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Research death began tough test of Miller's leadership

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**BODY:**

Last summer, Dr. Edward D. Miller was settled into a peaceful reign at Johns Hopkins Medicine, presiding over the construction of research and clinical buildings and helping to plan a biotechnology park that could revitalize the East Baltimore campus.

Then, his well-ordered world was transformed.

Since the death in June of a young woman in a flawed medical experiment, the tall, silver-haired anesthesiologist has added crisis management to his duties, huddling with lawyers, wrangling with regulators and trying to change the culture of a humbled institution.

"This was probably the most taxing of years," said Miller, 59. "The Ellen Roche death was a difficult one, not just for the institution, but for me personally. It happened on my watch, and I have a daughter the same age. It's one of those things you don't get away from."

Much of Miller's leadership has been invisible to outsiders. He spoke publicly only twice during last summer's crisis, prompting criticism that he should have assumed a higher profile in acknowledging the school's shortcomings and expressing his commitment to improving patient safety. And when Miller did speak - he angrily denounced federal regulators who briefly suspended human studies at Hopkins - some faculty members and alumni felt that he projected arrogance that didn't help the institution's cause.

Miller has few regrets about his stewardship, saying he is more comfortable delegating the public role to others. And while he's heard that some have thought his defense of Hopkins arrogant, he believes that he justly stood up when the government had taken extreme action and left no room for discussion.

"Most people would say, 'You should have been more conciliatory,'" Miller said. "But my view was that nobody

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appreciated the magnitude of what a shutdown of this size would do to the institution and to the patients who were in those studies."

Some faculty members say they were heartened that Miller defended Hopkins, noting that he quickly softened his tone and mobilized the school to improve safety.

"It didn't hurt to have someone react initially by essentially defending what was right with the institution," said Dr. John Griffin, chairman of the neurology department. "On the other hand, when it became clear there were aspects that needed to be worked on, he did a nice job of changing the focus and bringing people together to do what needed to be done."

Miller came to Hopkins in 1994 to run the anesthesiology department, leaving a chairmanship at Columbia University. Three years later, he was appointed to the consolidated position of dean and chief executive by trustees who hoped that he would bring peace to an institution riven by administrators who had run the hospital and medical school as separate fiefdoms.

A calm, avuncular style

Most say he has accomplished that with a calm, avuncular style and a knack for bringing people together.

But he has been tested in a difficult year that began with Roche's death in an asthma experiment and continued with a court decision that challenged the ethics of a lead-paint study at the affiliated Kennedy Krieger Institute. Most recently, Hopkins has coped with an outbreak of infections among patients who had been examined with defective bronchoscopes, instruments used to peer inside patients' lungs.

The troubles began in May when Miller learned that Roche, a 24-year-old lab technician at Hopkins' asthma and allergy center, had become ill after inhaling a chemical in an experiment designed to reveal how healthy lungs defend against irritants. By then, Roche's lungs were failing, and she was connected to a breathing machine at the Johns Hopkins Bayview Medical Center.

"What I thought was that this was the worst-case scenario," Miller said. "A human subject goes into a straightforward clinical trial. You're praying you're going to get through it, that she's going to be OK."

Miller said he received reports from the doctors who cared for Roche but didn't go to her bedside because he did not want to place undue pressure on those who were struggling to save her.

"They had pulled out all measures to save her," Miller said. "It was progressively, continually downhill. You almost couldn't believe it was happening. ... You never knowingly get anybody into a trial that had that potential outcome."

Miller said he met with Roche's father, Bernard J. Roche Jr., about two weeks after her death June 2 to explain the findings of the Hopkins' internal investigation. He had to explain that the study should never have been conducted. Doctors failed to discover reports - readily available on the Internet - that the chemical, hexamethonium, produced fatal reactions when used as a hypertension drug a generation earlier. And doctors "mised" volunteers by calling it a drug, when in fact it no longer had government approval.

The meeting took place at a Reisterstown law office. To his surprise, Miller found Mr. Roche to be cordial and composed.

"I think he was trying to take in all the facts," Miller said. "You guess he was trying to intellectualize what was going on, to handle all his emotional feelings about this." Mr. Roche, who later reached a confidential settlement with Hopkins, has declined to discuss his daughter's death with the press.

Within days of that meeting, officials at the federal Office for Human Research Protection announced that it was

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shutting down all human studies until Hopkins overhauled its safety and review systems. Before reporters and television cameras, Miller denounced the OHRP as a fledgling agency that had taken "draconian" measures against an institution that enjoyed a century-long record of excellence.

Miller said he heard complaints about those remarks, though less from faculty members than alumni. One graduate, he said, wrote him a long letter that said, in effect, "That's the Hopkins arrogance. You should take your medicine and be quiet."

He said he might have reacted more calmly if the bad news had been delivered by Dr. Greg Koski, the agency's director. Koski understands that sentiment but said he relied on officials who had conducted the on-site inspection.

"I'm not sure that reaction was the most constructive at the time," Koski said. "But it was a very difficult situation and, clearly, over the last several months his tone has changed. He has come to realize that there were serious problems that needed to be addressed."

While pitted on opposite sides of a tense situation, Miller and Koski, also an anesthesiologist, say they have known and respected each other for years. At Columbia in the late 1980s, Miller unsuccessfully tried to recruit Koski from Massachusetts General Hospital.

In November, when Hopkins was well into reforming its review system, Koski accepted Miller's invitation to speak to department chairmen about human research protections. Koski, who talked about "what it means to establish a culture of conscience rather than a culture of compliance," said he was warmly received.

Troubles continue

Hopkins took another blow in August when the state's highest court harshly criticized the lead-paint study. Conducted by Kennedy Krieger but approved by a Hopkins review board, the study measured environmental lead levels in homes that had received varying degrees of renovation. The court compared the research to the notorious Tuskegee study of untreated syphilis.

Though Miller calls the charges unfair - saying researchers were trying to find an affordable way to protect children from being poisoned - he said he didn't feel it was his place to answer the criticism because Kennedy Krieger had conducted the study.

The latest crisis occurred when Hopkins doctors noticed an abnormally large number of Pseudomonas infections in patients who had been examined with bronchoscopes and later traced the problem to a manufacturing defect. The scopes had been voluntarily recalled, but the notice was delivered to a Hopkins loading dock.

Hopkins doctors say two patients may have died and an unknown number sickened by the scopes. The hospital has advised more than 400 patients that they might be at risk and should come back to be checked.

"People said this is really going to look bad ... because we had the other issues," Miller said. "But the important thing was, we had to let patients know."

Though the events of the past year "chewed up" enormous amounts of time, Miller said he has more recently been able to turn his attention toward fund raising, the completion of four new buildings on campus, and the plan to transform a deteriorating neighborhood north of campus into a biotech park. And by this summer, review board members should be caught up with the backlog of studies that have been delayed by the federal shutdown.

Though he seems to have maintained his even disposition, Miller said he has been around too long not to worry that new problems can occur.

"Every time you ... put a patient to sleep, you worry that there could be a bad outcome," Miller said.

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Doctors, he said, should have the same fear every time they enroll someone in a medical experiment.

"I think if you don't have that fear, reasoned fear, you're cavalier in taking care of patients," he said. "And you can't be."

**GRAPHIC:** Photo(s), 1. Dean: Dr. Edward D. Miller says Ellen Roche's death "was a difficult one, not just for the institution, but for me personally."; 2. Few regrets: Dr. Edward D. Miller says he believes he justly stood up when regulators announced a shutdown of Hopkins' human studies.; JED KIRSCHBAUM : SUN STAFF

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