ridge and not in use then. When large doses (over 100 rads) are given these days, they are nearly always focused in small areas and spread over many days.

Eli Glatstein, chief of the NCI's radiation oncology branch, said, "I don't think whole-body irradiation is a particularly good treatment myself, but a lot of it was done in the 1960's and 1970's, and is still done for certain types of chronic leukemia."

Alvin Mauer of St. Jude's Hospital said that several centers experimented with whole-body irradiation in the 1960's, although they never produced techniques considered useful now. By the mid-1960's, he said, it was "pretty well recognized" that chemotherapy was the standard technique for treating childhood leukemia. It was also generally known, he claimed, that the major sanctuary for leukemic cells which could not be reached by drug therapy was the central nervous system. By 1965 St. Jude's had started a program in which chemotherapy was augmented with strong doses (2400 rads) of radiation to the cranium to kill leukemic cells in the nervous system. The exposures were spread over a period of 2½ weeks. The procedure was improved in 1967 to include radiation of the spinal cord. From then until the mid-1970's, Mauer claimed, this was the standard approach for treating acute lymphocytic leukemia in children. Although he would not have used Oak Ridge's techniques, Mauer said, "I don't think they were necessarily out of keeping with what other people were doing at this time."

Oak Ridge officials have begun to respond to questions raised by the 20 August press conference, and Bibb said that he looks forward to appearing at Representative Gore's inquiry, for he thinks the laboratory will benefit from a closer scrutiny of the record.

—ELIOT MARSHALL

*Roentgens measure radioactive emissions, and rads measure absorbed radiation.

05 MAY 85 12:11

Disposition:

Fo: J.ALEXANDER1 (DOE524)
From: J.SHERWOOD (DOE1604) Posted: Tue 28-May-85 11:03 EDT Sys 64
Subject: DEPARTMENT OF ENERGY :department of energy mrs sexton in a telephc
* UPI NATIONAL Wire
Acknowledgment Sent

From: NEWS Posted: Tue 28-May-85 3:44 Sys 97
To: J.SHERWOOD
Subject: DEPARTMENT OF ENERGY :department of energy mrs sexton in a telephc
* UPI NATIONAL Wire

adv 6:30 am edt

Parents sue government over son's leukemia death

WASHINGTON (UPI) — The parents of a 6-year-old boy who died of leukemia accused the federal government today of treating him as "a human guinea pig" by using experimental radiation on him instead of conventional chemotherapy.

Lawyers for Mary Sue and Talmon Sexton of Kingsport, Tenn., said they would file a \$10 million lawsuit against the federal government today charging it with "unethical and improper" experiments that led to the death of their son, Dwayne, in 1968.

The suit, to be filed in U.S. District Court for the District of Columbia, said Dwayne "was deprived of his best chance of survival" and his family suffered emotional and psychological damage because of medical care he received at an Oak Ridge, Tenn., clinic run by the Atomic Energy Commission.

"As a direct and proximate result of the government's negligent and unlawful conduct, Dwayne Sexton was unwittingly treated as a human guinea pig," the suit said.

Dwayne was diagnosed as having acute lymphatic leukemia in July 1965 after his parents took him to the clinic on the recommendation of a family doctor.

After discussion with clinic staff, the Sextons agreed to the use of an experimental radiation treatment on their son.

The treatment, which court documents said never had been tried on animals, involved removing bone marrow from Dwayne's body and subjecting it to radiation before injecting it back into him.

About two weeks after the treatment, Dwayne's leukemia went into remission. But 13 weeks later, Dwayne suffered a relapse and began chemotherapy. When he failed to respond, the Sextons agreed to another experimental treatment in which Dwayne's entire body was exposed to radiation for 3 hours.

The boy died Dec. 29, 1968.

The Oak Ridge clinic was one of several research facilities set up by the Atomic Energy Commission to explore medical use of radiation. The clinic was closed in the 1970s, and, since then, the AEC has been replaced by the Department of Energy.

Mrs. Sexton, in a telephone interview, said she and her husband, who have three sons, did not file the suit earlier because they were unaware the government's treatment had been negligent. She said they began to question the treatment in 1981 when an investigative reporter interviewed them for a story.

"We want to make sure it definitely will not happen to someone

1022322

Arthur Bryant, an attorney representing the Sextons on behalf of Trial Lawyers for Public Justice, said the case is unusual because it accuses the government of negligence in implementing its experimental medical program.

"It's a lot more than a simple wrongful death suit," he said.

"This was a little boy who had a chance of surviving and they destroyed his only chance of surviving."

adv 6:30 am edt

upi 05-28-85 03:43 aed

Disposition:
End of Mail.

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1022323

Report on Congressional Hearing by
House Science and Technology Subcommittee on Investigations and Oversight
Chaired by Rep. Albert Gore, Jr. (D-Tennessee, Fourth District)
Regarding the Mother Jones Controversy

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 - A. Patients were never "used as human guinea pigs" in the sense conveyed by the Mother Jones article; i.e., as unknowing victims of experiments for purposes without regard to their best interests. The patients' needs always came first.
 - B. Dwayne Sexton, the child exploited in the Mother Jones article, did not receive high levels of radiation "to test man's tolerance of radiation in space," but in a last-ditch effort to save his life. Conventional chemotherapy and other treatments had failed. The child was dying after more than three years of various therapies in the ORAU hospital and clinic; his doctors concluded that the high levels of radiation were essentially the only means left to extend his life. In fact, he had lived 3.5 years after first entering our clinic with acute lymphocytic leukemia.

- C. It is true that patients did receive experimental treatments with total body irradiation and that some of the data was used as part of a retrospective study to determine levels of human radiation tolerance. However, the treatment protocols were not influenced or biased in any way to enhance these evaluations. This study also examined 3000 patient records from 45 other hospitals that used total body irradiation in leukemia therapy. Ironically, the Sexton boy's irradiation therapy actually occurred after ORAU had completed the report to NASA and the National Academy of Sciences on high-level radiation in 1967--the year before the Sexton boy died. In 1968 the primary clinical research interest was in protracted and fractionated low-level radiation and not in single-dose exposures.
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2. At the Gore subcommittee hearings, the points outlined above and many others were effectively presented by both DOE, ORAU, and former clinic employees and patients. Immediately following the hearings, Rep. Gore was quoted as saying the Mother Jones charges had been "essentially refuted." A report from the House subcommittee is expected late this fall.

* * * *

1022325

Dec. 1984

Review - Felling and Kannan

Tennessee Supreme Court Rejects Application by Sexton
To Review Appeals Court Decision

The Tennessee Supreme Court has rejected an application filed by Mary Sue Sexton which requested that court to review a decision of the State Court of Appeals which was favorable to ORAU in the case Sexton versus ORAU. The Supreme Court held that the application seeking its review was not filed within time specified in its rules.

The original suit was filed in Anderson County Circuit Court in 1981 by Mary Sue Sexton, the mother of a patient who died in ORAU's former cancer hospital of acute leukemia in 1968. That court dismissed the case saying that its filing came after the statute of limitations had run. The court rejected plaintiff's allegation that there had been fraudulent concealment by ORAU. It affirmed its holding when asked by A Sexton to reconsider them.

The plaintiffs appealed that decision to the Tennessee Court of Appeals, Eastern District. The three-judge panel reviewed the decision and affirmed the trial court's ruling in June 1984. The plaintiffs had the right to request a review by the Tennessee Supreme Court but they filed beyond the time established by law for seeking review and the Supreme Court declined to review the decision of the Court of Appeals and

the Trial Court. The plaintiffs have asked the Supreme Court to reconsider its holding.

A hearing ^{was held} by a subcommittee of the U.S. House of Representatives in September 1981 ^{in which} ~~called~~ witnesses ^{were called} and ~~received~~ documents. ^{received} ~~The~~ ^{Albert Gore, Jr. was the chairman of the} subcommittee reached the decision that the charges against ORAU had been "essentially refuted" by the testimony.

Subcommittee which conducted the hearing. He was quoted by the Oak Ridge as saying: "I think the testimony ~~is~~ essentially refuted the charges."

Diane —

I told Bill Felling you and Sandra had written an accurate story & done a good job, but that I do not think it is wise for defendants to publish articles about litigation. He may decide that in this case he wants the article published.

Phil

1022327

OAK RIDGE ASSOCIATED UNIVERSITIES
Oak Ridge, Tennessee

Consent to Experimental Treatment

I authorize the performance upon _____
(myself or name of patient)
of the following treatment: Total Body Irradiation

(State nature of treatment)

The nature and purpose of the treatment, possible alternative methods of treatment, the risks involved, and the possibilities of complications have been explained to me. I understand that this treatment is not the usual treatment for my disorder and is therefore experimental and remains unproven by medical experience so that the consequences may be unpredictable.

DATE: 3 Dec '68 _____
(Name of person authorized to consent for patient)

WITNESS: _____

I have talked with _____ about
the proposed course of treatment to be given _____
including the following: * pharmacologic and observation of
therapy & possible effects

C. L. Edwards _____ 3 Dec '68
Physician Date

*Physician should indicate experimental drugs, radioisotopes, radiation therapy, and/or possible placebo or sham therapy.

CONSENT TO EXPERIMENTAL TREATMENT MED-146(2-67)

1022328

OAK RIDGE ASSOCIATED UNIVERSITIES
Oak Ridge, Tennessee

Patient Admittance Agreement

The Oak Ridge Institute of Nuclear Studies (ORINS) Medical Research Hospital is operated by Oak Ridge Associated Universities (ORAU) for the U. S. Atomic Energy Commission (AEC) for the conduct of certain clinical research programs. These programs are mainly in areas allied to the application of radiation and radioisotopes to medicine and other health sciences.

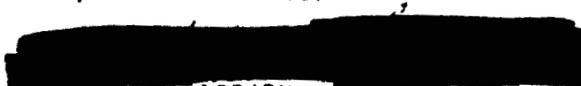
I understand that I have been accepted as a patient for admission to the hospital, or as an outpatient, because my physical condition has been determined by the hospital staff to make me a suitable patient for a currently active clinical research project.

I further understand that while a patient at the research hospital examinations, treatments, and tests may be prescribed which are experimental in nature and I hereby consent to such examinations, treatments, or tests. Notwithstanding the above, I reserve the right to a full explanation of any such proposed examination, test, or treatment and the right to withdraw my consent. I further reserve the right to withdraw completely should I find that I am unable to continue.

I further understand that I can remain in the research hospital only so long as I am needed for research purposes, and that I must be discharged when my participation in a study is completed and when, in the opinion of the hospital staff, my medical condition permits. In such event, I understand that ORAU, its officers, employees, and agents, cannot assume responsibility for any continued medical care.

The above statements have been explained to me by the member of the Medical Division staff named below. I understand and accept the statements.

I have not been influenced in making this agreement by any representations or statements regarding improvement in my physical condition or the probable results of any treatments received, but instead expressly assume all risks incident to my hospitalization, care, and treatment.

 _____
Patient's signature
Pete M. Hill

Medical Division staff member's signature
24 Nov. 67

Date
Parent or guardian's signature

PATIENT ADMITTANCE AGREEMENT MED-13(2-67)

1022329

OAK RIDGE INSTITUTE OF NUCLEAR STUDIES
MEDICAL DIVISION

PATIENT AGREEMENT

In consideration of my being accepted and admitted to the Research Hospital operated by the Oak Ridge Institute of Nuclear Studies, I, on behalf of myself, my heirs, executors, administrators, and assigns, covenant, understand and agree as follows:

1. To hereby release and discharge the Oak Ridge Institute of Nuclear Studies, its officers, agents, and employees from any actions, damages or claims resulting from my hospitalization in said hospital and/or any treatments and care received while in said hospital or by reason of my having been a patient therein.

2. That any treatments administered to me may be experimental.

3. That I have not been influenced in making this agreement by any representations or statements regarding improvement in my physical condition or the probable results of any treatments received, but instead expressly assume all risks incident to my hospitalization, care and treatment.

4. I understand that but for this agreement on my part, I would not be accepted and admitted as a patient in said hospital.

5. I covenant that I have carefully read the foregoing and fully understand the meaning and contents thereof, and have executed the same of my own free will and choice.

Date 7-2-1965

Signed [Redacted]
Patient 46 years

WITNESSES:

[Redacted]
[Redacted]

[Redacted]
Parent or Guardian

[Redacted]
Mother

OAK RIDGE INSTITUTE OF NUCLEAR STUDIES
MEDICAL DIVISION

PATIENT ADMITTANCE AGREEMENT

In consideration of my being accepted and admitted to the Research Hospital operated by the Oak Ridge Institute of Nuclear Studies, I, on behalf of myself, my heirs, executors, administrators, and assigns, covenant, understand and agree as follows:

1. To hereby release and discharge the Oak Ridge Institute of Nuclear Studies, its officers, agents, and employees from any actions, damages or claims resulting from my hospitalization in said hospital and/or any treatments and care received while in said hospital or by reason of my having been a patient therein.

2. That any treatments administered to me may be experimental.

3. That I have not been influenced in making this agreement by any representations or statements regarding improvement in my physical condition or the probable results of any treatments received, but instead expressly assume all risks incident to my hospitalization, care and treatment.

4. I understand that but for this agreement on my part, I would not be accepted and admitted as a patient in said hospital.

5. I covenant that I have carefully read the foregoing and fully understand the meaning and contents thereof, and have executed the same of my own free will and choice.

Date July 27 1965

Signed [Redacted]
Patient 48 years

WITNESSES:

[Redacted Signature]

[Redacted Signature]
Father or Guardian

[Redacted Signature]

[Redacted Signature]
Mother

OAK RIDGE INSTITUTE OF NUCLEAR STUDIES
MEDICAL DIVISION
OAK RIDGE, TENNESSEE

AUTHORITY TO OPERATE

DATE 8-22-65

(If competent, patient should sign in space indicated. If a minor or incapable of signing, representative should sign in lower space.)

THIS IS TO CERTIFY THAT THE UNDERSIGNED, CONSENT TO THE ADMINISTRATION OF WHATEVER ANESTHETICS AND THE PERFORMING OF WHATEVER OPERATION, IN THE OPINION OF THE MEDICAL STAFF, MAY BE NECESSARY OR ADVISABLE.

NAME [REDACTED] ADDRESS [REDACTED]

EXCEPTIONS, IF ANY _____

WITNESS Mr. Mackley R.N. SIGNATURE OF PATIENT
[Signature]

PATIENT IS A MINOR yes OR STATE WHY INCAPABLE OF SIGNING [REDACTED]

SIGNATURE _____

1022332

OAK RIDGE INSTITUTE OF NUCLEAR STUDIES
MEDICAL DIVISION
OAK RIDGE, TENNESSEE

AUTHORITY TO OPERATE

DATE Aug

(If competent, patient should sign in space indicated. If a minor or incapable of signing, representatives should sign in lower spaces.)

THIS IS TO CERTIFY THAT THE UNDERSIGNED, CONSENT TO THE ADMINISTRATION OF WHATEVER ANESTHETICS AND THE PERFORMING OF WHATEVER OPERATION, IN THE OPINION OF THE MEDICAL STAFF, MAY BE NECESSARY OR ADVISABLE.

[REDACTED] NAME ADDRESS

EXCEPTIONS, IF ANY _____

WITNESS _____ SIGNATURE OF PATIENT _____

PATIENT IS A MINOR OR STATE WHY INCAPABLE OF SIGNING _____

Mary E. Switlow - R.N.

SIGNATURE [REDACTED]

We understand and agree to a special experimental procedure designed to try to help our child who has acute leukemia. This will consist of removing bone marrow from the child, subjecting the marrow to radiation designed to kill the leukemic cells, and subsequently injecting these cells into the mother. At a later date it is planned to operate on the mother to drain lymph from the thoracic duct to obtain cells that can be injected back into the patient in an effort to combat the leukemia.

Since this is a new and experimental procedure, there are some risks involved for both mother and child. The nature of these has been explained to us and we are willing to accept them.

Our acceptance of this procedure is entirely voluntary. The staff of the Medical Division has put no pressure on us to agree to this, and has freely offered more conventional treatment as an alternative.

[REDACTED]

8-5-65
Date

Mildred V. Houts, R.N.
Witness

SEXTON, DWAYNE
221470

OAK RIDGE ASSOCIATED UNIVERSITIES
27 11 67 Oak Ridge, Tennessee

Patient Admittance Agreement

The Oak Ridge Institute of Nuclear Studies (ORINS) Medical Research Hospital is operated by Oak Ridge Associated Universities (ORAU) for the U. S. Atomic Energy Commission (AEC) for the conduct of certain clinical research programs. These programs are mainly in areas allied to the application of radiation and radioisotopes to medicine and other health sciences.

I understand that I have been accepted as a patient for admission to the hospital, or as an outpatient, because my physical condition has been determined by the hospital staff to make me a suitable patient for a currently active clinical research project.

I further understand that while a patient at the research hospital examinations, treatments, and tests may be prescribed which are experimental in nature and I hereby consent to such examinations, treatments, or tests. Notwithstanding the above, I reserve the right to a full explanation of any such proposed examination, test, or treatment and the right to withdraw my consent. I further reserve the right to withdraw completely should I find that I am unable to continue.

I further understand that I can remain in the research hospital only so long as I am needed for research purposes, and that I must be discharged when my participation in a study is completed and when, in the opinion of the hospital staff, my medical condition permits. In such event, I understand that ORAU, its officers, employees, and agents, cannot assume responsibility for any continued medical care.

The above statements have been explained to me by the member of the Medical Division staff named below. I understand and accept the statements.

I have not been influenced in making this agreement by any representations or statements regarding improvement in my physical condition or the probable results of any treatments received, but instead expressly assume all risks incident to my hospitalization, care, and treatment.

Patient's signature

Medical Division staff member's
signature

Parent or guardian's signature

Date

PATIENT ADMITTANCE AGREEMENT MED-13(2-67)

1022335

DATE :

1. hypox and inject this material in the leg, expecting
an immunological response from the parent's
assembly formed anti-toxic antibodies.

W. W. W. W.

8.2.65

The mother has accepted to go ahead with
the procedure. She will be hospitalized and
worked up. He has developed an edematous
area at the site of IV injection of bright
yellow tissue. No other area of edema
or redness. Asymptomatic, bright color
appetite

W. W. W. W.

8.4.65

He is in good condition. His mother received
the yellow aspiration today by Dr. Vidaver.
He will have low serum albumin. Known
under general anesthesia, trace serum albumin
trace & probably some fibrin. This serum will
be injected in green latex to his mother.

W. W. W. W.



PATIENT'S NAME

J11670

Keop. No.

PROGRESS NOTE

Abdomen (cont): normal consistency. The spleen is not palpable. The bowel sounds are normal. There is no other organomegaly or masses palpable.

Genital and Rectal: Normal external genitalia for this age. Circumcised penis. Rectal examination negative.

Extremities: There is an area of ecchymosis on the left ankle as noted previously. There is a mild bruise in his right knee, with some excoriations. There is no swelling or pain in the joints.

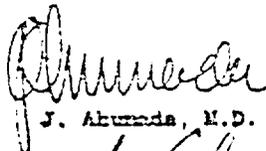
Neurological: Deep tendon reflexes are normal bilaterally. Abdominal cutaneous and cremasteric reflexes present and normal. No abnormal reflexes elicited.

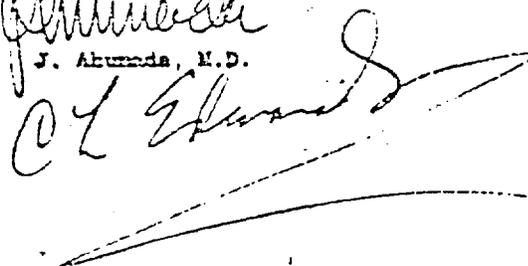
Lymphatics: There is lymph node enlargement present in both axillary and inguinal areas. The size of the former varies from 0.5 to 1.0 cm and the latter are very small, approximately 0.5 cm. They are firm in consistency, nontender, movable, and there are no changes present of the overlying skin.

On admission, this patient was seen by Dr. Edwards and Dr. Vodopick. A bone marrow aspiration was done and the diagnosis of acute lymphoblastic leukemia was made. The plan for this child is to start treatment with one of the conventional therapeutic means and then attempt bone marrow injection from him to his parents, to perform later transfusion of lymph from the parents' thoracic duct into his blood stream.

Impression: Acute lymphoblastic leukemia.

/seh


J. Ahumada, M.D.



INSTRUCTIONS FOR RELEASE OF BODY

Body of [redacted] to be released to West FUNERAL HOME.

(Name of deceased)

Opelika Tennessee

Signed [redacted]

Relationship mother Date 29 Dec 68

Father

NOTICE TO FUNERAL HOME

I, _____ of _____ FUNERAL HOME NOTIFIED OF

Death at _____ A.M. P.M.

Signed _____

Funeral Home notified Body is ready to be released at _____ A.M. P.M.

Signed _____

RELEASE OF BODY

Body of deceased released to and accepted by West FUNERAL HOME.

Signed Walter [unclear]

Date Dec 29, 1968

OAK RIDGE INSTITUTE OF NUCLEAR STUDIES
Oak Ridge, Tennessee

Request for Autopsy

NAME OF DECEASED _____ ROOM _____

BED NO. _____ HOSPITAL CASE NO. 511670 AGE 6 SEX Male

MARITAL STATUS OF DECEASED IS: (Encircle word that applies)

SINGLE MARRIED WIDOWED SEPARATED (but not divorced) DIVORCED

TIME OF DEATH Dec 29 1968 0100
Month Day Year Hour

1. I hereby certify that I assume custody of the body of the above-designated deceased for purpose of burial, and assume responsibilities connected therewith.
2. I hereby authorize the Pathologist of the Oak Ridge Institute of Nuclear Studies and such person or persons as he may designate to perform an autopsy on the body of my SON
(State relationship of deceased to signor.)

I authorize him, too, to have present at that autopsy such persons as he may deem proper.

3. The autopsy here authorized may be either a complete or partial autopsy. Such organs and tissues may be removed as the physician performing the autopsy considers necessary for study subsequent to the autopsy, to accomplish the purposes of the autopsy, to eliminate undesirable radioactivity, or for therapeutic purposes. (If the nature and extent of this autopsy or the right to remove parts of the body are to be limited in any way, those LIMITATIONS SHOULD BE CLEARLY STATED BELOW). In the absence of any stated limitations, it is to be understood that the pathologist by whom the operation is performed is to be the sole judge of the nature and extent of the autopsy. He is specifically authorized to examine the cranial contents and the femur, if such examination is necessary to complete study of the case.

LIMITATIONS (Specify): LIMITED TO CHEST + ARMS WITH ORGANS REPLACED
PER EXAMINATION

4. After the autopsy, the body should be released to: WEST TUNNAC HOME
ONEIDA TOWN

5. I FURTHER CERTIFY THAT I HAVE READ AND UNDERSTAND ALL THE FOREGOING.

DATE 29 Dec 68 SIGNATURE _____
ADDRESS _____

WITNESSES: 1. Harold K. Sneyd 2. _____

Revision of March 1957.
Med. 0139

OAKU Path # 9254

Abdomen (cont):

normal consistency. The spleen is not palpable. The bowel sounds are normal. There is no other organomegaly or masses palpable.

Genital and Rectal:

Normal external genitalia for this age. Circumcised penis. Rectal examination negative.

Extremities:

There is an area of ecchymosis on the left ankle as noted previously. There is a mild bruise in his right knee, with some excoriations. There is no swelling or pain in the joints.

Neurological:

Deep tendon reflexes are normal bilaterally. Abdominal cutaneous and cremasteric reflexes present and normal. No abnormal reflexes elicited.

Lymphatics:

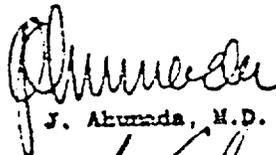
There is lymph node enlargement present in both axillary and inguinal areas. The size of the former varies from 0.5 to 1.0 cm and the latter are very small, approximately 0.5 cm. They are firm in consistency, nontender, movable, and there are no changes present of the overlying skin.

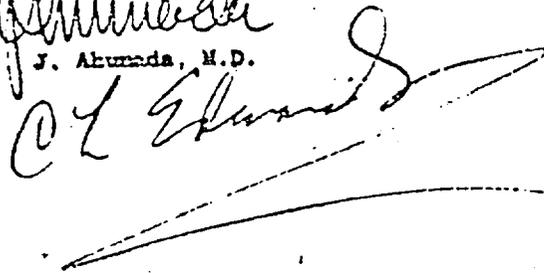
On admission, this patient was seen by Dr. Edwards and Dr. Vodopick. A bone marrow aspiration was done and the diagnosis of acute lymphoblastic leukemia was made. The plan for this child is to start treatment with one of the conventional therapeutic means and then attempt bone marrow injection from him to his parents, to perform later transfusion of lymph from the parents' thoracic duct into his blood stream.

Impression:

Acute lymphoblastic leukemia.

/veh


J. Akumada, M.D.



DATE :

lymph and inject this material in the toy, expecting
an immunological response from the parent's
possibly formed auto immune outtakes.

Blum

8.2.65

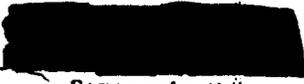
The pt's mother has accepted to go ahead with
the procedure - She will be hospitalized and
worked up - He has developed an edematous
area at the site of IV injection in right
elbow flexure - no other area of edema
or edema. Asymptomatic, weight is poor
appetite

Blum

8.4.65

Pt. in good condition - His mother received
bone marrow aspiration today by Dr. Volzinger.
He will have bone marrow aspiration tomorrow
under general anesthesia, tissue from femoral
head & probably right tibia - This marrow will
be mediated & given later to his mother.

Blum



PATIENT'S NAME

511670

Hosp. No.

PROGRESS NOTE

1022341

Dec. 1984

Review - Felling and Kannan

Tennessee Supreme Court Rejects Application by Sexton
To Review Appeals Court Decision

The Tennessee Supreme Court has rejected an application filed by Mary Sue Sexton which requested that court to review a decision of the State Court of Appeals which was favorable to ORAU in the case Sexton versus ORAU. The Supreme Court held that the application seeking its review was not filed within time specified in its rules.

The original suit was filed in Anderson County Circuit Court in 1981 by Mary Sue Sexton, the mother of a patient who died in ORAU's former cancer hospital of acute leukemia in 1968. That court dismissed the case saying that its filing came after the statute of limitations had run. The court rejected plaintiff's allegation that there had been fraudulent concealment by ORAU. It affirmed its holding when asked by A Sexton to reconsider them.

The plaintiffs appealed that decision to the Tennessee Court of Appeals, Eastern District. The three-judge panel reviewed the decision and affirmed the trial court's ruling in June 1984. The plaintiffs had the right to request a review by the Tennessee Supreme Court but they filed beyond the time established by law for seeking review and the Supreme Court declined to review the decision of the Court of Appeals and

1022342

the trial Court. The plaintiffs have asked the Supreme Court to reconsider its holding.

A hearing ^{was held} by a subcommittee of the U.S. House of Representatives in September 1981 ^{in which} ~~called~~ witnesses ^{were called} and ^{received} documents. ^{Albert Gore, Jr. was the chairman of the} ~~The~~ subcommittee reached the decision that the charges against ORAU had been "essentially refuted" by the testimony.

Subcommittee which conducted the hearing. He was quoted by the Oak Ridge as saying: "I think the testimony ~~is~~ essentially refuted the charges."

Diane —

I told Bill Felling you and Sandra had written an accurate story & done a good job, but that I do not think it is wise or defensible to publish articles about litigation. He may decide that in this case he wants the article published.

Phil

STATEMENT USED BY NASA IN ANSWER TO INQUIRY:

The facts are that NASA learned of the studies being conducted and in 1964 requested that the agency be supplied with data in a form that would be usable to it to study what astronauts might expect when and if exposed to radiation in space. NASA funding went mainly to obtain this data in proper form. Some \$65,000* funds did help to pay for some patient monitoring equipment. The Oak Ridge people categorically deny that the studies of cancer patients were in any way changed or extended to satisfy NASA requests nor were any such requests made by NASA.

*estimate to be verified

8/20/81

1022344

STATEMENT USED BY NASA IN ANSWER TO INQUIRY:

The facts are that NASA learned of the studies being conducted and in 1964 requested that the agency be supplied with data in a form that would be usable to it to study what astronauts might expect when and if exposed to radiation in space. NASA funding went mainly to obtain this data in proper form. Some \$65,000* funds did help to pay for some patient monitoring equipment. The Oak Ridge people categorically deny that the studies of cancer patients were in any way changed or extended to satisfy NASA requests nor were any such requests made by NASA.

*estimate to be verified

8/20/81

1022345

STATEMENT USED BY NASA IN ANSWER TO INQUIRY:

The facts are that NASA learned of the studies being conducted and in 1964 requested that the agency be supplied with data in a form that would be usable to it to study what astronauts might expect when and if exposed to radiation in space. NASA funding went mainly to obtain this data in proper form. Some \$65,000* funds did help to pay for some patient monitoring equipment. The Oak Ridge people categorically deny that the studies of cancer patients were in any way changed or extended to satisfy NASA requests nor were any such requests made by NASA.

*estimate to be verified

8/20/81

1022346

Pls tell Kief
that:
Rosenberg
Mrs. Sexton
K.Z. Morgan
Dr. Peter Weisman
Baltimore cancer
Research center
will be on NBC
"Today show" at
7:45 a.m. tomorrow.

1022347

How Much Radiation Can An Astronaut Withstand?
NASA Used Dwayne Sexton To Find Out.

INFORMED CONSENT

BY HOWARD L. ROSENBERG

The dimly lit hallway weaved left and right like a maze. Clutching Dwayne's small hand, Mary Sue Sexton fell in step behind the white-coated technician. They passed a control panel and walked through a wrought-iron gate into the chamber. The room was dark except for a brilliant halo over an empty, aluminum bed.

Dwayne climbed over the nylon net surrounding the bed and settled into the trough-shaped berth. Mary Sue exchanged reassuring smiles and a hesitant wave with her six-year-old son. Then she turned and stepped back out to wait in the hall.

Mary Sue could not see the eight cones pointing toward Dwayne from the shadows, but she could hear a slight hum as the shielding was removed and the teletherapy machines began bathing the young boy in what one of the doctors later called a "sea of radiation."

Unknown to Mary Sue Sexton, her son Dwayne was serving as part of a government experiment: He was helping to find the parameters of the radiation sickness syndrome—precisely how large a dose it would take to cause a person to lose his appetite, get nauseous and vomit.

At least 89 cancer patients, including Dwayne Sexton, were systematically exposed to large doses of radiation between 1960 and 1974 in two specially

designed chambers at the Institute of Nuclear Studies in Oak Ridge, Tennessee. Medical confidentiality has prevented identification of most of these patients. Information provided by medical personnel at the facility and a telephone canvassing of one area of Tennessee led to the unfolding story of Dwayne Sexton and how he was used to obtain data for the United States' space program. It is hoped that the publication of this account will spur other patients who went through these experiments or their families to come forward with more information about the controversial treatments.

Based on an 18-month *Mother Jones* investigation and a review of thousands of pages of documents obtained under the Freedom of Information Act (FOIA), it appears that the radiation treatments began as a legitimate attempt to improve cancer therapy techniques. However, dozens of interviews, the Freedom of Information Act documents and consultations with leading medical and scientific authorities reveal that these treatments evolved into something quite different:

- The Oak Ridge Institute, where the treatments were conducted, was an Atomic Energy Commission (AEC) clinic used for simultaneous research experiments on animals and humans.

- Leading authorities on radiation protection, and even the AEC itself in its review of these experiments, judged that the treatments were of little, if any, benefit to the patients. The man who oversaw the experiments, how-



1022348

ever, is today one of the government's chief experts on the effects of radiation.

- The government doctors administering the treatments knew of other therapy techniques—using either different types of radiation exposure or chemotherapy—that were superior. At least in Dwayne Sexton's case, the government scientists at Oak Ridge initially withheld these better-established cancer treatments.

- The clinic facilities were "substandard" according to the government itself, and the AEC eventually forced its own clinic to close down.

- Patients did not offer their *fully informed* consent to be

part of some experiments. And some patients, like Dwayne Sexton, were subjected to several different types of experiments.

- Though the treatments were administered as cancer therapy, one primary purpose was to obtain data for the United States' space program on human reactions to radiation.

HOW IT BEGAN

NASA, the National Aeronautics and Space Administration, urgently needed data on human sensitivity to radiation, and the cancer patients who came through the doors of the Oak Ridge Institute of Nuclear Studies became the human guinea

pigs who provided this information.

Animals had been the first to breach the boundaries of space. Dogs and chimpanzees and monkeys were metamorphosed into avian creatures, hurtling through the stratosphere atop rockets. Down below, scientists were wrestling with unanswered questions about how human beings would stand up to the effects of radiation. Nausea and vomiting caused by radiation sickness were possibly manageable ailments on the ground. But to an astronaut wearing an oxygen mask, they could prove fatal.

Hard data on human radiosensitivity was vital to NASA. But who would volunteer to be exposed to potentially lethal doses of radiation? In Oak Ridge, Tennessee, a pathologist at the AEC's clinic, Clarence Lushbaugh, agreed to search for some of the answers NASA wanted.

ATOMIC CITY, USA

Oak Ridge is called the "Energy Capital of the World" nowadays. It used to be known as the "Atomic City." This was the town created by Uncle Sam to produce fuel for the Manhattan Project's A-bombs during World War II. Hidden in hollows amid rolling hills of black oak, massive factories for producing bomb-grade uranium rose up within a perimeter of total military security. The limestone ridges along the snaking Clinch River offered natural protection from air attack. Power from the Tennessee Valley Authority was in plentiful supply.

Today Oak Ridge's broad, main avenues are still lined with Army barracks, converted and refurbished as apartment buildings. The "downtown" area is a modern shopping center. The denizens of the "Energy Capital" are a curious mix of rural-bred hill people and scientists and technicians from around the world. One out of every 35 Oak Ridgers holds a Ph.D. degree—one of the highest per capita ratios in the nation.

Clarence Lushbaugh arrived in 1963 to head the AEC clinic's ominously titled "Applied Radiation Biology Division." A short, balding man with a combative personality, Lushbaugh likes to say he "grew up in the gutters" of Cincinnati, Ohio, where his name,

Clarence, "was a fighting name—you had to protect a name like Clarence." Most of his friends now call him "Lush," but the feisty attitude of his youth has not mellowed much in 65 years. The nameplate behind Lushbaugh's desk informs visitors that he is the HSOBIC—Head-Son-Of-a-Bitch-In-Charge.

Educated at the University of Chicago, where he received his bachelor's degree, a Ph.D. in pathology and an M.D. in medicine, Lushbaugh began his career in 1949 as a pathologist in Los Alamos, New Mexico—another "atomic city." He doubled as the government town's coroner. In

1963, Lushbaugh moved to rural Tennessee and became a member of the staff of the Oak Ridge Institute.

"In Los Alamos," he explains, "we had plenty of radioisotopes and plenty of machinery, but we didn't have a whole lot of sick people because it was a rather young population." Oak Ridge offered the same access to radioisotopes plus a large group of Tennesseans who were grateful for free medical attention at the AEC clinic.

The Oak Ridge Institute had a mandate from the Atomic Energy Commission—which was then the government agency charged with promoting nuclear energy—to conduct research into the "beneficial applications of radiation." Some significant achievements did come out of Oak Ridge's clinic, including the development of a cobalt 60 (C-60) teletherapy machine, which served as a prototype for others now used in cancer therapy at hospitals across the country.

Lushbaugh was teamed with eminent hematologist Gould Andrews. Lushbaugh's star was rising. Andrews "was probably the world-renowned expert in taking care of persons with radiation injuries." Lushbaugh says modestly, "and I was the world-renowned expert at trying to figure out what went wrong at the autopsy table."

If someone was acutely irradiated in an accident, no matter when or where, Andrews was called in to give medical attention. His hunched figure was unmistakable—he was afflicted with extreme curvature of the spine. Andrews was a compas-

Patients did not offer their fully informed consent, and facilities were criticized as "substandard."

sionate and competent attendant to his patients, but whenever his medical ministrations failed, it was Lushbaugh's turn. Lushbaugh did the autopsies.

Shortly after his arrival in Oak Ridge, Lushbaugh won a NASA contract to conduct a retrospective analysis of the effects of radiation: a hunt for the point at which the syndrome symptoms appear. He looked for clues in the medical charts of cancer patients who had been treated with radiotherapy. By the end of 1964, Lushbaugh had compiled data on more than 3,000 patients at 43 different hospitals.

But the retrospective analysis had its limitations. The patients had received varying doses of radiation, and their doctors had not kept detailed notes on reactions in the systematic manner of a research scientist. A "prospective" study was needed. Oak Ridge was the ideal place for the study and Lushbaugh was the ideal choice to conduct it. By carefully monitoring patients during and after radiotherapy at the clinic, Lushbaugh and his associates could be on the lookout for syndrome symptoms and could correlate them with the exact dose of radiation received.

"BENEFICIAL" USES?

In 1960, the Oak Ridge clinic had begun operating a therapy chamber known as METBI—the Medium-Exposure-Rate Total-Body Irradiator. Built in a special wing of the tiny clinic, METBI was designed for experiments testing spray irradiation as a treatment for blood cancers. It was part of the Atomic Energy Commission's effort to use its nuclear wares to find those "beneficial applications of radiation."

Prior to World War II, researchers at the Memorial Sloan-Kettering Cancer Center in New York discovered that by spraying a leukemia victim's total body with X-rays, the radiation could be used to depress the bone marrow and kill cancerous blood cells forming there. Then, during the war, scientists found that injections of radiophosphorus and several nitrogen mustards could achieve essentially the same results at only a fraction of the cost. "In essence," said one of the AEC's consulting physicians, "spray irradiation techniques were superseded by simpler and better techniques."

Lushbaugh agrees. "The hematologists began using these nitrogen mustards," he says, "and so they began hogging all these patients with leukemia. . . . Well, obviously, the radiotherapists and the whole damn field of radiologists were not going to put up with that. So they came along with a system for doing the same things as the nitrogen mustards, [the difference being that] you don't have to hold the guy down and stick needles in him."

What they came along with at Oak Ridge was METBI—and a new twist in the technique of spray irradiation. Doctors

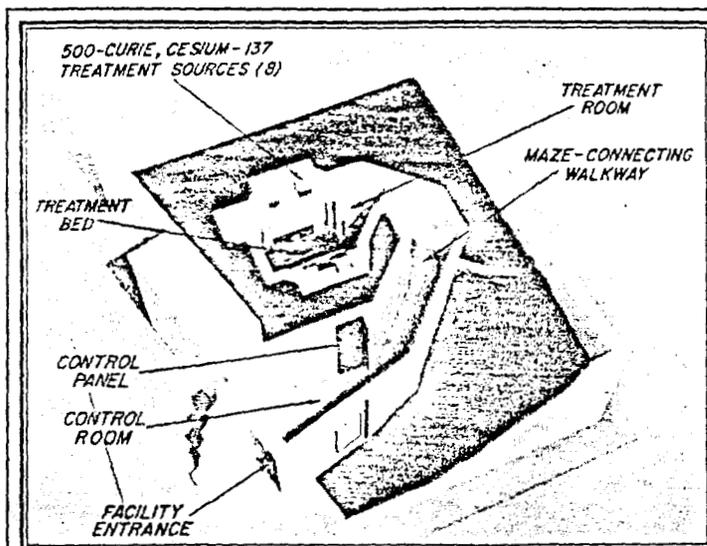
at Sloan-Kettering . . . had an X-ray machine to spray their patients, but the Oak Ridgers thought that radiation-emitting isotopes like C-60 and cesium 137 (Ce-137) would be more flexible than a bulky machine.

Lushbaugh explains it this way: "See, with an X-ray tube, you would put the person on the floor in the fetal position, with his knees drawn up, and you'd zap him from the right side with an X-ray machine and then you'd flip him over and irradiate him from the other side." The METBI facility was a quantum improvement.

The doctors could zap their patients in a specially designed room with doses ranging from 1.8 rads per hour (1.8r) to 300

rads per hour (300r). These are extremely high doses—an ordinary chest X-ray is about one-tenth of a rad—but the exposures were and are considered therapeutic in treating some cancers. But as we will see in Dwayne Sexton's case and those of the other 88 patients in these experiments, the massive radiation doses were not only part of a treatment plan, but also a way of gathering data for the space program.

The treatment of leukemia patients in METBI began as soon as the facility was operational. Gould Andrews directed the clinical hematology staff. Lushbaugh monitored the cancer patients for signs of the



This is a model of the METBI facility at Oak Ridge. Here and in another chamber 89 cancer patients were treated with high levels of radiation. The project apparently began as an attempt to improve cancer therapy. Ultimately, the experiments benefited NASA.

syndrome. Many aspects of the syndrome were already known even then. The government's handbook for the holocaust, *The Effects of Nuclear Weapons*, reports that "for doses between 200 and 1,000 rads the probability of survival is good at the lower end of the range, but poor at the upper end. The initial symptoms are similar to those common in radiation sickness . . . the larger the dose, the sooner will these symptoms develop."

As part of the federally funded Oak Ridge Associated Universities—a consortium of 50 colleges and universities throughout the South—the AEC clinic had a ready-made network from which to draw patients. Doctors in the rural South regularly referred cancer patients to Oak Ridge. Among them were people suffering from Hodgkin's disease, chronic lymphocytic leukemia, chronic granulocytic leukemia, polycythemia rubra vera, idiopathic thrombocytopenia and lymphosarcoma cell leukemia.

The Oak Ridge researchers began their study by exposing patients to 50 or 100 rads at a time in the METBI chamber at a rate of 1.5 rads per minute. According to an internal progress report written in 1970, doctors involved in the experiments apparently never really thought these large doses would benefit the patients much, but since the cancer victims would probably require radiotherapy anyway, the scientists at Oak Ridge hoped to obtain some of the syndrome data NASA wanted. "It was not our plan to evaluate the long-

... property of Oak Ridge Associated Universities

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range effectiveness of these relatively large individual doses." Andrews, Lushbaugh and their colleagues explained in the report. "This would have required establishing a total treatment plan with this technique, which we were not prepared to do."

The scientists wanted to "be able to add or substitute other forms of treatment," which is not surprising, in light of the fact that the doctors virtually admitted that the METBI exposures were *not even the best method of treating the cancer patients with radiation*. "One should not infer from this study," they wrote in a candid assessment of the experiment, "that we expected these individual or infrequently given exposures to produce better clinical results . . . at present, we feel that some pattern of fractionated exposure [small doses of radiation in several treatments] probably offers a preferable approach for total-body radiotherapy."

What these large, single exposures in the METBI chamber *did* offer was the best opportunity to monitor for the radiation sickness syndrome. According to a report of the experiment provided to NASA, at least two patients at Oak Ridge received doses of 500 rads prior to a treatment called "bone marrow transplantation." Obviously, these two people were ideal subjects for the doctors involved in the NASA study to monitor for the syndrome.

ENTER, DWAYNE SEXTON

It was June of 1965 and the humid air was just hinting at the oppressive Tennessee summer ahead when three-year-old Dwayne Sexton first took sick. The auburn-haired boy just wasn't his usual self. First-born child of Talmon and Mary Sue Sexton, Dwayne had his daddy's dimpled chin, his mother's wide, brown eyes and enough energy to keep them both busy. That summer he changed. "Dwayne just wanted to sit or lay down," his mother remembers. "He was tired, run-down."

They visited the family doctor, who diagnosed Dwayne as anemic and prescribed liquid iron and vitamin B-12. The treatment didn't help much. Dwayne's normally rosy cheeks remained pale and waxy. Mary Sue insisted the doctor hospitalize him and find out what was wrong. Blood transfusions began in an attempt to counter the anemia. Finally, Mary Sue asked the doctor point-blank: "Does Dwayne have leukemia?" The physician said no, and then suggested that maybe the cause and cure of Dwayne's illness could be found at Oak Ridge. The arrangements had already been made. Mary Sue began keeping detailed notes in a journal.

On July 27, Dwayne checked into the Oak Ridge clinic for the first time. A chest X-ray was taken and bone marrow was withdrawn from his hip for a test. Mary Sue just happened by a room where one of the doctors was confiding the bad news

to Talmon: Dwayne had acute lymphatic leukemia.

Two days later Mary Sue wrote in her journal: "The medical staff discussed a type of treatment they would like to try on Dwayne. It was stated it could possibly be a cure for him. We know there is no hope at all for Dwayne except for a short life for him of from six weeks or maybe up to a year and a half, and he would be so sick so much of the time."

Mary Sue and Talmon agonized over the decision. "We decided it was worth the risk we would have to take for a chance at a cure for Dwayne," she noted in the journal. "We were reassured that the experiment was promising enough to take a chance with."

Mary Sue asked the doctor, "Does Dwayne have leukemia?" He suggested a cure might be found at Oak Ridge.

The doctors told the Sextons that Dwayne's case was virtually hopeless. They mentioned that there were various possible treatments but pointed out that, at best, all the treatments might do is provide a temporary reprieve. The Oak Ridge researchers then explained that they were interested in "bone marrow transfers," Mary Sue recalls. "They said it was experimental and would kill the leukemia cells. They offered that as an alternative. We took it as a desperate move for the health of our child."

THE CONSENT FORM

Both Dwayne's parents signed a consent form drafted by the Oak Ridge doctors. It reads, in part, "We understand and agree to a special experimental procedure designed to try to help our child who has acute leukemia. This will consist of removing bone marrow from the child, subjecting the marrow to radiation designed to kill the leukemic cells and subsequently injecting these cells into the mother . . . there are some risks involved for both mother and child. The nature of these has been explained to us, and we are willing to accept them."

In fact, the signing of the form by the Sextons did not really constitute "informed consent." Dwayne's parents were apparently misled into believing that the experimental bone marrow transfer was his best and only hope for survival. However, that treatment was clearly untried, and several better alternatives for treating acute lymphatic leukemia were widely known and available. According to Dr. Peter Wiernik, director of the Baltimore (Maryland) Cancer Research Center and a former official of the National Cancer Institute, a therapy protocol consisting of several chemical agents was the "common treatment at that time."

Instead of chemotherapy, eight days after his arrival at Oak Ridge, Dwayne was wheeled into the clinic's surgical arena and sedated. Bone marrow was carefully extracted through *seventeen* punctures in his legs, hips and breastbone. The marrow was then irradiated—probably in the METBI chamber. That afternoon, the irradiated bone marrow was

transferred into four syringes and injected into each of Mary Sue's hips and arms.

For Mary Sue, the injections were merely a painful irritant, but she was stoic about her discomfort. After all, her pain might help save Dwayne's life. But her eyes welled with tears when she pulled back the sheet covering her son's unconscious body and began counting the puncture wounds in his legs and chest.

On August 16 there was more surgery. A small incision was made in Mary Sue's left thoracic duct just above the collarbone, and a tube was inserted. For five days fluid drained through the tube into a plastic vacuum bag. This "serum" was filtered and then injected into Dwayne.

The doctors had hoped that Mary Sue's healthy body would build up antibodies, which would destroy the leukemic cells injected into her. Then, the antibodies in her blood serum could be used to fight the leukemic cells produced in Dwayne's bone marrow. But by mid-November of 1965, it was clear that this experiment had failed. Dwayne Sexton's condition was worsening.

"It was a superb idea," says the Baltimore Cancer Center's Peter Wiernick. "But you just cannot do those things in humans first thing." Medical authorities contacted by *Mother Jones*

agreed that it is simply unethical to inject cancer cells into a healthy human being, unless it is clearly a last resort. In Dwayne's case, it was not. Other therapies, whose worth was already proven, were readily available at the time. Today, research into cancer therapies using antibodies is still under way at several facilities, including the National Cancer Institute. Yet even now, 16 years after Dwayne's treatment, the experiments are conducted largely on laboratory animals and on human cancer cells in laboratory dishes.

After the failure of the bone marrow transfer, the Oak Ridge Institute doctors belatedly began treating Dwayne Sexton with chemotherapy.

A NEW GIMMICK

The Oak Ridge researchers were collecting syndrome data in earnest at that time, but the METBI facility had its problems and limitations. In addition, the Oak Ridgers had a new theory they wanted to test: Could they alleviate some of the side effects of the therapy by using lower doses of radiation over days or even weeks of continuous exposure?

By 1967, the AEC had financed the construction of a second facility at Oak Ridge: LETBI—the Low-Exposure-Rate Total-Body Irradiator. The difference between it and METBI was like the difference between the Ritz and a fleabag hotel. In fact, the paneled LETBI chamber was specifically designed and furnished to look like an ordinary hotel room where patients undergoing therapy could relax

and feel like they were on vacation. Except the LETBI chamber had no windows.

LETBI was really two rooms, one built within the other. The outer chamber was concrete. Inside, a smaller, wooden box was centrally positioned. Between the walls were eight cobalt 60 teletherapy machines, which created a radiation field that could administer doses as low as 1.5 rads per hour.

The radiation machines were operated and monitored remotely from an instrument console located in an adjacent control room. The panel also contained closed-circuit TV monitors, a communications system linked to the chamber and a read-out for the syndrome cord—an umbilical specifically

developed to study the vital functions of patients as they underwent these new radiation treatments. The 65-foot umbilical was used to search for syndrome symptoms.

By monitoring read-outs, technicians could watch for subtle changes in respiration that would indicate nausea. The syndrome study had advanced to the point where the doctors knew a patient was about to get sick and vomit before the patient did.

The patients "would really run the whole thing," Lushbaugh explains. "Just by [the patient] opening the door [to leave the chamber], the whole thing would turn off, and he'd go out

and take a leak and go back in, and somebody would bring him his meals."

Lushbaugh was successful in coming up with data that helped determine how much radiation it took to induce the syndrome. But NASA still wanted to know whether milder symptoms of radiation sickness might reduce an astronaut's ability to perform routine tasks in space.

DWAYNE'S LAST CRISIS

A series of strategically placed mirrors enabled Mary Sue to watch Dwayne in the METBI chamber. He thumbed a well-worn comic book contentedly while the machines were turned on. Just four months shy of his seventh birthday, Dwayne had become all-too-familiar with the routine of hospital life. Over three and a half years, he had spent countless days at the Oak Ridge clinic. Despite the failure of the bone marrow transfer, chemical therapies had kept his leukemic cells in remission—until this new crisis.

Mary Sue silently mumbled a prayer. On Thanksgiving Eve 1968, blood had begun trickling from Dwayne's nostrils and oozing from the back of his throat. Mary Sue could not stop the hemorrhaging. The Sextons sped the 70-mile drive from their home in Robbins, Tennessee.

Now she watched anxiously as Dwayne began to fidget on the aluminum bed. The only hope for prolonging his life, the doctors said, was to depress Dwayne's bone marrow with a



This picture of the Sexton family was taken in September 1967, about a year before Dwayne, on the right, died at the Oak Ridge clinic.

large enough dose of radiation to kill the cancer cells growing there. It was risky. The amount of radiation would also kill other cells and effectively knock out his body's immunity to bacteria. Dwayne would have to be closely guarded against deadly infection.

From METBI, Dwayne was wheeled into the nearby LETBI chamber, which the Oak Ridge doctors were using as a germ-free isolation ward. The umbilical monitor was strapped around his waist. The doctors told Mary Sue they needed to watch his vital signs carefully. They *didn't* tell her they were using the umbilical to collect data for their NASA study. Dwayne Sexton accepted this latest radiation therapy without a whimper.

"That radiation dose they gave Dwayne may have done the job," Mary Sue says now of the attempt to arrest the growth of the cancer cells, "but I think it done it a bit too much, possibly." In the following weeks, Dwayne's weight dropped by half to less than 30 pounds.

He barely had the strength to lift his head off the pillow, but he enjoyed picking through a flood of letters and Christmas cards, which poured in from relatives and friends. Mary Sue slept beside Dwayne in an empty bed, keeping a constant vigil. "Dwayne didn't care what they did to him," she says, "as long as his Mommy was there. It was like a fairy tale. He was such a brave little boy."

Dwayne knew intuitively his life was ending. "Don't cry, Mommy," he told Mary Sue as she stroked his forehead. "I'm going to be with Jesus."

OF MICE & MEN

Medical science has its own system of judging advances in treatment and therapy. Teams of doctors with expertise in the particular area of research carefully consider and evaluate their fellow doctors' projects.

On several occasions during the LETBI and METBI experiments, inspectors from the AEC visited the Oak Ridge clinic. Judging by the documentary records available, most of the so-called peer reviews by doctors who scrutinized the facility were less than laudatory. One reviewer charged "the directors weren't paying enough attention to what was going on. There had been a previous site visit a couple of years before mine, and their report was ignored."

The report of the review team dispatched to Oak Ridge in March 1974 could not be ignored. They called the clinical facilities "substandard" and recommended the facility be shut down or the program be moved elsewhere. Dr. William Bibb, now the Energy Department's director of research in Oak Ridge, argues that the clinic was closed because "it was giving exquisite care to the people it was taking care of, but it was not providing any research results at all."

On the contrary, the evidence indicates that patients were not receiving "exquisite care." The physicians' judgments of which therapy might be most beneficial to the patients may have been clouded by their desire to come up with "beneficial applications of radiation" for the AEC and syndrome data for NASA. The cancer patients who came to the clinic for help became, in effect, laboratory animals.

In a confidential report, members of the AEC review team that visited the clinic in 1974 expressed their uneasiness with the low quality of the facility and the poor patient care. They characterized the nuclear medicine program as "very pedestrian" and gave the clinical hematology division "an unfavorable rating." But more importantly, the reviewers discovered that some patients at the clinic may have had their lives jeopardized: just beneath the wooden floor of the LETBI chamber, the Oak Ridge researchers had suspended on plastic cords approximately 50 cages of laboratory mice.

Leukemia patients, especially those undergoing radiotherapy like Dwayne Sexton, are virtually defenseless against infection. In hospitals they are carefully isolated from any source of harmful bacteria. Yet, at Oak Ridge, the clinicians were experimenting by irradiating mice and men simultaneously and thus, according to the AEC re-

port, exposing the patients to potentially deadly infection from the animal cages hung directly below the LETBI treatment chamber.

Twice a week, animal caretakers crawled between the inner and outer shells of the LETBI facility to provide fresh food and water for the mice. They carried the dirty cages "through the patient area to an elevator and down to the cage washer," noted the AEC review report. "This entire arrangement seems to be questionable because of the necessity of transporting the animals, animal wastes and equipment through areas used by patients who frequently have compromised host defense mechanisms." In other words, patients whose bodies are incapable of fighting off infection. "This area," the reviewers wrote, "would appear to be highly prone to severe infestations of vermin."

Human guinea pigs are essential to every discovery designed to prolong life, relieve suffering or improve the quality of the human condition. Sooner or later, someone has to submit to new therapies to determine whether they are effective or useless. Doctors routinely comb the professional journals of their various disciplines, searching for clues of discovery provided by their peers' successes and failures.

The 14 years of experiments by the Oak Ridge researchers provided few of those clues. Clarence Lushbaugh did produce a 224-page report on the LETBI and METBI studies for NASA, but he did not publish a single scientific paper on the

Morgan believes he was "misled" about the clinic. "My hope & trust were misplaced," he says now.

experiments in any recognized journal because "we never considered them to be of enough scientific quality." In his report's summary, Lushbaugh cautioned that the studies should "not be considered definitive." In fact, the experiments raised more questions than they answered.

WERE PATIENTS HELPED?

In their confidential report, the AEC reviewers lambasted the researchers for their work, which they labeled "dismal." The report explicitly says the METBI and LETBI programs evolved "without adequate planning, criticism or objectives." The bone marrow transplant experiments received especially harsh criticism. "In view of accepted therapeutic modalities, ethical questions were raised with respect to the protocols employed in these studies," the confidential AEC report read.

The chamber experiments didn't even result in any appreciable improvement in radiotherapy techniques. "There is little if any clinically useful data on the METBI and LETBI programs," one of the AEC reviewers wrote in his confidential report four years later. "LETBI has been used long enough to establish (if I understand Dr. Lushbaugh correctly) that a very low dose rate does not offer any advantage over the administration of the dose at a higher rate in small, daily fractions."

Was the purpose of the experiments primarily to provide data for the space program?

In the beginning, Lushbaugh and Andrews wrote in 1970, a principal objective of the experiments "was to seek information that might lead to improved radiation therapy." However, that noble search for the light of knowledge was soon corrupted. "During the course of the study," they noted in their progress report, "the urgent need arose for information on hematologic effects in man, since the National Aeronautics and Space Administration was faced with potentially high levels of radiation exposures in space exploration."

In short, the syndrome search took precedence. It is not surprising that the METBI and LETBI experiments—with respect to cancer therapy—would get a lower priority: Lushbaugh and Andrews admitted in their 1970 progress report that they did not expect "these individual or infrequently given exposures to produce better clinical results" and that a different radiation treatment "probably offers a preferable approach for total-body radiotherapy."

Despite the documentary evidence, Lushbaugh denies emphatically the suggestion that the experiments were conducted principally for NASA's benefit. He claims his monitoring program was simply "piggybacked" onto the LETBI and METBI cancer therapy treatments. The Energy Department's William Bibb also denies that the search for the

syndrome motivated the experiments. "It was the AEC that financed that," Bibb says. "With or without the NASA study, that program would have gone on." Yet, Lushbaugh's 1975 report to NASA clearly states that "the radiobiologic studies" were "carried out with joint AEC and NASA support during the years 1964 to 1974." NASA's support was financially crucial, especially in the experiments' final years.

According to Allen Webb, chemist at the clinic during the experiments, "In the early 1970s, Lushbaugh had to kick asses and pull strings to get enough money to keep LETBI running. NASA provided the monies."

Lushbaugh himself estimates that during the ten years

NASA sponsored his research, the space agency provided "three or four million dollars." The records available are limited to the period between 1969 and 1976 and account for payments by NASA of only \$799,766 of the total amount. Lushbaugh's colleague, R.C. Ricks—who coauthored the report for NASA—says that with the exception of about \$5,000 he spent for bicycle ergometry equipment, NASA paid his salary and Lushbaugh's salary, and the rest of "the funds were spent primarily for salaries for people to be at LETBI."

Clearly, the paper trail of evidence leads directly to the space agency. An at-

achment to NASA purchase orders (signed by AEC officials and authorizing funds for the project) notes that "the 'Prospective' Human Radiation Sensitivity studies will be continued and will be increased in number in both LETBI and METBI as more patients appropriate to this type of therapy are referred to us." Without NASA money, there would not have been enough cash to continue.

Did the LETBI and METBI radiation experiments actually benefit the patients?

The AEC's reviewers answered that question with an unequivocal and emphatic no. "There has been little thought," they wrote in a disturbing assessment of the experiments, "as to therapeutic utility or potential long-range consequences." In any medical facility, what is best for the patient should always be of paramount importance; and yet, the AEC reviewers accused the Oak Ridge researchers of ignoring whether the therapy they employed was doing any good. Unfortunately, at least 89 cancer patients—including Dwayne Sexton—passed through the LETBI and METBI chambers before the government came to that belated conclusion and itself ordered a halt to the experiments.

THE AFTERMATH

Gould Andrews left the Oak Ridge clinic after the AEC ordered the facility closed and joined the faculty of the University of Maryland. Lushbaugh asserts that it was

—Continued on page 44



Clarence Lushbaugh, who has testified about exposing Oak Ridge patients to radiation, now says his role was not significant.

Photograph by Howard Rosenberg

INFORMED CONSENT

CONTINUED FROM PAGE 37

Andrews who determined which patients should be irradiated in the chambers and how big a dose they should get. However, a number of those involved in the experiments remembered that a committee of the clinic's staff—including Lushbaugh—made the determinations collectively. Andrews cannot speak for himself. He died in the summer of 1980.

Dr. Karl Z. Morgan was the director of the Oak Ridge National Laboratory's Health Physics Division during the LETBI and METBI experiments. Morgan is known throughout the world as the "father of health physics," a science dedicated to the prevention of radiation damage. He is probably the leading figure on radiation protection in the United States and, as such, could hardly be called "antinuclear." Currently a professor of physics at the Georgia Institute of Technology, Morgan believes that during his tenure at the Oak Ridge national laboratory, he was sadly confused about the purpose and results of the LETBI and METBI radiation experiments.

"I naively thought that the purpose of this nearby center [the clinic] was to use ionizing radiation in the treatment of cancer in a manner that had been proven to offer justifiable hope of remission and, in some cases, a cure," Morgan says today. "I believe I was misled, and my hope and trust in this program were badly misplaced."

As it turns out, one of Morgan's lifetime friends, his childhood Sunday school teacher, was one of the 89 patients who went to the Oak Ridge clinic for help and became a subject for the radiation syndrome study. Information about the nature of this clinic has, for Morgan, a special pain.

"The evidence strongly suggests," Morgan continues carefully, "that the purpose of this program was not what we were led to believe." Though Morgan trained dozens of medical doctors himself in methods of using radiation for human benefit, he says he is "appalled, overcome with consternation and filled with a deep sense of indignation" by the news that the cancer patients treated at the Oak Ridge clinic really became guinea pigs for the space program. "It causes one to wonder," Morgan concludes, "whether the members of the medical profession who were responsible could have been sincere the day they took the Hippocratic oath."

Clarence Lushbaugh still has his offices at the clinic itself, but now he is the director of the Oak Ridge Associated Universities' Medical and Health Sciences Division and brags that "only God can retire me." Just months after the review team concluded its damaging report on the clinic, Lushbaugh was awarded another ongoing contract, this one by the Energy Department to conduct an epidemiological analysis of possible health risks to nuclear workers at the Energy Department's Oak Ridge plants.

Lushbaugh's new research project could be another potential bombshell if it confirms the results of a previous study of nuclear workers. That study, by University of Pittsburgh professor Thomas Mancuso, revealed—after 12 years of work—that nuclear workers at the Energy Department's Hanford, Washington, atomic works suffered a significant increase in the incidence of certain types of cancer at radia-

tion exposure levels *well below* "safe" limits.

While Lushbaugh has no experience in conducting epidemiological analyses, as in this new study, he does have experience in coming up with the sort of data the government likes. In his final report to NASA on the LETBI and METBI experiments, Lushbaugh explained that one of his objectives in undertaking the project was that "these unbiased clinical observations were sorely needed to defend existing environmental and occupational radiation exposure constraints from attack by well-meaning, but impractical, theorists."

In the past, when the government faced troubles because nuclear workers or atom bomb test victims were suing Uncle Sam for injuries they sustained, Lushbaugh was counted on to offer "expert testimony" against them. That was exactly what took place in U.S. District Court in Las Vegas, Nevada, on May 16, 1977.

Seven years earlier an underground nuclear bomb test at the nearby Nevada Test Site went awry. Scientists had miscalculated the power of the so-called Baneberry bomb, and a mushroom cloud broke through the earth's crust and rose some 10,000 feet into the sky. The cloud began drifting toward an AEC base camp. Setting aside their own safety, 13 guards frantically evacuated the camp. Three of the 13 later died of leukemia, apparently because of their exposure to unsafe amounts of radiation. Two of the widows sued the federal government. Clarence Lushbaugh testified against one of the women.

Lushbaugh now denies he had any significant role in the actual operation of METBI and LETBI. Yet, to prove his own expertise on radiation effects during his testimony at the Baneberry widow's trial, Lushbaugh described the LETBI and METBI experiments. He testified that "we ourselves exposed persons to various total-body doses of radiation, and this was an ongoing study that I worked in and subsequently I became the leader of it, and we radiated persons with various kinds of leukemias in a specially designed room where they actually lived in a sea of radiation with their daily dose."

Dwayne Sexton died at the Oak Ridge clinic on December 29, 1968, a month after his last therapy session in METBI. A limited autopsy was performed. The cause of death was determined to be acute strep and staph infection.

*It seems we only miss you more
As each passing day goes by
Yes, our hearts have all been broken
Yet we try hard not to cry
You were such a bright spot in our lives
Since the first day you came
There's an empty place in our home
That will never be the same*

—from a poem dedicated to Dwayne, by Mary Sue Sexton, written three months after his death

In the entire history of the United States Manned Spaceflight Program, not a single astronaut ever received a high-enough dose of radiation to suffer from the syndrome. Dwayne Sexton did.

Howard L. Rosenberg is the author of Atomic Soldiers (Beacon Press, 1980). He also describes himself as "a writer and rider" on the staff of Jack Anderson's "Washington Merry-Go-Round." Supplementary research for this article was contributed by the Environmental Policy Center.

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8/20/81 - 11 a.m. - Press conf. at ORAU
Local Area - Immunotherapy

Admissions

7/27/65
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2/25/66
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2/3/67
11/27/67
11/24/68

9/65
11/25/66
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1/4/68
12/29/68

11/68 Relapse
not response
to chemo
Decided to
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Not for
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Chemo on 1st adv for 17
days - did cell work as with mother -
immunotherapy - 12/65 again chemo
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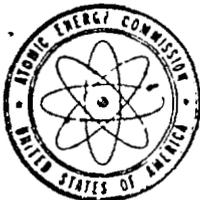
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UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

May 9, 1974

James L. Liverman, Director
Division of Biomedical and
Environmental Research

PROGRAM REVIEW OF THE MEDICAL DIVISION OF OAK RIDGE ASSOCIATED UNIVERSITIES

The following considerations have led to a proposal to change the structure of the program in the Medical Division of ORAU.

1. Oak Ridge does not have an appropriate demographic base with tertiary hospital facilities and a range of active programs in clinical investigation.

The present clinical facilities of the Medical Division do not meet the standards necessary for accreditation.

On the basis of program evaluation and institutional environment, it was recommended that clinical investigation should not be continued at ORAU Medical Division.

2. The nuclear medicine program and parts of the clinical oncology program could be incorporated into the East Tennessee Cancer Center at the University Memorial Hospital in Knoxville.

This would strengthen the development of the Cancer Center and provide the necessary environment for Medical Division programs.

3. The immunology and biochemistry programs of the Division are geographically, operationally and intellectually isolated in the present ORAU structure.

These programs would be more effective in association with the ORNL Biology Division.

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- James L. Liverman

- 2 -

May 9, 1974

4. The Medical Division of ORAU has been effective in conducting educational programs for physicians in management of radiation accidents and in assessment of radiation damage in man. These programs should be continued and perhaps associated with the capability to develop regional plans for the contingency of industrial exposure and accidental release of radioactivity.

Exploration of the feasibility and implication of these propositions should be started in negotiations with representatives of the concerned institutions. Several issues should be addressed:

1. The cost of providing adequate space and facilities in the Cancer Center in Knoxville.
2. The attitudes of the staff at ORAU and Knoxville concerning the amalgamation.
3. The cost and extent of new facilities in the Oak Ridge Hospital that would serve as demonstration and instructional areas for radiation accident programs.
4. The impact of the proposed changes on other components of the ORAU program.
5. The need to satisfactorily relocate personnel in the ORAU Medical Division.
6. The ability of ORAU to mount a broad program in the sociology, epidemiology and contingency planning related to accidental exposure of human populations to radioactivity.



Charles E. Carter, M.D.
Manager, Biomedical Programs
Division of Biomedical and
Environmental Research

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UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

April 16, 1974

ORAU REVIEW

For several years there has been growing concern over institutional and programmatic problems of the Medical Division of ORAU. The discussion of these problems which follows is based upon the comments of reviewers who visited the laboratory on March 4, 5 and 6, 1974.

A. The Institutional Setting

1. The clinical facilities are substandard with respect to licensing and accreditation guidelines and replacement is sought by ORAU through new construction in a wing of the Oak Ridge Hospital.
2. The Medical Division conducts an investigative program in an area of relatively low population, in the absence of a tertiary hospital program adequate for the provision of specialized patient populations and services, and essentially isolated from the critical climate of academic clinical investigation.
3. The laboratories in the main building vary from adequate to marginal and are housed in a structure originally designed for other purposes and a short life time. The marmoset building contains good, permanent laboratories and the biochemistry building is considered to be sound and provides good laboratory facilities. The separation of these facilities makes effective interaction of professional personnel and the synergistic development of programs virtually impossible.
4. The animal facilities are separated in several buildings and except for the marmoset building all are considered to be strikingly inadequate with respect to construction, provision of animal care, quality control, separation of species, and sanitation. The animal care programs suffer from lack of professional supervision.

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B. Programs

The several programs in the Medical Division vary widely in quality.

1. Clinical Hematology. The reviewers gave this program an unfavorable rating.
 - a. The METBI and LETBI programs were viewed as evolving without adequate planning, criticism or objectives, and have achieved less in substantial productivity than merits continued support.
 - b. The marrow transplantation program came under severe criticism. In view of accepted therapeutic modalities, ethical questions were raised with respect to the protocols employed in these studies. The leadership of this program is not defined; the coordination with immunology is ineffective. The number of patients accessible to the study is small and argues against the continuation of transplant clinical investigation at ORAU.
2. Nuclear Medicine
 - a. Radiopharmaceutical program. It was recognized that Dr. Hayes had demonstrated a high degree of capability and achievement. Questions were raised about the scope and directions of the ¹¹¹In project, the absence of physical chemical data on Gallium complexes, and a discernible tendency for the program to drift without defined goals. The isotope production facility at ORNL is an asset to the program, but in order to be effective, a significant nuclear medicine clinical facility at a large teaching and research hospital is necessary. The program suffers by its present isolation.
 - b. Clinical program. The number of nuclear medicine procedures performed is small and the interaction with Oak Ridge Hospital is minimal. The reviewers recognized Dr. Edwards' clinical competence and the dedication which he has brought to the program. There were questions about the design and evaluation of the Gallium cooperative study which limit the value of the collected data. The bone-scan investigation of Dr. Goswitz received unfavorable review comments.
3. Immunology. The reviewers gave this program top rating. Dr. Gengozian was recognized as a productive, innovative worker with well-defined research goals. It was recommended that increased support should be directed to this group.

4. Biochemistry. The projects under Dr. Snyder's direction were considered to be of high priority and productive of significant achievement. It was felt that he was intellectually, as well as geographically, isolated from the Medical Division. The reviewers raised the question of whether Dr. Snyder might not have more productive interactions in another laboratory setting.
5. Computer Services. This program is under the administrative control of Mr. Harmon, Dr. Andrews' administrative assistant, an arrangement which reviewers considered to be inappropriate for effective development of these facilities. In 1968 an IBM-1800 with peripherals was purchased. In 1972 a PDP-11/20 was brought in, and since then there have been efforts to interface the computers. This system is not good computer science. An effort to use virtual memory concepts with the disc through the IBM-1800 and the change of the system from time sharing to multi-programming are laudable efforts, but not essential to any scientific program at ORAU. Interface attempts to the Ohio Nuclear Scanner and the gamma camera were questioned because the investigators lack sound notions as to what is to be done with the encoded data. Ideas of image enhancement and quantitation were not well thought through. Other critical comments of the reviewers related to the inappropriateness of a patient information data system for a small clinical service of eight patients per day, and to the random and unproductive interaction of the staff of the computer center with other investigators. It was observed that the use of computer service for the biostatistics associated with the Gallium study and other data analysis programs is appropriate, but could be implemented with or without the present computer hardware.
6. Experimental Pathology. Dr. Swartzendruber, an electron microscopist with considerable experience and achievement, received strong support from reviewers for his work on the biophysics and ultrastructural aspects of Gallium localization in tumors. There was less enthusiasm about his pursuing x-ray spectroscopy and transmission electron microscopy in anything other than collaborative efforts with available instruments at ORNL.

Dr. Nelson, a pathologist who does the routine work of the center, has recently received training in Germany. The reviewers were cautious in viewing his entry into a demanding and competitive

program concerning the distribution and kinetics of labeled circulating stem cells. Although an enthusiastic and careful worker, it was felt that his lack of research experience, training, and scientific achievement might advise a collaborative effort or some opportunity for supervision.

7. Radiation Accidents; Human Radiation Exposure. The broad experience of Dr. Lushbaugh and his achievement in published assessment of human radiation exposure were considered by reviewers to have great value. Although a large part of his research effort is funded by NASA, it was considered to be effectively supportive of AEC missions and well done. It was reported by reviewers that the computer services have not provided adequate consultative treatment on statistical problems. Dr. Lushbaugh's new findings on colonic cancer in one strain of the marmoset were considered by reviewers to be a significant discovery worthy of substantial support.

Drs. Andrews and Lushbaugh have been an effective team in dealing with problems of radiation accidents.

8. Microbiology. The comments of reviewers were generally unfavorable with respect to this program. The routine microbiology of the clinical services is handled by competent technicians and appeared to be of high quality. Dr. Tyndall was reported by reviewers to have little interest or background in clinical microbiology; as a result, some of the crucial studies of patients with total body irradiation have neither been followed up nor initiated. Dr. Tyndall's studies of Gallium were evaluated as being inadequately planned, isolated from consultation with immunologists and molecular biologists, and not coordinated with the principal responsibilities of the microbiology program.
9. Cytogenetics. Dr. Littlefield was appointed to work with Dr. Goh on a project supported by NIH dealing with cytogenetic effects of oral contraceptives in women. When Dr. Goh left ORAU, Dr. Littlefield became principal investigator and succeeded to responsibility in a study with many methodological problems. Dr. Littlefield was considered by the reviewers to be a technically competent cytogeneticist who had performed creditably, but who had not yet matured scientifically as an independent investigator. It was felt that the Medical Division had not developed a cytogenetics research program, and that much of Dr. Littlefield's effort was spent in unplanned and unused clinical supporting services. Dr. Littlefield has the potential to become a competent independent scientist.

10. Physics and Instrumentation. The work of Roger Cloutier and Evelyn Watson on problems of dosimetry was recognized as having outstanding merit. The cooperative work with Walter Snyder of ORNL suggested that a more suitable association for work on dosimetry might be at ORNL. The work by Gibbs on the whole-body counter is almost entirely in support of dosimetry studies.

The work of Morris was viewed as instrumentation development proceeding independently of carefully assessed needs for problem solving. The projects were considered to be of low priority.

C. Administration of the Medical Division

In general, the reviewers were unanimous in their judgment that ORAU Medical Division was an institution with a creditable history, but one that is now faced with serious problems. While respectful of the administrative leadership of the division, it was recognized that the institution lacked the cohesion and scientific leadership to overcome the fragmentation of programs, variable scientific quality and inadequacy of clinical setting. These judgments, though strong in advocacy of change, were not made without recognition of the dedication and achievement of Dr. Andrews in a formidably difficult situation.

Recommendations

A: Clinical Research Programs

The proposed construction of facilities in the Oak Ridge Hospital will not provide the clinical setting necessary for the development and sustenance of a clinical research program in nuclear medicine, radiotherapy and clinical oncology. There are several options to be considered.

1. Phase out programs in clinical research.
2. Disperse those clinical programs with good competitive standing to regional University Medical Centers for independent funding.
3. Transfer programs in nuclear medicine and oncology to the East Tennessee Cancer Center at the University of Tennessee Memorial Hospital in Knoxville.
4. Concentrate on a nuclear medicine program at Oak Ridge which places little emphasis on clinical research and heavy emphasis on basic mechanisms, isotope production and instrumentation development in association with Oak Ridge National Laboratory.

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These options were proposed and discussed in some detail by our reviewers. The concensus supported the consolidation of clinical research and supporting programs, such as experimental pathology, with the University Hospital and Cancer Center in Knoxville. Such a development would considerably strengthen both institutions.

At this time, all of the factors which will influence decisions in the several institutions involved are not known; and we view this recommendation as an opening move in a series of negotiations, many of which depend on the status of the Cancer Center program at Knoxville.

B. Radiation Accidents and the Social Strategy for Dealing with Human Exposure to Environmental Radiation

1. The extensive experience of Drs. Lushbaugh and Andrews in problems of radiation accidents argues for supporting a facility in Oak Ridge which would consist of a demonstration unit in the Oak Ridge Hospital with laminar flow rooms and a decontamination area suitable for treatment of accident subjects. This facility would serve as a focus for a teaching program addressed toward physicians and public health officials who are charged with responsibility in environmental health planning.
2. The above program should be coordinated with a sociological research and assessment program at the ORAU campus which would address problems of preventive and response planning for environmental contamination resulting from accidents and nuclear fuel release. This program might develop with well-defined relationships to the "think tank" for energy options which ORAU has initiated.
3. It might also be appropriate at this time to think about centralizing the information processing and some components of the human epidemiology programs relating to occupational exposure and health assessment of workers at a facility such as that proposed for ORAU. The computer center now serving the Medical Division might then be transferred and restructured to serve this function.

C. The Immunology Program and the Biochemistry Program should be brought into administrative association with ORNL and as soon as feasible into that laboratory. The strength of these programs and the adequacy of present facilities is recognized, and alternative options might be considered.

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- D. The Medical Physics and Instrumentation Program would be more appropriately developed in ORNL. The recognized merit of Dr. Cloutier's work in dosimetry would undoubtedly lead to the possibility of incorporating his program into a combined effort at the Cancer Center, University of Tennessee Hospital in Knoxville, should this proposition be developed.
- E. In recognizing the potential of Dr. Littlefield to develop as an independent investigator in cytogenetics, a transfer of her program to the cytogenetics group at ORNL is recommended.
- F. The Microbiology Program might be identified with several institutions; at this time no recommendation is made.

In making these recommendations, there is recognition of the dislocation and discomfort they entail. There is a determination, however, to deal sensitively and considerately with the people involved. At the outset it should be realized that we are embarking on a series of meetings with several concerned parties; we propose several recommendations to orient the discussions. With considerable firmness we respond to the recommendation of our reviewers and our staff that the present configuration of the Medical Division of ORAU must change.

As a consequence of these recommendations, certain actions with respect to construction of facilities are entailed.

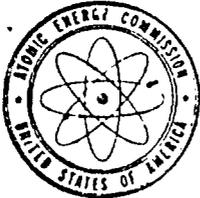
1. ORAU and AEC should not enter into an agreement with Oak Ridge Hospital for the construction of a 26-30 bed clinical facility.
2. The possibility of a demonstration accident treatment facility with an attached decontamination unit as part of the new construction being planned at Oak Ridge Hospital should be explored. This facility might contain two laminar flow rooms, offices and a conference area.
3. There should be no new construction of animal facilities.

The changes resulting from these recommendations should take place over a period of two to three years.

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UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

May 9, 1974

James L. Liverman, Director
Division of Biomedical and
Environmental Research

PROGRAM REVIEW OF THE MEDICAL DIVISION OF OAK RIDGE ASSOCIATED UNIVERSITIES

The following considerations have led to a proposal to change the structure of the program in the Medical Division of ORAU.

1. Oak Ridge does not have an appropriate demographic base with tertiary hospital facilities and a range of active programs in clinical investigation.

The present clinical facilities of the Medical Division do not meet the standards necessary for accreditation.

On the basis of program evaluation and institutional environment, it was recommended that clinical investigation should not be continued at ORAU Medical Division.

2. The nuclear medicine program and parts of the clinical oncology program could be incorporated into the East Tennessee Cancer Center at the University Memorial Hospital in Knoxville.

This would strengthen the development of the Cancer Center and provide the necessary environment for Medical Division programs.

3. The immunology and biochemistry programs of the Division are geographically, operationally and intellectually isolated in the present ORAU structure.

These programs would be more effective in association with the ORNL Biology Division.

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ORGANIZATION & MANAGEMENT - 3

ORAU

James L. Liverman

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May 9, 1974

4. The Medical Division of ORAU has been effective in conducting educational programs for physicians in management of radiation accidents and in assessment of radiation damage in man. These programs should be continued and perhaps associated with the capability to develop regional plans for the contingency of industrial exposure and accidental release of radioactivity.

Exploration of the feasibility and implication of these propositions should be started in negotiations with representatives of the concerned institutions. Several issues should be addressed:

1. The cost of providing adequate space and facilities in the Cancer Center in Knoxville.
2. The attitudes of the staff at ORAU and Knoxville concerning the amalgamation.
3. The cost and extent of new facilities in the Oak Ridge Hospital that would serve as demonstration and instructional areas for radiation accident programs.
4. The impact of the proposed changes on other components of the ORAU program.
5. The need to satisfactorily relocate personnel in the ORAU Medical Division.
6. The ability of ORAU to mount a broad program in the sociology, epidemiology and contingency planning related to accidental exposure of human populations to radioactivity.



Charles E. Carter, M.D.
Manager, Biomedical Programs
Division of Biomedical and
Environmental Research

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UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

April 16, 1974

ORAU REVIEW

For several years there has been growing concern over institutional and programmatic problems of the Medical Division of ORAU. The discussion of these problems which follows is based upon the comments of reviewers who visited the laboratory on March 4, 5 and 6, 1974.

A. The Institutional Setting

1. The clinical facilities are substandard with respect to licensing and accreditation guidelines and replacement is sought by ORAU through new construction in a wing of the Oak Ridge Hospital.
2. The Medical Division conducts an investigative program in an area of relatively low population, in the absence of a tertiary hospital program adequate for the provision of specialized patient populations and services, and essentially isolated from the critical climate of academic clinical investigation.
3. The laboratories in the main building vary from adequate to marginal and are housed in a structure originally designed for other purposes and a short life time. The marmoset building contains good, permanent laboratories and the biochemistry building is considered to be sound and provides good laboratory facilities. The separation of these facilities makes effective interaction of professional personnel and the synergistic development of programs virtually impossible.
4. The animal facilities are separated in several buildings and except for the marmoset building all are considered to be strikingly inadequate with respect to construction, provision of animal care, quality control, separation of species, and sanitation. The animal care programs suffer from lack of professional supervision.

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B. Programs

The several programs in the Medical Division vary widely in quality.

1. Clinical Hematology. The reviewers gave this program an unfavorable rating.
 - a. The METBI and LETBI programs were viewed as evolving without adequate planning, criticism or objectives, and have achieved less in substantial productivity than merits continued support.
 - b. The marrow transplantation program came under severe criticism. In view of accepted therapeutic modalities, ethical questions were raised with respect to the protocols employed in these studies. The leadership of this program is not defined; the coordination with immunology is ineffective. The number of patients accessible to the study is small and argues against the continuation of transplant clinical investigation at ORAU.
2. Nuclear Medicine
 - a. Radiopharmaceutical program. It was recognized that Dr. Hayes had demonstrated a high degree of capability and achievement. Questions were raised about the scope and directions of the ^{111}In project, the absence of physical chemical data on Gallium complexes, and a discernible tendency for the program to drift without defined goals. The isotope production facility at ORNL is an asset to the program, but in order to be effective, a significant nuclear medicine clinical facility at a large teaching and research hospital is necessary. The program suffers by its present isolation.
 - b. Clinical program. The number of nuclear medicine procedures performed is small and the interaction with Oak Ridge Hospital is minimal. The reviewers recognized Dr. Edwards' clinical competence and the dedication which he has brought to the program. There were questions about the design and evaluation of the Gallium cooperative study which limit the value of the collected data. The bone-scan investigation of Dr. Goswitz received unfavorable review comments.
3. Immunology. The reviewers gave this program top rating. Dr. Gengozian was recognized as a productive, innovative worker with well-defined research goals. It was recommended that increased support should be directed to this group.

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4. Biochemistry. The projects under Dr. Snyder's direction were considered to be of high priority and productive of significant achievement. It was felt that he was intellectually, as well as geographically, isolated from the Medical Division. The reviewers raised the question of whether Dr. Snyder might not have more productive interactions in another laboratory setting.
5. Computer Services. This program is under the administrative control of Mr. Harmon, Dr. Andrews' administrative assistant, an arrangement which reviewers considered to be inappropriate for effective development of these facilities. In 1968 an IBM-1800 with peripherals was purchased. In 1972 a PDP-11/20 was brought in, and since then there have been efforts to interface the computers. This system is not good computer science. An effort to use virtual memory concepts with the disc through the IBM-1800 and the change of the system from time sharing to multi-programming are laudable efforts, but not essential to any scientific program at ORAU. Interface attempts to the Ohio Nuclear Scanner and the gamma camera were questioned because the investigators lack sound notions as to what is to be done with the encoded data. Ideas of image enhancement and quantitation were not well thought through. Other critical comments of the reviewers related to the inappropriateness of a patient information data system for a small clinical service of eight patients per day, and to the random and unproductive interaction of the staff of the computer center with other investigators. It was observed that the use of computer service for the biostatistics associated with the Gallium study and other data analysis programs is appropriate, but could be implemented with or without the present computer hardware.
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Dr. Nelson, a pathologist who does the routine work of the center, has recently received training in Germany. The reviewers were cautious in viewing his entry into a demanding and competitive

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- 4 -

program concerning the distribution and kinetics of labeled circulating stem cells. Although an enthusiastic and careful worker, it was felt that his lack of research experience, training, and scientific achievement might advise a collaborative effort or some opportunity for supervision.

7. Radiation Accidents; Human Radiation Exposure. The broad experience of Dr. Lushbaugh and his achievement in published assessment of human radiation exposure were considered by reviewers to have great value. Although a large part of his research effort is funded by NASA, it was considered to be effectively supportive of AEC missions and well done. It was reported by reviewers that the computer services have not provided adequate consultative treatment on statistical problems. Dr. Lushbaugh's new findings on colonic cancer in one strain of the marmoset were considered by reviewers to be a significant discovery worthy of substantial support.

Drs. Andrews and Lushbaugh have been an effective team in dealing with problems of radiation accidents.

8. Microbiology. The comments of reviewers were generally unfavorable with respect to this program. The routine microbiology of the clinical services is handled by competent technicians and appeared to be of high quality. Dr. Tyndall was reported by reviewers to have little interest or background in clinical microbiology; as a result, some of the crucial studies of patients with total body irradiation have neither been followed up nor initiated. Dr. Tyndall's studies of Gallium were evaluated as being inadequately planned, isolated from consultation with immunologists and molecular biologists, and not coordinated with the principal responsibilities of the microbiology program.
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The work of Morris was viewed as instrumentation development proceeding independently of carefully assessed needs for problem solving. The projects were considered to be of low priority.

C. Administration of the Medical Division

In general, the reviewers were unanimous in their judgment that ORAU Medical Division was an institution with a creditable history, but one that is now faced with serious problems. While respectful of the administrative leadership of the division, it was recognized that the institution lacked the cohesion and scientific leadership to overcome the fragmentation of programs, variable scientific quality and inadequacy of clinical setting. These judgments, though strong in advocacy of change, were not made without recognition of the dedication and achievement of Dr. Andrews in a formidably difficult situation.

Recommendations

A: Clinical Research Programs

The proposed construction of facilities in the Oak Ridge Hospital will not provide the clinical setting necessary for the development and sustenance of a clinical research program in nuclear medicine, radiotherapy and clinical oncology. There are several options to be considered.

1. Phase out programs in clinical research.
2. Disperse those clinical programs with good competitive standing to regional University Medical Centers for independent funding.
3. Transfer programs in nuclear medicine and oncology to the East Tennessee Cancer Center at the University of Tennessee Memorial Hospital in Knoxville.
4. Concentrate on a nuclear medicine program at Oak Ridge which places little emphasis on clinical research and heavy emphasis on basic mechanisms, isotope production and instrumentation development in association with Oak Ridge National Laboratory.

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- 6 -

These options were proposed and discussed in some detail by our reviewers. The concensus supported the consolidation of clinical research and supporting programs, such as experimental pathology, with the University Hospital and Cancer Center in Knoxville. Such a development would considerably strengthen both institutions.

At this time, all of the factors which will influence decisions in the several institutions involved are not known; and we view this recommendation as an opening move in a series of negotiations, many of which depend on the status of the Cancer Center program at Knoxville.

B. Radiation Accidents and the Social Strategy for Dealing with Human Exposure to Environmental Radiation

1. The extensive experience of Drs. Lushbaugh and Andrews in problems of radiation accidents argues for supporting a facility in Oak Ridge which would consist of a demonstration unit in the Oak Ridge Hospital with laminar flow rooms and a decontamination area suitable for treatment of accident subjects. This facility would serve as a focus for a teaching program addressed toward physicians and public health officials who are charged with responsibility in environmental health planning.
 2. The above program should be coordinated with a sociological research and assessment program at the ORAU campus which would address problems of preventive and response planning for environmental contamination resulting from accidents and nuclear fuel release. This program might develop with well-defined relationships to the "think tank" for energy options which ORAU has initiated.
 3. It might also be appropriate at this time to think about centralizing the information processing and some components of the human epidemiology programs relating to occupational exposure and health assessment of workers at a facility such as that proposed for ORAU. The computer center now serving the Medical Division might then be transferred and restructured to serve this function.
- C. The Immunology Program and the Biochemistry Program should be brought into administrative association with ORNL and as soon as feasible into that laboratory. The strength of these programs and the adequacy of present facilities is recognized, and alternative options might be considered.

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- D. The Medical Physics and Instrumentation Program would be more appropriately developed in ORNL. The recognized merit of Dr. Cloutier's work in dosimetry would undoubtedly lead to the possibility of incorporating his program into a combined effort at the Cancer Center, University of Tennessee Hospital in Knoxville, should this proposition be developed.
- E. In recognizing the potential of Dr. Littlefield to develop as an independent investigator in cytogenetics, a transfer of her program to the cytogenetics group at ORNL is recommended.
- F. The Microbiology Program might be identified with several institutions; at this time no recommendation is made.

In making these recommendations, there is recognition of the dislocation and discomfort they entail. There is a determination, however, to deal sensitively and considerately with the people involved. At the outset it should be realized that we are embarking on a series of meetings with several concerned parties; we propose several recommendations to orient the discussions. With considerable firmness we respond to the recommendation of our reviewers and our staff that the present configuration of the Medical Division of ORAU must change.

As a consequence of these recommendations, certain actions with respect to construction of facilities are entailed.

1. ORAU and AEC should not enter into an agreement with Oak Ridge Hospital for the construction of a 26-30 bed clinical facility.
2. The possibility of a demonstration accident treatment facility with an attached decontamination unit as part of the new construction being planned at Oak Ridge Hospital should be explored. This facility might contain two laminar flow rooms, offices and a conference area.
3. There should be no new construction of animal facilities.

The changes resulting from these recommendations should take place over a period of two to three years.

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RECEIVED BY _____ DATE _____ TIME _____

Dwayne Jester

MESSAGE
 RETURNED COPY SENT WISHES AN APPOINTMENT
 WILL CALL AGAIN IS WAITING TO SEE YOU

File ST F12 ATTACHED
OF (or extension)

YOU WERE CALLED BY - YOU WERE CALLED BY -

TO: _____
MEMORANDUM OF CALL _____
PLEASE PRINT NAME AND PHONE NUMBER

1022377

STATE OF TENNESSEE

28TH JUDICIAL CIRCUIT CIRCUIT COURT

MARK SUE SEXTON, Mother and next friend of TALMON DEWAYNE
SEXTON, Deceased,

PLAINTIFF

vs.

OAK RIDGE ASSOCIATED UNIVERSITIES, Agent for Service,

DEFENDANT

Stephen S. Lawrence
Badger Avenue
Oak Ridge, Tenn.

CIVIL ACTION

NO. L-2728

SUMMONS

TO THE ABOVE NAMED DEFENDANT(S):

You are hereby summoned and required to serve upon Kathleen M. Tucker

Plaintiff's Attorney, whose address is 520 Butternut Street, N.W. Washington, D.C. 20012

an answer to the complaint which is herewith served upon you within (30) days after service of this summons upon you, exclusive of the day of service. If you fail to do so, judgment by default will be taken against you for the relief demanded in the complaint.

Witness, Thomas J. Alderson, Clerk, Circuit Court, at office, Clinton, Tennessee, this 15th day of March, A.D. 19 82

THOMAS J. ALDERSON, CLERK, CIRCUIT COURT

BY: Thomas J. Alderson
Deputy Clerk

No. L-2728	STATE OF TENNESSEE 28TH JUDICIAL CIRCUIT CIRCUIT COURT	vs.	MARK SUE SEXTON, Mother and next friend of TALMON DEWAYNE SEXTON, Deceased,	OAK RIDGE ASSOCIATED UNIVERSITIES	SUMMONS IN CIVIL ACTION	Issued the <u>15th</u> day of <u>March</u> , 19 <u>82</u>
						at <u>1:30</u> o'clock <u>P</u> . M.
BY: <u>Thomas J. Alderson</u> Deputy Clerk						

Received this _____ day of _____, 19____ Deputy Sheriff _____

RETURN ON SERVICE OF SUMMONS

I hereby certify and return, that on the _____ day of _____, 19____
at _____ o'clock, _____ M. I served this summons together with the complaint herein as follows: _____

1022378

SHERIFF - DEPUTY SHERIFF

This summons is issued pursuant to Rule 4 of the Tennessee Rules Civil Procedure.

IN THE CIRCUIT COURT FOR ANDERSON COUNTY, TENNESSEE

MARY SUE SEXTON, Mother)
and next friend of TALMON)
DEWAYNE SEXTON, Deceased,)
2333 Cranshaw Drive)
Kingsport, Tennessee,)

Plaintiff)

vs.)

NO L-2728

Oak Ridge Associated Universities,)
A Tennessee Corporation listed as)
a Non-Profit Organization, with)
agent for service of process being)
Stephen S. Lawrence, Badger Avenue,)
Oak Ridge, Tennessee 37830,)

Defendant)

C O M P L A I N T

Comes the Plaintiff, Mary Sue Sexton, Mother and next friend of Talmon Dewayne Sexton, and files this her Complaint and for cause of action shows to the Court the following:

1. That she is the mother and natural guardian of Dewayne Sexton, who died December 29th, 1968.
2. That at the time of his death the Decedent, Dewayne Sexton, was suffering from acute lymphoblastic leukemia.
3. That the Decedent, Dewayne Sexton, had been a patient at the Oak Ridge Associated Universities Medical Center in Oak Ridge, Tennessee, since July 27th, 1965. That during the time the Decedent was a patient at Oak Ridge Associated Universities, the treatment he received was not consistent with the standard of care which patients received in the same or similar circumstances in the same or similar localities, for lymphoblastic leukemia. That the parents of the Decedent,

FILED this the 15th day of March
19 87, at 3:30 o'clock P. M.
THOMAS J. ALDERSON, Circuit Court Clerk
By *Carroll Alderson, S.C.*

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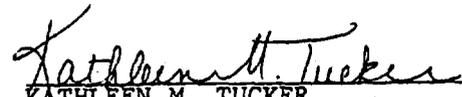
Dewayne Sexton, were improperly advised of the consequences of the treatment, and there was a failure to provide adequate information so that fully informed consent could be given to the treatment received by the Decedent.

4. That as a direct result of the failure of the Decedent to receive the proper care at Oak Ridge Associated Universities, the Decedent, Dewayne Sexton, had a shortened life expectancy.

5. That the Plaintiff, Mary Sue Sexton, had no knowledge or did not suspect any improper treatment on the part of the doctors who treated the Decedent at Oak Ridge Associated Universities until June of 1981, at which time she was informed that there could be improper treatment involved in this particular situation. It has only been recently that the Plaintiff has been informed that the purpose for these programs was not necessarily the proper treatment of the patient but may have been for other motives, and thus caused the treatment not to conform with the applicable standard of care at that time.

5. That the Defendant, Oak Ridge Associated Universities, through its agents, has concealed the purpose of these treatments and thus the statute of limitations would be tolled until such time as the Plaintiff discovered the lack of adequate treatment in this case.

WHEREFORE, Plaintiff demands judgment in the amount of SEVEN HUNDRED FIFTY THOUSAND DOLLARS (\$750,000.00), and costs and demands a jury to try this action.


KATHLEEN M. TUCKER
Attorney for Plaintiff
520 Butternut Street, N.W.
Washington, D.C. 20012
(202-882-5508)

COST BOND

We, the undersigned principal and surety, acknowledge ourselves as such in an amount not to exceed \$250.00, conditioned as in prosecution bonds.

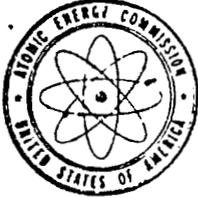
Mary Sue Sexton, by atty

Kathleen M. Tucker

THIS INSTRUMENT PREPARED BY
W. HOLT SMITH, ATTORNEY-AT-LAW
501 HIGHWAY 68 WEST, SWEETWATER,
TENNESSEE 37874
615-337-3576

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UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

May 9, 1974

James L. Liverman, Director
Division of Biomedical and
Environmental Research

PROGRAM REVIEW OF THE MEDICAL DIVISION OF OAK RIDGE ASSOCIATED UNIVERSITIES

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On the basis of program evaluation and institutional environment, it was recommended that clinical investigation should not be continued at ORAU Medical Division.

2. The nuclear medicine program and parts of the clinical oncology program could be incorporated into the East Tennessee Cancer Center at the University Memorial Hospital in Knoxville.

This would strengthen the development of the Cancer Center and provide the necessary environment for Medical Division programs.

3. The immunology and biochemistry programs of the Division are geographically, operationally and intellectually isolated in the present ORAU structure.

These programs would be more effective in association with the ORNL Biology Division.

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May 9, 1974

4. The Medical Division of ORAU has been effective in conducting educational programs for physicians in management of radiation accidents and in assessment of radiation damage in man. These programs should be continued and perhaps associated with the capability to develop regional plans for the contingency of industrial exposure and accidental release of radioactivity.

Exploration of the feasibility and implication of these propositions should be started in negotiations with representatives of the concerned institutions. Several issues should be addressed:

1. The cost of providing adequate space and facilities in the Cancer Center in Knoxville.
2. The attitudes of the staff at ORAU and Knoxville concerning the amalgamation.
3. The cost and extent of new facilities in the Oak Ridge Hospital that would serve as demonstration and instructional areas for radiation accident programs.
4. The impact of the proposed changes on other components of the ORAU program.
5. The need to satisfactorily relocate personnel in the ORAU Medical Division.
6. The ability of ORAU to mount a broad program in the sociology, epidemiology and contingency planning related to accidental exposure of human populations to radioactivity.

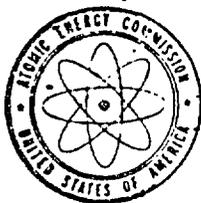


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UNITED STATES
ATOMIC ENERGY COMMISSION
WASHINGTON, D.C. 20545

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ORAU REVIEW

For several years there has been growing concern over institutional and programmatic problems of the Medical Division of ORAU. The discussion of these problems which follows is based upon the comments of reviewers who visited the laboratory on March 4, 5 and 6, 1974.

A. The Institutional Setting

1. The clinical facilities are substandard with respect to licensing and accreditation guidelines and replacement is sought by ORAU through new construction in a wing of the Oak Ridge Hospital.
2. The Medical Division conducts an investigative program in an area of relatively low population, in the absence of a tertiary hospital program adequate for the provision of specialized patient populations and services, and essentially isolated from the critical climate of academic clinical investigation.
3. The laboratories in the main building vary from adequate to marginal and are housed in a structure originally designed for other purposes and a short life time. The marmoset building contains good, permanent laboratories and the biochemistry building is considered to be sound and provides good laboratory facilities. The separation of these facilities makes effective interaction of professional personnel and the synergistic development of programs virtually impossible.
4. The animal facilities are separated in several buildings and except for the marmoset building all are considered to be strikingly inadequate with respect to construction, provision of animal care, quality control, separation of species, and sanitation. The animal care programs suffer from lack of professional supervision.

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B. Programs

The several programs in the Medical Division vary widely in quality.

1. Clinical Hematology. The reviewers gave this program an unfavorable rating.

- a. The METBI and LETBI programs were viewed as evolving without adequate planning, criticism or objectives, and have achieved less in substantial productivity than merits continued support.
- b. The marrow transplantation program came under severe criticism. In view of accepted therapeutic modalities, ethical questions were raised with respect to the protocols employed in these studies. The leadership of this program is not defined; the coordination with immunology is ineffective. The number of patients accessible to the study is small and argues against the continuation of transplant clinical investigation at ORAU.

2. Nuclear Medicine

- a. Radiopharmaceutical program. It was recognized that Dr. Hayes had demonstrated a high degree of capability and achievement. Questions were raised about the scope and directions of the ¹¹¹In project, the absence of physical chemical data on Gallium complexes, and a discernible tendency for the program to drift without defined goals. The isotope production facility at ORNL is an asset to the program, but in order to be effective, a significant nuclear medicine clinical facility at a large teaching and research hospital is necessary. The program suffers by its present isolation.
- b. Clinical program. The number of nuclear medicine procedures performed is small and the interaction with Oak Ridge Hospital is minimal. The reviewers recognized Dr. Edwards' clinical competence and the dedication which he has brought to the program. There were questions about the design and evaluation of the Gallium cooperative study which limit the value of the collected data. The bone-scan investigation of Dr. Goswitz received unfavorable review comments.

3. Immunology. The reviewers gave this program top rating. Dr. Gengozian was recognized as a productive, innovative worker with well-defined research goals. It was recommended that increased support should be directed to this group.

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4. Biochemistry. The projects under Dr. Snyder's direction were considered to be of high priority and productive of significant achievement. It was felt that he was intellectually, as well as geographically, isolated from the Medical Division. The reviewers raised the question of whether Dr. Snyder might not have more productive interactions in another laboratory setting.
5. Computer Services. This program is under the administrative control of Mr. Harmon, Dr. Andrews' administrative assistant, an arrangement which reviewers considered to be inappropriate for effective development of these facilities. In 1968 an IBM-1800 with peripherals was purchased. In 1972 a PDP-11/20 was brought in, and since then there have been efforts to interface the computers. This system is not good computer science. An effort to use virtual memory concepts with the disc through the IBM-1800 and the change of the system from time sharing to multi-programming are laudable efforts, but not essential to any scientific program at ORAU. Interface attempts to the Ohio Nuclear Scanner and the gamma camera were questioned because the investigators lack sound notions as to what is to be done with the encoded data. Ideas of image enhancement and quantitation were not well thought through. Other critical comments of the reviewers related to the inappropriateness of a patient information data system for a small clinical service of eight patients per day, and to the random and unproductive interaction of the staff of the computer center with other investigators. It was observed that the use of computer service for the biostatistics associated with the Gallium study and other data analysis programs is appropriate, but could be implemented with or without the present computer hardware.
6. Experimental Pathology. Dr. Swartzendruber, an electron microscopist with considerable experience and achievement, received strong support from reviewers for his work on the biophysics and ultrastructural aspects of Gallium localization in tumors. There was less enthusiasm about his pursuing x-ray spectroscopy and transmission electron microscopy in anything other than collaborative efforts with available instruments at ORNL.

Dr. Nelson, a pathologist who does the routine work of the center, has recently received training in Germany. The reviewers were cautious in viewing his entry into a demanding and competitive

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program concerning the distribution and kinetics of labeled circulating stem cells. Although an enthusiastic and careful worker, it was felt that his lack of research experience, training, and scientific achievement might advise a collaborative effort or some opportunity for supervision.

7. Radiation Accidents; Human Radiation Exposure. The broad experience of Dr. Lushbaugh and his achievement in published assessment of human radiation exposure were considered by reviewers to have great value. Although a large part of his research effort is funded by NASA, it was considered to be effectively supportive of AEC missions and well done. It was reported by reviewers that the computer services have not provided adequate consultative treatment on statistical problems. Dr. Lushbaugh's new findings on colonic cancer in one strain of the marmoset were considered by reviewers to be a significant discovery worthy of substantial support.

Drs. Andrews and Lushbaugh have been an effective team in dealing with problems of radiation accidents.

8. Microbiology. The comments of reviewers were generally unfavorable with respect to this program. The routine microbiology of the clinical services is handled by competent technicians and appeared to be of high quality. Dr. Tyndall was reported by reviewers to have little interest or background in clinical microbiology; as a result, some of the crucial studies of patients with total body irradiation have neither been followed up nor initiated. Dr. Tyndall's studies of Gallium were evaluated as being inadequately planned, isolated from consultation with immunologists and molecular biologists, and not coordinated with the principal responsibilities of the microbiology program.
9. Cytogenetics. Dr. Littlefield was appointed to work with Dr. Goh on a project supported by NIH dealing with cytogenetic effects of oral contraceptives in women. When Dr. Goh left ORAU, Dr. Littlefield became principal investigator and succeeded to responsibility in a study with many methodological problems. Dr. Littlefield was considered by the reviewers to be a technically competent cytogeneticist who had performed creditably, but who had not yet matured scientifically as an independent investigator. It was felt that the Medical Division had not developed a cytogenetics research program, and that much of Dr. Littlefield's effort was spent in unplanned and unused clinical supporting services. Dr. Littlefield has the potential to become a competent independent scientist.

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10. Physics and Instrumentation. The work of Roger Cloutier and Evelyn Watson on problems of dosimetry was recognized as having outstanding merit. The cooperative work with Walter Snyder of ORNL suggested that a more suitable association for work on dosimetry might be at ORNL. The work by Gibbs on the whole-body counter is almost entirely in support of dosimetry studies.

The work of Morris was viewed as instrumentation development proceeding independently of carefully assessed needs for problem solving. The projects were considered to be of low priority.

C. Administration of the Medical Division

In general, the reviewers were unanimous in their judgment that ORAU Medical Division was an institution with a creditable history, but one that is now faced with serious problems. While respectful of the administrative leadership of the division, it was recognized that the institution lacked the cohesion and scientific leadership to overcome the fragmentation of programs, variable scientific quality and inadequacy of clinical setting. These judgments, though strong in advocacy of change, were not made without recognition of the dedication and achievement of Dr. Andrews in a formidably difficult situation.

Recommendations

A: Clinical Research Programs

The proposed construction of facilities in the Oak Ridge Hospital will not provide the clinical setting necessary for the development and sustenance of a clinical research program in nuclear medicine, radiotherapy and clinical oncology. There are several options to be considered.

1. Phase out programs in clinical research.
2. Disperse those clinical programs with good competitive standing to regional University Medical Centers for independent funding.
3. Transfer programs in nuclear medicine and oncology to the East Tennessee Cancer Center at the University of Tennessee Memorial Hospital in Knoxville.
4. Concentrate on a nuclear medicine program at Oak Ridge which places little emphasis on clinical research and heavy emphasis on basic mechanisms, isotope production and instrumentation development in association with Oak Ridge National Laboratory.

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These options were proposed and discussed in some detail by our reviewers. The concensus supported the consolidation of clinical research and supporting programs, such as experimental pathology, with the University Hospital and Cancer Center in Knoxville. Such a development would considerably strengthen both institutions.

At this time, all of the factors which will influence decisions in the several institutions involved are not known; and we view this recommendation as an opening move in a series of negotiations, many of which depend on the status of the Cancer Center program at Knoxville.

B. Radiation Accidents and the Social Strategy for Dealing with Human Exposure to Environmental Radiation

1. The extensive experience of Drs. Lushbaugh and Andrews in problems of radiation accidents argues for supporting a facility in Oak Ridge which would consist of a demonstration unit in the Oak Ridge Hospital with laminar flow rooms and a decontamination area suitable for treatment of accident subjects. This facility would serve as a focus for a teaching program addressed toward physicians and public health officials who are charged with responsibility in environmental health planning.
2. The above program should be coordinated with a sociological research and assessment program at the ORAU campus which would address problems of preventive and response planning for environmental contamination resulting from accidents and nuclear fuel release. This program might develop with well-defined relationships to the "think tank" for energy options which ORAU has initiated.
3. It might also be appropriate at this time to think about centralizing the information processing and some components of the human epidemiology programs relating to occupational exposure and health assessment of workers at a facility such as that proposed for ORAU. The computer center now serving the Medical Division might then be transferred and restructured to serve this function.

- ## C. The Immunology Program and the Biochemistry Program should be brought into administrative association with ORNL and as soon as feasible into that laboratory. The strength of these programs and the adequacy of present facilities is recognized, and alternative options might be considered.

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- D. The Medical Physics and Instrumentation Program would be more appropriately developed in ORNL. The recognized merit of Dr. Cloutier's work in dosimetry would undoubtedly lead to the possibility of incorporating his program into a combined effort at the Cancer Center, University of Tennessee Hospital in Knoxville, should this proposition be developed.
- E. In recognizing the potential of Dr. Littlefield to develop as an independent investigator in cytogenetics, a transfer of her program to the cytogenetics group at ORNL is recommended.
- F. The Microbiology Program might be identified with several institutions; at this time no recommendation is made.

In making these recommendations, there is recognition of the dislocation and discomfort they entail. There is a determination, however, to deal sensitively and considerately with the people involved. At the outset it should be realized that we are embarking on a series of meetings with several concerned parties; we propose several recommendations to orient the discussions. With considerable firmness we respond to the recommendation of our reviewers and our staff that the present configuration of the Medical Division of ORAU must change.

As a consequence of these recommendations, certain actions with respect to construction of facilities are entailed.

1. ORAU and AEC should not enter into an agreement with Oak Ridge Hospital for the construction of a 26-30 bed clinical facility.
2. The possibility of a demonstration accident treatment facility with an attached decontamination unit as part of the new construction being planned at Oak Ridge Hospital should be explored. This facility might contain two laminar flow rooms, offices and a conference area.
3. There should be no new construction of animal facilities.

The changes resulting from these recommendations should take place over a period of two to three years.

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