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December 6, 1999

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Dear Mr. Secretary:

I am writing concerning two regulations currently being considered by the N.R.C. I urge that both be adopted.

The first one would impose working hour limits on employees at nuclear power plants. This should be enacted because it is even more dangerous to the public to have fatigued power plant workers than fatigued surgeons or airline pilots, in that so many more people are potentially affected.

The second proposed regulation would mandate the training of those in authority regarding employee protection regulations, and then apply sanctions against individuals violating the employee protection regulation. This should be done

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because brave individuals who speak out in the interests of public safety should be encouraged and protected, not harmed. I am enclosing an article from Sunday's New York Times, concerning attempts to encourage whistle-blowers in the medical field, which I think is pertinent.

It seems obvious to me, and I should think to any reasonable person, that adoption of both these measures is crucial. I urge the commission to do so.

Very truly yours,
Joanne McCrary

Editorial and Op-Ed pages, 0-1
Education Advertising
Careers in Education and
Health Care Employment

The New York Times
Week in Review

Sunday, December 5, 1999
Section 4

Do No Harm

Breaking Down Medicine's Culture of Silence

By SHERYL GAY STOLBERG

DR. MICHAEL LEONARD, an anesthesiologist and chief of surgery for Kaiser Permanente in Denver, was operating on a cancer patient a few months ago when he reached into a drawer for medicine. Inside were two vials, side by side. Both had yellow labels. Both had yellow caps. One was a paralyzing agent, which Dr. Leonard had correctly administered to keep the patient still during the operation. The other was the reversal agent, which he needed next. "I grabbed the wrong one," Dr. Leonard recalled. "I used the wrong drug."

It would have been easy for the doctor to keep quiet; the drug wore off and the patient was not harmed. Instead, he talked — to the surgeon and scrub nurses, the patient's wife and the hospital pharmacist, who has since relabeled the paralyzing agents with red stickers and put them in a separate drawer. He also talked to his five partners, whose reaction unnerved him.

"Four of the five of them said, 'You know, I've done the same thing,' " Dr. Leonard said. "One of them said, 'I did the same thing last week.' And I'm thinking, I've been chief of this department for five years. Now I'm chief of surgery. And nobody has ever said to me, 'We have this problem.' A lot of it comes back to this culture of silence."

That culture of silence, and why it needs to be broken, was the unstated theme of a report that shook the medical profession last week. The study, by the independent Institute of Medicine, estimated that in hospitals alone mistakes, from drug mix-ups to surgical errors to misdiagnoses, kill as many as 98,000 people yearly. In addressing basic safety, it said, health care is at least a decade behind other high-risk industries.

The report is likely to turn the Congressional debate over patients' rights on its head. That discussion revolves around whether patients should be able to sue their health plans; this one revolves around what health care can do to create a climate in which patients are less likely to sue because mistakes are less likely to occur in the first place. The report's authors called on Congress to create a new agency that would collect data on medical errors, analyze their causes, identify trends and recommend changes, in much the same way Dr. Leonard changed the drug labels from yellow to red.

"To err is human," the institute panel concluded, "but errors can be prevented."

The idea that doctors make mistakes is, of course, nothing new. But the idea that mistakes can be prevented by changing systems has been slow to catch on, in part because doctors rarely talk openly about their errors. The pat explanation is that they are afraid of being disciplined, or sued. But it is not the whole truth, says Dr. Lucian Leape, a professor of health policy at Harvard Medical School who studies medical error.

"Physicians are taught that it's your job not to make a mistake," Dr. Leape said. "It's like a sin. The

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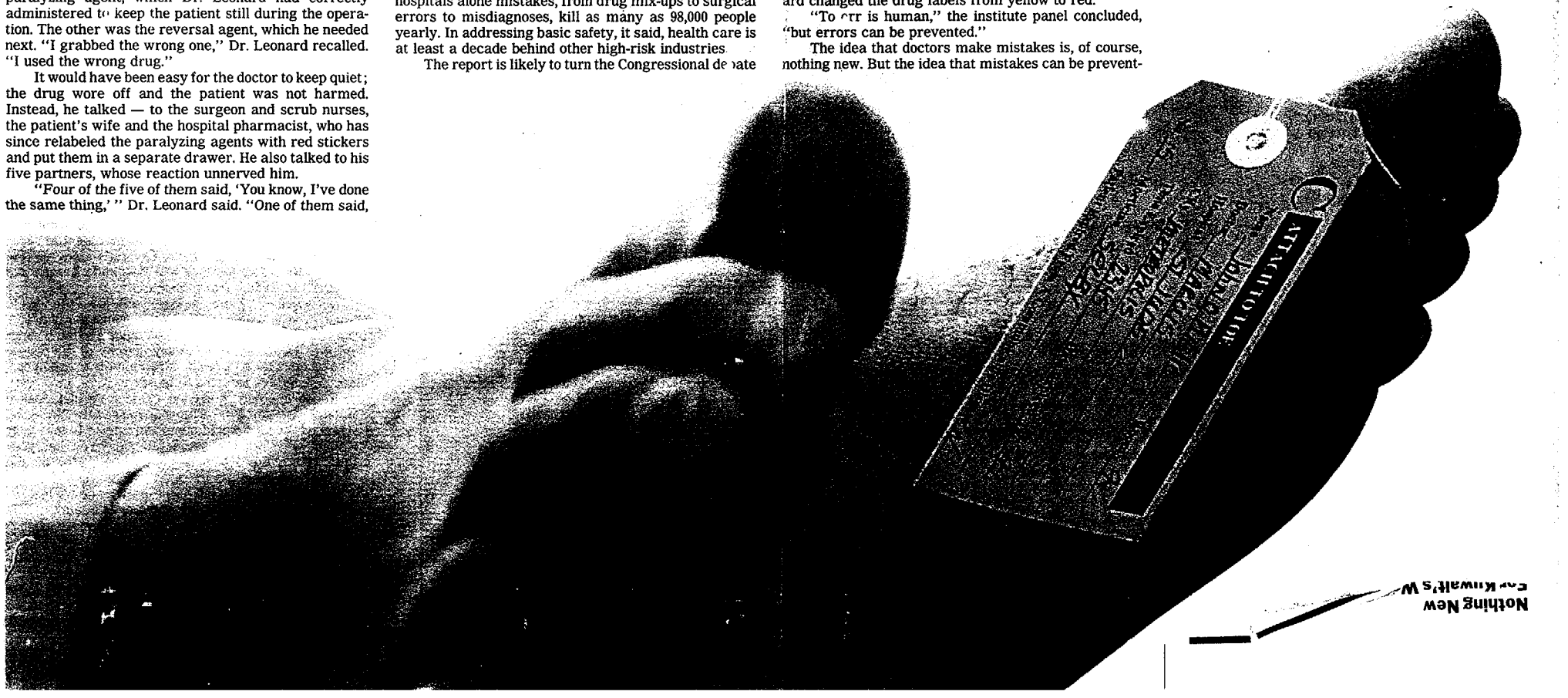

Nothing New
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Breaking Down Medicine's Culture of Silence

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whole concept of error as sin, as a moral failing, is deeply ingrained in medicine, and it is very destructive. It means people cannot talk about it, because it is too painful."

There are two ways to think about human error, experts say. Error can be understood as a matter of negligence, a willful disregard for standards. Or it can be understood in the context of normal human frailty. When people hear about medical errors — the surgeon who amputates the wrong leg, the oncologist who delivers a chemotherapy overdose — they assume bad doctors are to blame.

In fact, the opposite is true, says Dr. Donald Berwick, president of the Institute for Healthcare Improvement, a Boston research center. The vast majority of medical mistakes are committed not by bad apples, he says, but by good doctors trying to do the right thing, working under conditions that do not account for the fact that they are human.

Anesthesiologists have already made several equipment changes that have saved thousands of lives and, Dr. Leape said, also cut their malpractice premiums in half.

"You don't get to safe systems that have human beings in them by yelling at them or asking them to try harder," Dr. Berwick said. "You need to engineer the work environment so that normal human limits are respected."

AVIATION has done precisely this over the past two decades. In 1976, the risk of dying in an airplane accident was one in two million; today it is one in eight million. Dr. Robert Helmreich, an expert in human factors analysis at the University of Texas at Austin, said the change came about from pioneering studies that found that the majority of airline accidents are caused not by technical failures but by breakdowns in communications — "exactly the thing that pilots were never taught."

Today, pilots are given intensive training in what Dr. Helmreich calls "the human aspects of flight." Junior pilots — who, like young doctors, may be too intimidated to criticize their superiors — are taught that if they see a mistake, it is their duty to speak up. Simulators teach airline crews teamwork.

For the past several years, Dr. Helmreich has been working to bring these same techniques of "crew resources management" to health care. Dr. Leonard, who is among Dr. Helmreich's disciples, recently visited Southwest Airlines to observe a pilot training session. But just as important as training, the experts say, is a change in culture that makes it permissible to talk about mistakes.

When a plane accident results in death or serious injury, the National Transportation Safety Board investigates. When a hospital patient dies, doctors convene what is known as an "M and M" conference, for morbidity and mortality, to analyze the death and discuss how it might have been prevented. Most doctors find them extremely useful. But there is no way of disseminating these findings nationwide.

That is the role the Institute of Medicine envisions for the new federal agency, which it calls the Center for Patient Safety. Its plan calls for mandatory reports on any mistake that causes death or serious injury, which the agency would collect and make available to the public (including malpractice lawyers).

But the lesson of the airlines is that it is just as important to report mistakes that don't hurt anybody. Aviation has a voluntary system, independent of the Federal Aviation Administration, in which pilots and other crew members submit confidential reports about mistakes. These reports are analyzed and alerts are issued as needed.

"If tomorrow morning, I take off in my airplane and I see a problem in the air traffic system that could lead somebody into the side of a mountain, the whole world of aviation can know about it in the next 24 to 48 hours," said John Nance, an aviation analyst. "'We have been working hard to get rid of the blame culture, which is so imbued in medicine," he added.

But in this litigious society, getting rid of medicine's blame culture may be easier said than done. To foster a better environment for reporting medical mistakes, the institute has recommended that information about errors that were harmless be protected from discovery in a lawsuit, a recommendation that predictably does not sit well with plaintiffs' lawyers.

At the same time, some wonder if it is wise to eliminate the notion of blame completely. "You've got to walk a very delicate line between the responsibility of the individual physician and a recognition that a system can determine behavior and promote error," said Dr. David J. Rothman, professor of social medicine at Columbia University.

THAT line was not lost on me. While preparing this article, I took my 15-month-old to an ear, nose and throat specialist. He prescribed Biaxin, an antibiotic, a half teaspoonful twice a day. Late that night, while I was interviewing Dr. Leape, the specialist left a message on my answering machine saying he had been flipping through his notes to double-check the day's work: the baby's dose was a quarter teaspoon, not half.

My first instinct was anger. How could he make such a mistake? If he had been using a computer to write his prescriptions, I knew, the machine would have checked the dose against my daughter's weight and flagged the error, recognizing the dose as too high. But computers cost money, and in today's managed care environment, most doctors are squeezed for cash. And in any event, as Dr. Leape pointed out, I should have been grateful, not mad. The doctor made a mistake. He caught it. He called me right away. Mistakes happen all the time.

Calculating Costly Mistakes

ALTHOUGH experts believe medical mistakes happen with alarming frequency, there is scant research to document them.

The Institute of Medicine study, which estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors, based those figures on two studies in three states: New York, Utah and Colorado.

The New York study was the most extensive. Dr. Lucian Leape, a professor of health policy at Harvard Medical School, analyzed discharge records of more than 30,000 patients from 51 state hospitals in 1984. He found that 3.7 percent suffered an injury from their treatment that was severe enough to disable them or prolong their hospital stay. Of these injuries, 58 percent were attributed to error; 13.6 percent were fatal.

When extrapolated to the number of people hospitalized in the country in 1997, the institute calculated there were 98,000 deaths.

The Colorado and Utah study, which was conducted in 1992, examined 15,000 records and used similar methodology to reach the lower figure of 44,000.

While there is no way to know if the numbers are going up or down, Dr. Leape said there was "every reason to think they have gone up," because hospital care is more complicated now and patients are sicker. In addition, he said, most medical errors are not reported and many are not recognized, even by the people who make them.

SHERYL GAY STOLBERG