

Profits Before Patients

The doctors at Karin Smith's health maintenance organization kept telling her she was fine. She knew that wasn't true. She was sick and getting sicker. Frustrated and frightened, she went to an independent physician. The news couldn't have been worse. Ms. Smith had advanced cervical cancer. If she had been properly diagnosed when she first sought help, at age 22, her chances of survival would have been 95 percent or better. Now she is 28 and doctors say it is unlikely she will see 30.

Ms. Smith (her real name) is a certified public accountant who lives with her husband, Pete, in Nashotah, Wis. Her H.M.O. is the Family Health Plan Cooperative of Milwaukee. Testifying in July before a Congressional committee investigating health care fraud, Ms. Smith said:

"Even though my medical records were fully documented with the classic physical characteristics and symptoms of cervical cancer, no doctor or medical practitioner associat-

gain, often at the expense of patients and over the concerns of caregivers.

Ms. Smith's H.M.O. is a nonprofit consumer cooperative. But it is inextricably entwined with the corporate culture that dominates American health care. Managed care is, in essence, corporate care. Decisions that once were made by doctors are being taken over by executives obsessed with the bottom line. In that environment patients can be processed as impersonally as any other commodity.

Ms. Smith testified that the owner of the laboratory that handled her tests, CBC Clinilab, had been on her H.M.O.'s board of directors, "and in order to receive the H.M.O.'s business he was provided with the competitors' bids in advance." That, she pointed out, is a form of "managed competition" that encourages contractors to offer services at "artificially low prices, which can only lead to a severe lack of quality control and excessive workloads."

Indeed, it turned out that the laboratory technician who misread Ms. Smith's Pap smears had been reading five times the federally recommended number of slides, and was working for four other labs simultaneously.

Efficiency and productivity are the twin shrines at which corporate executives worship. They are the stuff that bonuses are made of. But the effect of such devotion on patients like Ms. Smith can be catastrophic.

She said: "My cancer has spread throughout my lymphatic system, from my pelvis to my abdomen and, as of six months ago, to my neck. The fifth vertebrae of my upper spine is so completely infiltrated with the cancer that at any moment I could become paralyzed."

Ms. Smith sued and a settlement of \$6.3 million was reached with a dozen defendants, including the laboratory and the H.M.O. A spokesman for the H.M.O. said it ended its contract with CBC Clinilab in 1991. He said it was only later that H.M.O. officials learned that there were "very few" standards for screening Pap smears at the laboratory.

Ms. Smith and her husband had planned to take a vacation trip to Alaska last week. Haunted by uncertainty, they are trying to cram in as many experiences together as possible. But the spread of the cancer has been relentless and the trip had to be postponed. Ms. Smith was hospitalized unexpectedly, and on Friday she underwent surgery for the ninth time. □

The New York Times

SUNDAY, SEPTEMBER 11, 1994

Karin Smith could have been saved.

ed with my H.M.O. or its lab ever made the correct diagnosis."

Three Pap smears and three biopsies were performed. "All but the fifth test were misread by the lab my H.M.O. contracted with," Ms. Smith said. "Unfortunately, the one Pap smear they did read correctly was dismissed when they misread the biopsy they performed to confirm it. All six tests clearly indicated that I did, in fact, have cervical cancer."

Ms. Smith tried for three years to convince her H.M.O. doctors that she was ill. Her pleas for help went unheard because there is a new world of medicine in the United States, a world that pulsates to the impersonal and incessantly driving rhythms of corporate greed. Patients are not important in this world. They are little more than data entries in elaborate schemes to cut costs and bolster profits as radically as possible.

The smart set calls it managed care. The corporate types love it. They have plunged into all phases of the health care system with their single-minded pursuit of financial

National Report

The New York Times

THURSDAY, APRIL 13, 1995

Medical Laboratory Faces Charges in Cancer Deaths

By GINA KOLATA

The Milwaukee District Attorney brought charges of reckless homicide yesterday against a medical laboratory that has been accused of misreading Pap smears of two women who later died of cervical cancer.

Although charges of criminal misconduct are rare in cases of medical errors, a six-member inquest jury, similar to a grand jury, had recommended criminal charges against the physician in charge of the lab and a lab technician as well as the lab itself. The District Attorney, E. Michael McCann, struck a deal so that the doctor and the technician could avoid charges if they agreed to certain conditions on their work.

The charges arose after Karin Smith, a 29-year-old accountant from Nashotah, Wis., and Delores Geary, a 40-year-old mother of three from Oak Creek, Wis., died of cervical cancer. Medical experts testified at an inquest that their illnesses would have been treatable had their Pap smears, which contained cancerous cells, been properly read. Mrs. Smith, who died on March 8, had appealed to Mr. McCann to pursue criminal charges. Mrs. Geary died in 1993.

The American Medical Association said this was believed to be the first case in which a medical lab had been charged with a crime because of an error.

In testimony last year before a House subcommittee, Mrs. Smith said she had complained of gynecological problems in 15 office visits to her health maintenance organization, Family Health Plan, over three years.

"Even though my medical records were fully documented with the classical physical characteristics and symptoms of cervical cancer," she said, "no doctor or medical practitioner associated with my H.M.O. or lab ever made the correct diagnosis."

The H.M.O. performed three biopsies and three Pap smears, but the lab misread all but one of them, she testified. Had her cervical cancer been properly diagnosed in 1988, when the first Pap smear was misread, she testified, she would have had a 95 percent chance of survival. Her cancer was not diagnosed until she saw a doctor outside the H.M.O. in 1991.

Attempts to reach the H.M.O. by telephone last night were unsuccessful.

Mr. McCann said grave errors had been made because the laboratory's director, Dr. Robert Lipo, had paid its technician, June Fricano, on a piecework basis for reading Pap smears. As a consequence, Ms. Fricano read 31,000 slides for the lab, the Chem-Bio Corporation, in 1989 and 16,000 slides for another laboratory. In contrast, Mr. McCann said,

read no more than 12,000 slides a year.

In addition, Mr. McCann said, the lab's quality control program of randomly selecting slides to be re-screened "had broken down." "The issue here is not negligence," Mr. McCann said. "We are talking about something extremely serious that involves human life."

Mr. McCann said the penalty if the lab was convicted is a \$20,000 fine.

Martin Kohler, a lawyer for the laboratory, said he would file a motion saying, among other things, that a company could not be charged with homicide.

The women's families sued the Family Health Plan, where both were members; two doctors who had treated the women; the lab; the lab's director, and two pathologists, charging malpractice. Mrs. Smith and her husband, Peter, settled their lawsuit for \$6.3 million, and the Geary family settled for \$3.5 million.

Mr. McCann said he was not prosecuting Dr. Lipo or Ms. Fricano because "I felt it was in the best interests of the community to do it in this way," explaining that by not prosecuting he would be facilitating other lawsuits against them, if any, by other patients.

In return for not being prosecuted, Dr. Lipo agreed not to serve as a laboratory director again, not to supervise any cytotechnologists, and not to do any work in which he is responsible for quality control. Ms. Fricano agreed not to work on a piecework basis reading Pap smears, not to work more than 42 hours a week, and to obey all Federal and state regulations that govern the number of Pap smear slides that a technician can read in a day.

Patrick Dunphy, a lawyer for Mrs. Smith's family, said that although "Mike McCann made his decision for reasons I can understand," he wished that the District Attorney had abided by the jury's recommendations.

"I've done malpractice work for almost 20 years, and I've seen a lot of mistakes made by doctors and health care providers," Mr. Dunphy said. Those mistakes, he added, "are usually handled as negligence, as they should be." But these errors, he said, "went beyond bad mistakes — cost became more important than quality."

Some legal and medical experts said that although the prosecution was unusual, it was to be applauded.

George Annas, a health law professor at Boston University, said, "If the allegations are true in this case," then a homicide charge is a good idea. "When a healthy bottom line becomes more important than the health of patients, that's when criminal

An article on Thursday about charges of reckless homicide filed against a medical laboratory, the Chem-Bio Corporation of Oak Creek, Wis., misstated the surname of a Wisconsin lawyer involved in the case. He is Patrick Dunphy, not

Dunsee.

Karin Smith and Dolores Geary are dead, victims of the carelessness and human error of the healthcare providers they trusted. Their tragic stories will be the focus of what could be a landmark criminal case.

death

sentence

ILLUSTRATION BY GREG SPALENKA

by Erik Gunn

Erik Gunn is a Kenosha freelance journalist.

It had been weeks since they last made love.

Physical intimacy had become a source of terrible anxiety for Karin and Peter Smith. A minor annoyance at first, the bleeding that would occur afterward had grown steadily worse over the years. Eventually it was almost

nonstop, whether they made love or not.

And when they would feel brave enough to occasionally try, it wasn't an exciting fusion of romance and desire, a way for the young married couple to express their joy and mutual love. "It was more of a medical experiment," says Peter.

Now there was hope that would end.

Three times, Karin Smith's gynecologist froze her cervical tissue to cauterize what he thought was simply a troublesome but benign lesion on her cervix — perhaps a blood vessel too close to the surface. To make sure the condition fully healed, Karin and Peter had abstained.

At last they tried again. And once more Karin bled. Peter still vividly remembers the night: "She cried forever," he says.

Eventually they would learn the truth. Karin Smith suffered not from a minor quirk of anatomy but from cervical cancer that had gone undetected through a nearly a half-dozen tests. Tests that should have uncovered the disease and enabled an early cure were repeatedly misinterpreted, leading medical professionals up blind alleys.

When her illness was at last discovered, she was beyond hope of survival. And this past March, Karin Smith's death at age 29 set in motion what could become a landmark criminal case in Milwaukee County (see "A Criminal Offense?" page 54).

In April, an inquest jury ruled that Karin Smith and Dolores Geary, 40, who died in 1993 of a cervical cancer that also eluded early diagnosis, were not merely victims of unfortunate human error or the limits of science. They were, the jury concluded and District Attorney E. Michael McCann charged shortly afterward, victims of homicide at the hands of Chem-Bio Corp., an Oak Creek medical laboratory where their lives could have been saved by the proper interpretation of a diagnostic test: the Pap smear. That is the supreme irony in both women's deaths. Pap smears, in which a trained lab technician uses a microscope to examine cells scraped from the cervix, have been credited for increasing the cure rate for cervical cancer as much as 95 percent of all cases if detected early enough.

The test isn't foolproof; conscientious laboratory technicians can miss a cancer in as many as four out of 10 readings. Some in the health field even worry privately that the criminal charges are out of proportion to what might be an honest error.

But interviews and court records suggest that what happened to Dolores Geary and Karin Smith wasn't the result of simple mistakes. Instead, say their lawyers and survivors, both women died as a result of repeated and flagrant missteps by the laboratory and the doctors to whom they had entrusted their health and lives.

"A mistake means they're trying to do their job," says Keith Geary, the 43-year-old widower of Dolores Geary. "These people weren't even trying to do their jobs at all."

Peter Smith met Karin Knudsen when the two were students at the University of Wisconsin-Milwaukee and both took part in a business internship program. It wasn't love at first sight. "She thought I didn't take life too seriously, that I was too outgoing," Peter recalls. "She was very determined and reserved," studying 60 hours a week, by his estimate. "She was a real driver."

She ran up to 10 miles a day and ate steamed vegetables while he dined at Burger King. She played volleyball on an athletic scholarship while he hung out at bars, working as a campus representative for Anheuser-Busch Inc.

But for all of their differences, "we had a lot in common in our values," says Peter. By the time Peter graduated in May 1987 and launched a career selling insurance, they were dating steadily.

In December 1987, Karin graduated

second in her accounting class and accepted an offer from Arthur Andersen & Co. As an Andersen auditor, Karin was out of town half the time; meanwhile, Peter's sales territory for Liberty Mutual Insurance covered the western part of Wisconsin.

At their jobs, each chose health insurance plans. At Andersen, Smith says, Family Health Plan was about \$1,000 a year cheaper than other health insurance; his own employer offered Family Health at about \$800 a year less - and with no deductibles.

The HMO directly employs its primary-care doctors, most of them family physicians who work at seven clinics around the Milwaukee area. Historically, most of the specialists to which Family Health patients were referred were outside doctors - essentially subcontractors. In recent years, however, an eighth clinic, specializing in obstetrics and gynecology and staffed by directly employed doctors, has opened in West Allis.

For both Peter and Karin, the choice was easy. "We figured, 'We're both young, we're not going to use it anyway,'" Peter says on an overcast morning, sitting in his Nashotah home. "It was one of the worst decisions we ever made."

In September 1987, a few months before she graduated, Karin had complained during a routine medical exam at the UWM health center of bleeding after sexual intercourse. She switched from birth control pills to a diaphragm. A Pap smear was found to be normal.

Eight months later, in June 1988, Karin, now a member of Family Health Plan, visited the HMO's Airport Health Center (180 W. Grange Ave.). Again she reported occasional bleeding after intercourse. A physician's assistant put her back on birth control pills at her request and took a Pap smear sample.

As with all of Family Health Plan's Pap smear tests, Karin's was sent to Chem-Bio Corp. in Oak Creek. The laboratory had an exclusive contract with the HMO to analyze virtually all tests; under terms of the agreement, the lab was paid a flat fee every month for every patient enrolled in the plan, instead of for every test it actually analyzed.

Four days after Karin's exam, on June 27, Chem-Bio Corp.'s only full-time cytotechnologist, June Fricano, reported the Pap smear as negative.

At the time, Peter Smith didn't know much about the problem. The bleeding had

a criminal offense?



When the case against Chem-Bio Corp. is heard by Circuit Court Judge David Harshner beginning on December 4, jurors will have to decide whether a company can be held criminally responsible for the deaths of Karin Smith and Dolores Geary. It's an unprecedented case in Milwaukee County.

An attorney for Chem-Bio Corp.'s former owner, Dr. Robert Lipo, calls District Attorney E. Michael McCann's prosecution of the company "inappropriate" and "driven by the emotionalism of the victim." Executives at Family Health Plan, which is not charged in the criminal case but settled malpractice suits brought by both the Geary and Smith families, also takes exception to assertions of carelessness on the part of the

health maintenance organization.

Lipo also is not charged criminally, although he also was a party to the malpractice settlements with both families. He and lab technician June Fricano, also not charged, signed deferred prosecution agreements. Lipo is not allowed to work as a medical director supervising cytotechnologists and is prevented from overseeing quality control programs. Fricano may not work on a piece-rate basis or work more than 42 hours a week and must receive 18 hours of continuing education a year.

Lipo's lawyer, Frank Gimbel, says the civil case was recompense enough for the two women and their survivors. "Dr. Lipo had no intent to hurt these ladies," Gimbel says.

"He's a very dedicated medical professional and is very upset that their cancers were not detected either by the laboratory or by other medical professionals. When you go to criminal court and seek accountability from people, you

should be seeking accountability from someone who has a criminal mind.

Martin Kohler, who represents Chem-Bio Corp. itself, echoes Gimbel's view. "Our defense is that nobody should be sitting in criminal court. This was a tragic case. This is a case of malpractice and that's where it should have stayed. What you had were concerned, hardworking people, doing their best, and they made a mistake and two people died - vs. thousands of patients who didn't die. In my heart of hearts, I believe that this is not a crime."

But McCann draws the distinction by comparing two hypothetical drivers. Each drives through a school zone above the posted 15 mph limit. Each kills a child, although neither intends to do so. But one is traveling at 25 mph, the other at 50 mph.

"That sign says 15 precisely to preserve life and limb," says McCann. "There's no law that says at 35 it changes from negligence to criminal. That's something that

started out as little more than spotting. "She never really talked about it to me," he says. "Besides, I was 23 years old. What was I going to do?"

That September, they became engaged. Karin's medical difficulties became apparent to Peter, but neither worried unduly. With their busy schedules and separate lives, they didn't often sleep together; even when the bleeding did occur, it wasn't every time they had intercourse. Peter's attitude was practical: "Let's get this fixed."

In April 1989, Karin returned to the Airport Health Center and renewed her complaints of bleeding. The physician's assistant who examined her took another Pap smear and referred her to an obstetrician-gynecologist under contract with the clinic. Chem-Bio again reported the Pap smear as negative.

The gynecologist, Dr. Julie O'Reilly, wasn't satisfied and ordered a biopsy — a more serious test involving surgery to remove tissue. The biopsy samples also went to Chem-Bio, where pathologist Dr. Mark Molot studied them and diagnosed an unusual but benign proliferation of normal cells. Relying on his conclusions, O'Reilly

cauterized the tissue by freezing it.

Peter and Karin were married in September of that year. It was a big affair, with 275 guests. Karin planned most of the details; Peter got the beer. He jokes that she made her first bad decision as Mrs. Smith that night, telling the caterers to keep the champagne flowing. They went through 35 cases. Joy was in the air. "We'd been going out almost six years," Peter says, adding with a chuckle: "It was a long-awaited event."

Two months later, however, Karin Smith returned to O'Reilly with more bleeding. Reading a second biopsy, Chem-Bio pathologist Dr. Harold Biller also concluded that her condition was benign.

With the new year, Karin switched from health coverage at Andersen to Peter's coverage through Liberty Mutual. Although she was still with Family Health Plan, she now was assigned to the HMO's Bluemound Health Center (12500 W. Blue Mound Rd., Elm Grove) because Peter also went there for routine care. Karin's previous physician had taken her off of birth control pills again because of bleeding, but in May 1990, she asked the pharmacy at the new clinic for a renewal of her prescription — largely, Peter says, to regulate her menstrual periods, which had become profuse and irregular.

A month later, in early June, she called the doctor to report continued bleeding. He told her to stop taking birth control pills for six months. Two days later, she called again to report passing a blood clot. At the clinic the next day, her physician, Dr. David Olson, gave her a pregnancy test (it was negative) and reaffirmed his order to stop the pill. He didn't examine her further, however. And he didn't review her chart to see her history of bleeding — a step that might have rung alarm bells.

There's at least one reason for that: Karin's

old charts from the Airport Health Center were never transferred to Bluemound Health Center.

The bleeding continued. On June 17, Karin passed out. When she called the Family Health clinic the next day, a nurse told her to drink juice with sugar and then eat a high-protein food. On June 21, Karin called back and reported that she had now been bleeding almost continuously for 24 days. The next day, she returned to the clinic and underwent another Pap smear. For the first time, June Fricano, the Chem-Bio cytotechnologist, found the results to be abnormal. Pathologist Harold Biller recommended a biopsy to rule out cancer. But neither looked at the two earlier Pap smears or the biopsy that had been ruled negative.

By now, Smith had already been referred once again to a gynecologist. She wanted to go back to O'Reilly, but Family Health refused because O'Reilly was under contract only at the Airport clinic. Instead Smith had to see Dr. LaRoyce Chambers, the contracted gynecologist for the Bluemound clinic.

Chambers, apparently relying on the earlier biopsy interpretations of Chem-Bio pathologists Molot and Biller, sent a third biopsy to Chem-Bio, where Biller again found only a benign condition. In October, Karin Smith returned to Chambers. The bleeding had continued practically unabated — so much so that she and Peter had virtually given up sex.

Three times, Chambers cauterized her cervix, twice in December 1990 and again in early January 1991. After delays to make sure she had healed, the couple made love once again.

The bleeding returned.

Three and a half years after Karen Smith first reported problems of bleeding, the couple had no inkling of what they were facing, says Peter Smith. The doctors' various explanations "seemed to make sense," he says.

When she reported the renewed bleeding, Chambers told her she should come back another four or five times, Peter recalls. Because he was a specialist, Family Health Plan had to authorize the additional visits; it approved three. Karin felt frustrated but powerless. "She was always battling with them over the phone," Peter says. It was the first quarter of 1991; the Smiths were just finishing building their first home, in Sussex, and Karin was often out of town on auditing assignments. The struggle and the illness were wearing her down. "She was tired of having to fight just to get referrals," says Peter.

But when Chambers referred her to his partner, Dr. Neville Sender, for laser treat-



Karin Smith saw purpose in her death.

a jury decides. At some point, 12 people would agree that it's gone beyond negligence. I know by 50 (mph), 12 people are going to say that that's criminal."

Even if the prosecution succeeds, however, the victory may be more symbolic than tangible. None of the individual people involved faces criminal charges. The inquest jury had recommended charging Lipko and the lab technician, who erred in her reports on no fewer than four Pap smears taken from the two women. But McCann opted not to say it might impede future civil suits on behalf of other unnamed victims. No one will go to jail if McCann wins a conviction, and the company that would pay the \$20,000 maximum fine has already left the medical testing business.

Still, says Peter Smith, the criminal case has already begun to accomplish a goal that Karin Smith had carried for the rest of her life: to bring out into public view the errors that she blamed for her death.

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ment, Karin drew the line. "She was fed up," says Peter. At long last, they decided to seek another doctor's opinion. On May 15, 1991, Karin and Peter Smith went to the office of a gynecologist in private practice, Dr. William Stewart, who was recommended by a friend. His notes conveyed his alarm: "It bleeds like crazy," he wrote. "Needs gyn oncologist"—a specialist who treats gynecological cancers.

That night, Stewart called Dr. David Hoogerland at home. When Karin Smith asked Family Health Plan the next day to refer her to Hoogerland, the HMO at first refused: Contrary to the health plan's rules, officials said, the initial referral had come from Stewart, a non-Family Health Plan doctor. Pressed by Smith's own Family Health Plan doctors, however, the HMO's administrators reversed themselves the next day.

"At that point, we didn't care," Peter says; the couple was quite willing to spend the \$100 or so out of pocket the visit might have cost them. "The look in Dr. Stewart's eyes said we should get in."

Two days after seeing Stewart, Smith was in Hoogerland's office. He recommended a more aggressive form of biopsy, excising a cone-shaped piece of cervical

tissue. After another battle that lasted nearly two weeks, Family Health Plan reluctantly agreed to let her have the surgery at St. Mary's Hospital, where Hoogerland had operating privileges, instead of a hospital affiliated with the HMO.

Hoogerland's surgery on May 29 confirmed cervical cancer. "I thought she'd be devastated," says Peter. "She was just the opposite. She looked at Dr. Hoogerland and said, 'Well, at least we know what it is now.' She didn't cry at all—she said, 'We'll get through this.'"

"Of course," says Peter, "at that point, we didn't know how far it was."

Only later did it become clear how many mistakes had overlapped in Karin Smith's medical care.

Peter Smith believes that O'Reilly was on the right track in her handling of Karin. Had she gone back to O'Reilly, he believes, or had Karin's records from the Airport Health Center or from O'Reilly been transferred to her new doctors at Bluemound Health Center, the gravity of her condition might have become clearer sooner. But records were the least of her problem.

Karin's Pap test that was sent to Chem-Bio

an HMO argues its case



Family Health Plan, Chief Operating Officer David Bradford defends the HMO's overall record. In July, Family Health won provisional accreditation from the National Committee for Quality Assurance, an HMO industry accrediting group. And the insurer has scored at or above national averages on the Health Plan

Employer Data Information Set—a sort of national report card of insurance plans, says Phillip J. Dougherty Jr., manager of public affairs at Family Health.

Bradford and Family Health Medical Director Dr. James Chaillet say that the HMO has improved many of its procedures in the years since Karin Smith and Dolores Geary first underwent their erroneous Pap smears.

Family Health Plan's doctors, employees and board members are all enrolled under its policy, Bradford likes to point out. "When we're making decisions about care, we're not making them about faceless individuals." And as if to seek further endorsement, he notes that even with the lawsuits, both the Geary family and the Smiths remained in Family Health Plan.

Indeed, Family Health Plan did cover Karin Smith's care through her illness and death. But "after we filed suit, we didn't really utilize any of their doctors," Peter Smith says. "We were able to go anywhere we wanted to go." And after Karin's death, he took a leave from his job and promptly switched to a traditional insurance plan. As for the Geary family, Keith Geary says he would like to switch but can't because his own medical problems would make it hard for him to be accepted by another insurer.

in June 1988 and reported as negative in fact showed signs of cancer. The lab technician who had made that report, June Fricano, acknowledged as much in a 1992 deposition, after she reviewed the slide a second time during preparations for the civil suit that the Smiths filed against Family Health Plan, Chem-Bio, Fricano and others.

The April 1989 Pap smear—which Fricano had also labeled negative the first time she saw it—showed signs of cancer, too. In depositions, Fricano offered no explanation for why she didn't catch the cancer when the tests were first sent to her for screening.

A pathologist hired by the Smiths' lawyer, Patrick Dunphy, reviewed the December 1989 biopsy and found clear evidence of cancer, despite Chem-Bio pathologist Harold Biller's conclusion that it was benign. Indeed, Hoogerland has testified that the specific, seemingly innocuous, label that doctors had repeatedly placed on Karin's condition—"microglandular hyperplasia"—could not explain the bleeding that was her primary symptom.

When at last Karin's Pap smear did come back from Chem-Bio with the finding that it was abnormal, the lab never checked her earlier Pap smears; indeed, according to Dunphy and to former employees who testified in lawsuits by the Smith and Geary families against the lab and Family Health Plan, Chem-Bio lacked any kind of system for easily flagging and retrieving previous test slides of patients with abnormal results.

more than a year before Karin Knudsen's first misread Pap smear, Dolores Geary went to her Family Health Plan physician complaining of a bad period accompanied by pains that reminded her of labor. The February 1987 exam was supposed to have been for a complete physical, but that was scrapped because only 15 minutes had been set aside.

Geary's osteopath, Dr. Patrick McGrath, did a pelvic exam and took a Pap smear, which was sent to Chem-Bio. Although McGrath noted in his records that there appeared to be a white membrane on the cervix and that the cervix bled easily, he didn't mention either condition on the form that accompanied the Pap smear sample despite the fact that the form had a section to report "abnormal pelvic findings." (In a deposition last year, McGrath said he couldn't independently recall what he saw. But he insisted that he must have simply overstated the findings in his records since he didn't refer Geary to a specialist at the time.) The Pap smear was reported as normal.

In contrast to Karin Smith, whose problems seemed to grow steadily worse from her first report of bleeding, Dolores Geary didn't

report any significant gynecological symptoms for another two and a half years. Then, in October 1990, she complained of increasing tenderness in her breast and a pain in her pelvis. At the Family Health Plan Edgerton Health Center (6901 W. Edgerton Ave.), she was examined not by McGrath but by a physician's assistant, James Rayford. In her chart, Rayford reported an "angry-appearing cervix" that "bleeds easily with the insertion of a speculum tip." Rayford urged Geary to avoid heavy lifting. He took a Pap smear sample, which went to Chem-Bio. Like McGrath, his supervisor, Rayford made no mention of the unusual appearance of the



Dolores Geary:
Her tests explicitly
suggested cancer.

cervix when he filled out the request form for the test to be analyzed. The sample, said Chem-Bio's report, was "within normal limits."

Now matters got worse for Geary. Back in McGrath's office a month after her exam by Rayford, she reported pressure in her lower abdomen. McGrath rejected a

gynecological explanation and suggested that muscle strain was to blame.

Over the next three months, Geary went back to Family Health Plan five times, undergoing exams by Rayford, McGrath and consulting gynecologist Dr. Neville Sender. When Geary telephoned her clinic to report bleeding and a foul-smelling discharge in December, a Family Health Plan nurse told her to go home and raise her legs.

"The pain was getting so bad that she was doubled up on the couch," says Geary's husband, Keith. "It seemed like we were being a nuisance. She was calling every other, every third day. At a certain point, I had to calm my wife down before we went in there."

"I wish I hadn't."

In January 1991, Sender recommended a hysterectomy. As the pain got worse, the HMO advanced the surgery from April to mid-February. Geary's cancer was discovered in the operating room.

McGrath later said he believed the cancer had simply eluded medical technology. But court records show that both the 1987 and the 1990 tests explicitly suggested cancer. The cytotechnologist who read both tests was June Fricano. "If they would have caught that one back in '87," fumes Keith, "my wife probably would be alive today."

Indeed, while Dolores Geary's doctors relied on the lab to warn them of cancer from the Pap smear readings, the lab relied, in part, on doctors to determine how many sets of eyes would see the Pap smear slide. In her deposition in the Geary family lawsuit, June

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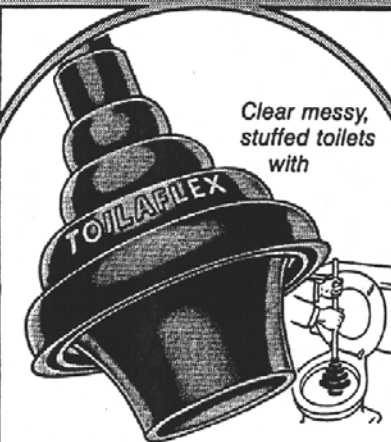
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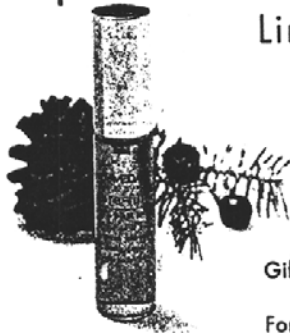
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Fricano observed that none of the requests for Dolores Geary's Pap tests noted any abnormal conditions in her pelvic exams — even though Rayford and McGrath noted problems in their own records. Had they put those findings in the order asking the lab to study the Pap smears, Fricano testified, the slides would have been flagged for re-reading by a pathologist.

Instead, she reported the Pap smears as negative and no one double-checked. Family Health Plan medical personnel relied on the negative reports and so didn't pursue the fatal implications of what they had seen in their own examinations.

And Karin Smith and Dolores Geary edged closer to death.

In 1979, Family Health Plan began operation as the first health maintenance organization in the Milwaukee area that directly employed its own staff of doctors. Doctors were paid on salary rather than for every office visit, hospitalization or procedure — a system aimed at holding down medical costs by removing the financial incentives for doctors to needlessly hospitalize patients or order surgery.

Family Health Plan was structured as a nonprofit consumer cooperative owned by subscribers. In 1987, the HMO spun off its administration into a for-profit company, Family Health Systems. Under the arrangement, the for-profit collects a management fee — nearly \$18 million last year, according to records from the state insurance commissioner — amounting to 9 percent of the nonprofit's gross revenues. (The arrangement, which Family Health executives say was aimed at allowing the insurer to more easily make acquisitions and engage in other business ventures through the for-profit entity, also has the effect of insulating the top executives from public scrutiny. While most insurers must publicly disclose the salaries of their officers in filings with the insurance commissioner, Family Health Systems isn't itself an insurer. Thus its executives, although they work for Family Health Plan, aren't, strictly speaking, on its payroll and aren't subject to the disclosure rule.)

Pathologist Robert Lipo had already incorporated Chem-Bio Corp. in 1974, with four shareholders: himself, pathologists Harold Biller and Mark Molot and a non-physician partner. When Family Health Plan was founded, Lipo joined its board of directors. When the for-profit was spun off, Lipo moved over to the Family Health Systems board. In 1994, he sold his interest in Family Health Systems for more than \$1.1 million.

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During his membership on the boards of first Family Health Plan and later Family Health Systems, Lipo's laboratory also held an exclusive contract to handle laboratory work for the HMO.

David Bradford, Family Health chief operating officer, steadfastly maintains the arrangement was kept above board. Lipo was always excluded from directors' discussions of the lab contract, says Bradford, and his dual role disclosed. And the contract was bid every two years to ensure it was at the best possible price.

In 1987, the HMO got a lower bid for lab services from West Allis Memorial Hospital. Instead of simply transferring the contract to West Allis, however, Bradford told Lipo what West Allis had bid. Chem-Bio matched the bid and kept the contract.

"The objective of the bidding... was to continue with a favorable vendor, someone who is providing what we believe to be good quality and service, but to make sure that the price that [Family Health Plan] paid for those services was in keeping with a fair market assessment of the value of those services," Bradford testified during the inquest last April. "We relied on the integrity of the team that worked in the laboratory to surrender the contract if it wasn't feasible for them to deliver."

In other words, Bradford said, he would have expected the lab to withdraw its bid as a matter of conscience if it couldn't effectively operate at the price Family Health Plan sought.

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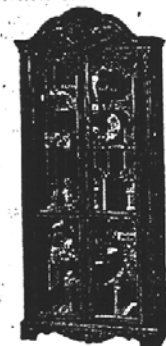
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In the fall of 1987, just a few months after Dolores Geary's first misread Pap smear and more than six months before Karin Smith's, *The Wall Street Journal* published a lengthy front-page story detailing the disturbing frequency with which clinical laboratory workers were barreling through their readings of Pap smears, missing cancer diagnoses in the process. In reaction, new federal laws and regulations limited cytotechnologists to reading no more than 100 Pap smear slides a day, echoing standards promoted by the American Society for Cytotechnology, a professional group.

The reason for those limits is that reading slides through a microscope is taxing work, requiring careful judgment. The 100-slide-per-day limit that government regulators ultimately imposed allowed almost five minutes per slide, a pace recommended by the College of American Pathologists.

During the late '80s at Chem-Bio, however, June Fricano was reading twice that in a day, according to depositions taken for the Smith and Geary lawsuits. In an October 1992 deposition, Lipo said he was aware of times when Fricano screened 160 or even 200 slides.

Moreover, the limits were to be applied to a cytotechnologist's total workload in a 24-

hour period. But Fricano wasn't just working at Chem-Bio Corp.; during the 1970s and '80s, she had at various times worked part time at any of seven other labs in the greater Milwaukee area. When Dunphy, the Smiths' lawyer, obtained invoices produced by Chem-Bio and three other labs where Fricano worked in 1988 and '89, he calculated she had read more than 43,000 Pap smear cases a year. If each of those cases involved two slides, Dunphy pointed out in a settlement letter to the defense attorneys in the Smiths' suit, "Fricano was probably reading in excess of 86,000 slides per year" — or two minutes a slide if she worked "eight hours per day, seven days a week without taking a single break."

Fricano worked on a piece-rate basis, getting paid \$2.50 for every slide she read. Under that arrangement, Chem-Bio Corp. alone paid her \$55,662 in 1989, her most lucrative year at the lab, Lipo told the Geary family's lawyer, Larry Brueggeman.

But either Fricano or Lipo evidently were uncomfortable with how regulators would view the pace at which she was working. In mid-1989 — after the passage of the bill limiting the pace of Pap smear readings but before regulations were written or implemented to carry out the law — June Fricano began putting her initials only on the first 100 Pap test reports she completed a day, even when the number of analyses went far over that. Lipo and Fricano disagree over whose idea that was. Fricano told the Geary family's attorneys it came from Lipo, fearful that state officials in charge of overseeing medical labs would complain she was reading too many. In his own deposition, however, Lipo said Fricano asked to stop initialing tests she read after the first 100 each day, citing the coming federal regulations.

At the breakneck pace at which Fricano worked, she might have been expected to make a mistake. But regulations required that a random 10 percent of all slides a technician had read as normal be rescreened by a pathologist to help ensure quality standards were maintained — meaning that if she made frequent errors, they should have come to light.

By the mid-1980s, however, Lipo wasn't picking the 10 percent at random. He was simply screening every slide for which the four-digit reference number ended in the digit 2. Fricano learned of that pattern. Indeed, when Betty Setum, another cytotechnologist, came to work for the lab in 1990, Fricano reportedly warned her: "Be really careful with any [case number] that ends in a 2 because those are the ones that they check for quality control," Setum testified in a 1992 deposition taken by an investigator for Geary lawyer Brueggeman and his associate, Phil O'Brien.

In her own deposition, Fricano denied giv-

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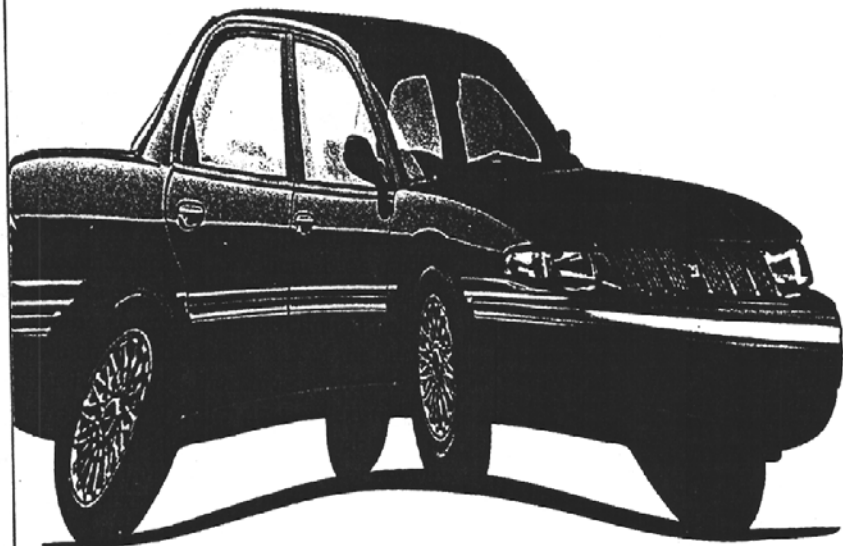
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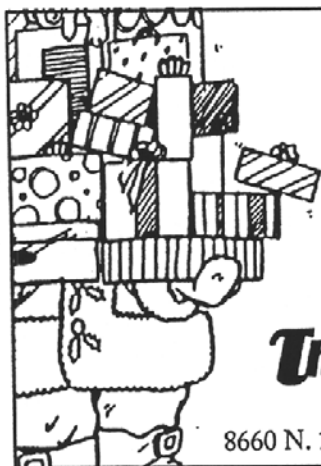
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ing any such warning but acknowledged she knew Lipo's pattern. Fricano testified that she in fact had once questioned the procedure as not being really random, but that Lipo had not changed it.

Lipo, meanwhile, claimed in his deposition that at the same time, he used a second, secret backup screening method: checking every other case number ending in the digit 0. Neither Fricano, Setum or even pathologist Harold Biller — who had been assigned increasing responsibility for quality control at the lab in the mid-1980s — knew anything of that procedure. Lipo testified he kept no records of it.

betty Setum had worked for nearly 20 years as a cytotechnologist when she took a job at Chem-Bio Corp. in September 1990 to be closer to her Oak Creek home. By that time, Chem-Bio Corp. had been acquired by a national chain, Damon Clinical Laboratories. Lipo and Biller remained in charge, however, and quality-control procedures had not been changed.

When Fricano told her just which tests would be rescreened, Setum was taken aback. Some months later, when she pressed Biller about what she felt was the lab's inadequate quality-control procedures, Biller snapped back: "I don't get paid to do quality control," according to Setum's testimony. (Biller, in his own deposition, denied any such conversation. He declined to return *Milwaukee Magazine's* telephone call.) Setum was shocked. The knowledge that her own errors could easily escape detection, she told *Milwaukee Magazine*, was "like being on a trapeze without a net."

She says she began putting additional quality-control measures in place. Then, in mid-February 1991, a call came from West Allis Memorial, where doctors had discovered Dolores Geary's advanced cervical cancer while removing her uterus. Did Chem-Bio still have copies of her 1987 and 1990 Pap smears? Setum found the slides and decided to look at them herself with a colleague, Norma Hajik, who had also recently joined the lab. The cancer was obvious in the 1987 slide, Setum and Hajik both testified later. Even now, Setum says, the memory of that slide gives her goose-flesh. "We were looking," she says quietly, "at someone's death sentence."

Setum took the slides from the laboratory to West Allis Memorial, where pathologist Dr. Jay Schamberg looked at them. "What's more frightening?" Setum asked Schamberg, according to the deposition she gave a year later. "The fact that June Fricano looked at those cells and didn't know what they were? Or that she never looked at them at all?"

Schamberg's reply came quickly and was chilling in its conviction: "She never looked at them at all," Setum recalls him saying. (In a

telephone interview, Schamberg said he didn't recall the remark, "but I might very well have said it." He did remember, however, that Setum was "very upset at the time.")

By then, Fricano had already left the laboratory. Damon Clinical Laboratories had fired her in early January for falsifying records. On a single Saturday, she had screened 80 Pap tests in the morning and 55 more in the afternoon, then dated her afternoon reports for Sunday. In her depositions, Fricano acknowledged the misrepresentation but claimed she had misunderstood the regulations and thought that under the law, a 24-hour period could end and the next begin at 12 noon, making her 135 slides conform to the daily limit on readings. She also insisted that the incident was an isolated event.

A few months later, Fricano went to work at Family Health Plan. The HMO canceled its contract with Damon, and in May 1991, set up an in-house operation to read Pap smears. Of five cytotechnologists hired, only one worked full time - June Fricano. Here, however, she was salaried, not paid by the slide.

Bradford testified at last April's inquest that he didn't know when he offered Fricano a job why she had left Chem-Bio; when he later found out, he warned her she would be fired if she ever violated the federal limits on the number of slides to be read in a day. He also insisted that she not moonlight at other labs. Sources at Family Health say that at the time Bradford hired Fricano, they were getting calls about her tainted record at Chem-Bio. Fricano stayed with the lab until the HMO shut it down in 1992 and again farmed out its laboratory work.

Meanwhile, word of problems at Chem-Bio Corp. had reached federal investigators. In May 1991, the Chicago regional office of the Health Care Financing Administration dispatched a team from the American Society for Cytotechnology to comb through laboratory records. Charles Bennett, associate regional administrator for the Chicago office, says of the 30,000 labs in his six-state territory, only one that has been investigated was worse than Chem-Bio Corp. The feds found inadequate records for Chem-Bio's quality-assurance program and no written procedures for it. Because Biller couldn't find a notebook in which he had kept records of the quality-assurance rescreenings, investigators weren't even sure that any such program existed. The investigators also faulted the lab for not adequately limiting the workload of its cytotechnologists.

The investigative team rescreened 739 cases and found 32 slides that Fricano had pronounced normal in fact had shown at least minor abnormalities. Other rescreenings followed by the lab and by Family Health. Of 40,000 cases from 1989 and 1990, Lipo said

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in a deposition, 241 that had been ruled negative by Fricano turned out to have some kind of abnormality serious enough that the patients received letters alerting them of the new findings.

Bennett's office moved to strip the lab of its federal permit allowing it to operate. Instead, the lab persuaded the feds to allow it to shut down the medical lab and avoid being formally sanctioned. When the lab closed in the fall of 1991, Betty Setum was one of those laid off.

In 1991, the Geary family sued Family Health Plan, Chem-Bio Corp., Lipo, Fricano and others in Milwaukee County circuit court and won an out-of-court settlement of more than \$3 million last year, a year after Dolores Geary died.

Karin and Peter Smith filed their lawsuit in 1992. But the Smiths' suit settled relatively quickly, as civil suits go—in June 1993 for \$6.3 million. Despite the money, settling wasn't easy, Peter says. "Karin really wanted to go to trial. She knew she was dying. The money wasn't an issue to either one of us. She wanted to bring this out in the public eye."

But as the settlement offers edged upward and her lawyer pointed out that appeals would tie up even a favorable jury verdict for years, she relented. From the final settlement amount, she donated \$250,000 for research and education in gynecological cancer. The couple bought a lakefront home in Nashotah, where Karin spent the last year and a half of her life between cancer treatments. "It was quiet and stress-free," Peter says. "She loved this house."

In that time, Smith also crusaded against cervical cancer and what she saw as the failings of managed healthcare. She testified in Congress opposing the Clinton administration's now defunct health reform package on the grounds that it would encourage the cost-cutting competition she blamed for both the lapses in her care. Laura Wittkin, executive director of the National Center for Patients' Rights in New York, says Smith's story is about more than a single lab's foul-up. "It shows there was no continuity of care," says Wittkin, whose group helped steer Smith to sympathetic legislators.

Karin Smith faced death with an equanimity that awes Peter Smith. "It was like our relationship went up to a higher plane," he says. "She was never afraid to die. She was always more worried about leaving me alone."

And she found solace in a faith that saw purpose in her death.

"It's a real weird feeling knowing that you're dying and you shouldn't be dying," says Smith. "But she elected to just accept it. She said, 'Somebody's going to have to speak out. Somebody's going to have to make sure that it doesn't happen again, and I guess it's me.'" ■