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IN HARM'S WAY

Abuses Endangered Veterans in Cancer Drug Experiments

By DEBORAH SONTAG

ALBANY - Carl M. Steubing, a decorated Battle of the Bulge veteran whose experience of war made him a pacifist but also instilled in him a zest for living life at full tilt, took his diagnosis of gastroesophageal cancer in 2001 as a challenge.

With a thatch of white hair and a rich baritone voice, Mr. Steubing, at 78, was not ready to succumb to illness. A retired music educator and wedding photographer, he remained active as a church choir director, expert cook, painter, golfer and fisherman. He was married to a woman 24 years his junior, and they had seven children and three grandchildren between them.

Mr. Steubing jumped at the chance to participate in an experimental drug study at the Stratton Veterans Affairs Medical Center in Albany, believing it offered him the hope of surviving longer. The research coordinator, Paul H. Kornak, told Mr. Steubing that he was "just a perfect specimen," with the body of a man half his age, according to Jayne Steubing, Mr. Steubing's widow.

He was not, though. Because of a previous cancer and poor kidney function, Mr. Steubing was not even eligible to participate in the experiment, according to government documents. Mr. Kornak, however, brushed that obstacle aside. He altered Mr. Steubing's medical records, according to prosecutors, and enrolled him in the study. He also posed as a doctor.

In 2001, Mr. Steubing endured about six periodic treatments with an aggressive three-drug chemotherapy combination. Each infusion made him violently ill and forced his hospitalization. He died in March 2002.

Last month, at the federal courthouse in Albany, Mrs. Steubing glared at Mr. Kornak, 53, as he pleaded guilty to fraud, making false statements and criminally negligent homicide in the death of an Air Force veteran, James DiGeorgio. When Mr. Kornak admitted to falsifying the medical data of "subject initials CMS" - Carl M. Steubing - Mrs. Steubing's face crumpled.

Mr. Kornak, who is scheduled to be sentenced in May, also agreed to cooperate in a widening investigation of the hospital's cancer research program. From 1999 to 2003, when he worked there, scores of veterans were, at the least, put at risk. But allegations of carelessness, fraud and patient abuse in the hospital's cancer research program predated Mr. Kornak, and employees say that administrators not only dismissed their concerns, but harassed them for standing up for the veterans.

"Research violations were a way of life at Stratton for 10 years," said Jeffrey Fudin, a pharmacist at the hospital. "Stratton officials turned a blind eye to unethical cancer research practices and punished those who spoke out against them. The whole Kornak episode could have been prevented."

According to Mr. Kornak's lawyer, E. Stewart Jones, there was a "clear systems failure," permitting a research culture where "rules weren't followed, protocols weren't applied and supervision was nonexistent."

It was also a culture whose descent into criminality forced the Department of Veterans Affairs nationwide to reckon with what an internal memorandum in 2003 described as "systemic weaknesses in the human research protections program, especially in studies funded by industry."

Excluding simple chart reviews, about 80 percent of the department's human research is financed by industry. The private sector pumps considerable cash into the system. In Albany, it accounted for \$500,000 of the \$1.15 million in research funding in 2004.

Mr. Kornak, who declined to be interviewed, does not appear to have derived financial gain from his fraud. The Albany hospital's research program, however, stood to benefit from the enrollment of patients, pulling in \$5,000 from the drug company Aventis for Mr. Steubing's participation.

Although veterans knew him as "Dr. Kornak," Mr. Kornak was not licensed to practice medicine. Mrs. Steubing first learned this a year after her husband's death when she read an article in The Times Union of Albany.

By 1993, Mr. Kornak had obtained and lost medical licenses in several states by forging his credentials and had pleaded guilty in Pennsylvania to felony fraud charges. The Albany hospital hired Mr. Kornak, who did attend some medical school, as a research coordinator, not as a physician. Nonetheless, he performed physical examinations, and his Veterans Affairs business card identified him as an M.D.

James A. Holland, Mr. Kornak's supervisor, was the real M.D. and the principal oncology researcher. Federal prosecutors said in court papers last year that Dr. Holland, too, was possibly facing criminal charges.

Dr. Holland, who now works at Archbold Memorial Hospital in Thomasville, Ga., declined to comment. Archbold, in a statement, said Georgia's medical board had investigated Dr. Holland's actions in Albany and found no evidence of misconduct.

In September, however, the Food and Drug Administration started proceedings to disqualify Dr. Holland from conducting further clinical research because he had "failed to protect" subjects under his care in Albany.

According to the F.D.A., patients' medical records were altered in at least five experimental drug studies, enabling veterans like Mr. Steubing to be enrolled in studies for which they were either too sick or too healthy to qualify. A patient with coronary disease, for instance, was enrolled in a study that excluded heart patients because of a risk of hemorrhages. A patient with impaired renal function was administered a drug toxic to kidneys that probably contributed to his death, the agency said.

"It kills me to think that the V.A. system deceived us," said Mrs. Steubing, the director of an upstate school for emotionally troubled children. "You see these youngsters at Walter Reed now and everybody's raving about the care they get. Well, Carl was one of those kids once, with a Bronze Star, a Purple Heart. And at the end of his life, his treatment was the antithesis of what you see on TV. It was such a betrayal."

It can be hard to determine whether an experimental treatment is the cause of a cancer patient's death. Mrs. Steubing will never know if her husband might have survived longer if he had undergone standard chemotherapy treatment or if he might have been spared the suffering he endured after each experimental infusion. The questions will always plague her, she said.

But, as Mr. Kornak's homicide conviction indicates, the authorities have attributed one death directly to his fraud. In 2001, Mr. DiGeorgio, 71, declined precipitously and died within two weeks of being infused with experimental drugs that he should not have been given.

"My husband trusted and confided in the V.A. in Albany, and he wouldn't go nowhere else," Judith DiGeorgio, his widow, said. "It's a disgrace what they did to him."

Jon A. Wooditch, a deputy inspector general for Veterans Affairs, said department employees were forbidden to answer questions for this article because of the continuing investigations. Officials from the inspector general's office have been questioning hospital employees in the last several weeks.

After Mr. Kornak's guilty plea, the hospital director, Mary-Ellen Piché, circulated a letter to the staff noting "many improvements in research since the events," among them that "credentials of researchers have been checked and confirmed" and that researchers have undergone ethics training.

Mr. Kornak, as it turns out, was so trained. As a certified clinical research professional, he had passed an examination covering such ethical topics as informed consent and clinical fraud.

Both Mrs. Steubing and Mrs. DiGeorgio have sued Mr. Kornak, Dr. Holland and the Department of Veterans Affairs. Mrs. Steubing's complaint, in a class-action suit, says that veterans were treated like "guinea pigs."

Overwhelmed Watchdogs

In the 1990's, because of a marathon of new drug development, the field of clinical research grew into a multibillion-dollar industry, overwhelming the systems developed to protect human research subjects.

The ethical model for those systems was born in 1947 after German physicians were convicted for performing crippling and deadly medical experiments on concentration camp prisoners. But the Nuremberg Code did not stop unethical research.

Well into the 1970's, the federal government sponsored human radiation experiments and the Tuskegee experiments, in which black men with syphilis were studied but not treated or told they had the disease.

Outrage over the Tuskegee experiments led to the gradual development of federal regulations governing clinical research. These regulations established the cornerstone protections for human subjects: a voluntary, informed consent process and oversight by an institutional review board, which would evaluate and monitor the scientific validity and ethical standards of studies.

In the 1990's, however, the surge in drug research strained the institutional review boards and raised new questions about conflicts of interest and government oversight.

Veterans Affairs doctors have done pioneering research on spinal cord injuries and schizophrenia and helped develop the cardiac pacemaker. But like universities and private research companies, the department has grappled with allegations of exploiting its human research subjects.

The veterans department's situation, though, was singular. Veterans, many unable to afford private health care, are a particularly captive and altruistic pool of subjects, "easy marks," said Alan Milstein, a lawyer for Mrs. Steubing.

And the department's huge, taxpayer-financed health care system, despite reports of significant improvements in quality of care, has struggled with issues of mismanagement. These problems include persistent complaints about abuse of power, cronyism and reprisals against whistle-blowers.

Speaking Up, to No Avail

Years before Mr. Kornak arrived at the Albany hospital in 1999, Mr. Fudin, a clinical pharmacist there, started expressing his concerns about the treatment of cancer patients.

Beginning in 1993, Mr. Fudin variously alleged that patients were placed in experimental studies without their consent, that patients who were ineligible for studies were nonetheless enrolled, and that patients were given "alternative therapies" that should have been classified as research. Veterans, he said, may have died as a result.

The former pharmacy manager, Anthony Mariano, shared his subordinate's concerns.

"Every violation, I hand-delivered packets of information to the chief of research, threw them down on his desk and demanded he do something to stop the research," Mr. Mariano said.

Instead, Mr. Fudin and Mr. Mariano found themselves under internal investigation. In 1996, Mr. Fudin was accused of patient abuse for refusing to dispense a certain cancer therapy. Mr. Fudin said he thought the therapy amounted to unsafe experimentation on patients. He was cleared of the charge, faced a second charge and again was cleared.

Claiming harassment and reprisal for whistle-blowing, Mr. Fudin filed a complaint with the Office of Special Counsel, a federal agency intended to protect federal employees. In late 1996, Veterans Affairs and Mr. Fudin reached a settlement. The department agreed to sponsor him for a doctorate in pharmacy by paying his tuition (\$21,986) and giving him a flexible work schedule.

"It is regretful that these investigations of your clinical practices took place," a senior Veterans Affairs official wrote to Mr. Fudin.

Still, Mr. Fudin said he was frustrated that his concerns about the cancer research program had not been addressed. His allegations were investigated in the mid-1990's, but the doctor who conducted the inquiry, Thomas Ferro, said it was cursory and, ultimately, thwarted.

"There is always a hidden agenda either to exonerate or convict in these internal investigations," said Dr. Ferro, who is now at the Veterans Affairs hospital in Richmond. "In this case it was to exonerate. I was buddies with the doctor I was deputized to investigate."

Dr. Ferro said he did "a fairly superficial investigation only oriented toward uncovering egregious errors, of which none were found." He reviewed about 10 patient charts, he said. He found a consent form missing in one and "consent form discrepancies" in others

Dr. Ferro said he also found "creative science" in the use of "alternative chemotherapeutic regimens." He said he was convinced that the oncologist was genuinely trying to help patients survive longer. "But," Dr. Ferro said, "it didn't strike me as prudent to be using alternative regimens when there was no clear-cut evidence they were helpful and the possibility that they might be harmful."

Dr. Ferro said he "watered down" his findings in his final report, stating that no major violations were found, but that "minor discrepancies" were. His superiors, however, did not like any mention of problems, and they whited out "minor discrepancies" and other negative phrases, Dr. Ferro said.

They asked Dr. Ferro to initial the deletions, and he protested, but eventually did so, he said, "so as not to be a troublemaker."

Dr. Ferro said he also recommended strict monitoring of cancer drug studies, and his ideas included having a chemotherapy expert "review the consent forms and review the documentation to make sure the patients were eligible for the studies."

But the recommendations were shelved, he said. "The solution to the Kornak problem yet to come was in that document," he said.

Both Mr. Fudin and Mr. Mariano faced additional internal investigations. Mr. Fudin was dismissed in 2001, and an administrative law judge ordered him reinstated in 2002.

Mr. Mariano, meanwhile, was criticizing a cost-saving drug substitution policy involving hypertension medication that he contended was harming patients who suffered from congestive heart failure. In 1999, after he published an article in a federal medical journal questioning the department's drug policies, he was, at one point, reassigned from the pharmacy to a locked psychiatric ward and given no duties.

Eventually, after a complicated legal process, Mr. Mariano said, he resigned under pressure in 2001, and he now works as a pharmacist for Wal-Mart.

Mr. Fudin and Mr. Mariano served as grand marshals for Albany's Memorial Day Parade in 2003, selected by local veterans honoring what they described as the men's courage in blowing the whistle. Some veterans wore T-shirts emblazoned with whistles and, on a rainy May day, blew whistles as they marched.

Convicted, Then Hired

In 1993 in Harrisburg, Pa., Judge William W. Caldwell of United States District Court sentenced Mr. Kornak to a \$2,500 fine and three years of probation for forging his credentials to obtain a medical license. Apparently, Mr. Kornak's history of fraud began with the falsification of a college transcript, and lie followed lie until he lost a medical license in Iowa, was denied one in New Jersey and was arrested in Pennsylvania.

"As we all know, a house built on sand will eventually fall, and a career whose foundation is built on deception likewise has fallen," Judge Caldwell said. "I think the conviction for this offense is going to make it extremely difficult, if not impossible, for Mr. Kornak to pursue a medical career."

Six years after Judge Caldwell's pronouncement, Mr. Kornak answered an advertisement for a research assistant position at the Albany veterans hospital's research institute.

It was 1999. Dr. William Hrushesky, then the chief oncologist, interviewed Mr. Kornak, according to *The Medical Research Law and Policy Report*, a trade publication. (Dr. Hrushesky did not respond to inquiries from *The New York Times*.)

Mr. Kornak told Dr. Hrushesky that he had lost his medical license because he could not document a year of medical school in Poland, according to the journal. Mr. Kornak "gave us a résumé with an M.D. on it and a lot of gaps," Dr. Hrushesky told the journal. "We decided to give him a chance."

Dr. Hrushesky also said he assumed that the research institute, a foundation that oversees industry grants for research, checked Mr. Kornak's credentials before hiring him. (Eventually, Mr. Kornak was hired away from the foundation by the veterans department itself.)

But at that point, the Veterans Affairs system did not require much background or credential checking for health professionals other than for physicians and dentists, and the system did not double-check to make sure that its hospitals actually did the required screening of doctors, according to a General Accounting Office report issued last year.

At the Albany veterans hospital, Dr. Holland inherited Mr. Kornak as a research associate. Mr. Fudin, the pharmacist, and other employees said Dr. Holland was swamped by the cancer patient load. According to an F.D.A. letter to Dr. Holland, he delegated far too much responsibility to unqualified subordinates in numerous drug studies.

Mr. Steubing was not a regular patient of the Albany hospital and, because he had private insurance, he was not a typical Veterans Affairs patient. He sometimes went to the veterans' hospital in Castle Point, N.Y., for checkups, but he used private physicians for important health issues.

In early 2001, when Mr. Steubing's gastroesophageal cancer was diagnosed, doctors at the Memorial Sloan-Kettering Cancer Center in Manhattan recommended a widely used two-drug chemotherapy regimen, which was available at Castle Point, closer to their home in Hopewell Junction.

At Castle Point, an oncologist suggested that Mr. Steubing see if he qualified for an experimental drug program, which added a third drug, Taxotere, to the mix. The study, sponsored by the drug company Aventis, involved both Sloan-Kettering and Veterans

Affairs in Albany. Sloan-Kettering had a waiting period, Mrs. Steubing said she was told. Albany did not.

The Steubings met with Mr. Kornak.

"Kornak was your classic good-time Charlie," Mrs. Steubing said. "Carl thought he could pick out a phony a mile away, but he really loved this guy."

Mr. Kornak never gave them any indication that Mr. Steubing did not qualify for the study, Mrs. Steubing said. Instead, he encouraged Mr. Steubing to continue with the regimen even though it was devastating him.

"Kornak would say: 'You're going to beat this. The odds are in your favor,'" Mrs. Steubing said. "Little did we know that what they were doing to Carl was probably hastening his death rather than extending his life."

Routine Visit Leads to an Inquiry

In December 2001, a clinical research associate for Ilex Oncology made a routine visit to the Albany veterans' hospital, where Ilex was sponsoring a bladder cancer study.

Ilex, a cancer drug company, was offering the Albany research program \$2,500 for each study subject. Such payments are a standard practice, and many researchers say that they barely cover the cost of conducting the studies. Critics of drug-testing practices, however, consider the payments a threat to scientific integrity.

Ilex's research associate discovered some paperwork that raised suspicions, according to Caren Arnstein, a spokeswoman for the Genzyme Corporation, which bought Ilex at the end of last year.

"Things about the dates didn't look right," Ms. Arnstein said. "If the results of a pathology report for a biopsy are dated prior to the biopsy being taken - something seemed off."

The discrepancies led to an audit by Ilex. In the spring of 2002, the Albany hospital began an internal review of the cancer research program, eventually referring the matter to the inspector general, according to The Times Union.

Ilex shut down the Albany study and alerted the F.D.A. The agency had also received another complaint, an F.D.A. official said.

In November 2002, the F.D.A. sent an investigative team to Albany. On average, it takes about a week to investigate a complaint. That team spent more than 50 days at the hospital. It studied the files of more than 50 research subjects and found problems in almost every one, according to its investigation report.

In January 2003, Mr. Kornak and Dr. Holland were dismissed. Mrs. Steubing got an unnerving call from a hospital official, telling her that her husband's care might have been "compromised."

"I said, 'Well, Dr. Kornak and Dr. Holland were so wonderful to us,' " Mrs. Steubing said. "There was dead silence on the line and I thought, 'Oh, it's them.' "

Shaking Up the System, Twice

The year that the Albany veterans research program hired Mr. Kornak, 1999, was supposed to be a year of reckoning for the \$1.2 billion research program at Veterans Affairs.

Federal regulators shook the system by suspending all human research at the West Los Angeles Veteran Affairs Medical Center, saying that it had been lax for years in obtaining informed consent and overseeing research.

News media reports about abuses of human subjects in West Los Angeles unleashed the fury of Congressional watchdogs, who asked the General Accounting Office to assess the safeguards for veterans who serve as research subjects. The office examined eight Veterans Affairs medical centers and reported "a disturbing pattern of noncompliance with regulations for the protection of human subjects."

Dr. Stephan Fihn, the acting director of research and development for Veterans Affairs, said in an interview: "Historically, we relied on the integrity of investigators. In the vast majority of cases, that worked. We did discover, well, the tendency is to say, bad apples. There were some pretty egregious violations.

"What Congress basically said was that the V.A. has to take a very active role. What was lacking in human subjects protection was a strong oversight and enforcement effort."

But the department did not change overnight, as the General Accounting Office said in a follow-up report four years later. It apparently needed a second shock to its system, and that came in 2003 when the problems in Albany - and the accidental fatal overdosing of a Veterans Affairs research subject in Detroit - came to light.

A new director of research for the department, Dr. Nelda Wray, ordered a nationwide review of research at Veterans Affairs medical centers and halted clinical research in Fargo, N.D., because the institutional review board there had all but ceased to function. She also ordered credential checks on researchers and ethics training for them.

By early 2004, the department's inspector general had accused Dr. Wray herself of ethical problems and improprieties, including the mishandling of funds provided to Veterans Affairs by drug companies. Her lawyers called the investigation "an easy and convenient tool to stop sorely needed reforms." She eventually left the department.

But there does appear to have been a sea change in the department's approach toward protecting the subjects of human research. An external nonprofit agency, the National Committee for Quality Assurance, was hired in 2001 to accredit the agency's programs to protect human subjects. The accreditation process, which requires medical centers to open up their research programs to full scrutiny, is rigorous.

At first, the committee met hostility.

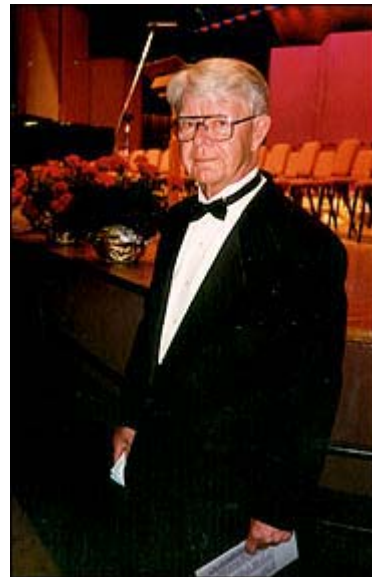
"We just showed up and started telling them what was wrong, and it was way too abrupt," said Brian Shilling, a spokesman for the committee. "But there's been a lot of education and culture change in the V.A. since then."

Just under a third of the veterans department's 118 research centers have been accredited so far. Some centers did not pass their initial reviews, and research was curtailed until they showed improvement. One medical center, in Northampton, Mass., failed to earn accreditation.

Albany has not yet applied.



Andrea Mohin/The New York Times
Jayne Steubing said her husband, Carl, was wrongly told he was healthy enough for an experimental cancer treatment.



Andrea Mohin/The New York Times
Mr. Steubing, a World War II veteran, became violently ill after treatments at the veterans hospital in Albany. He died in 2002.



Jeffrey Fudin, left, and Anthony Mariano, hospital pharmacists who spoke out.



Paul H. Kornak, who posed as a doctor for veterans, in 1999.