



STATE OF MARYLAND

DHMH

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Testimony of Nelson J. Sabatini

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Mr. Chairman, Members of the Subcommittee: I am Nelson J. Sabatini, Secretary of the Maryland Health Department. Thank you for inviting me to testify before you this morning and for allowing me to give you my perspective on recent events at Maryland General Hospital.

At this point we are all well aware of the problems that occurred in the hospital's laboratory. Briefly, for the record, the hospital failed to accurately perform hepatitis and HIV testing on more than one thousand individuals, placing the health and safety of these unsuspecting patients at risk.

While we are here primarily to talk about Maryland General, I think it would be a mistake to characterize this as an isolated event. In 1999, the Institute of Medicine published a report estimating that as many as 100,000 patients a year die from medical errors in hospitals. Let me repeat that. One hundred thousand patients die, from errors, every year. That's about two thousand a week – about 250 a day nationally. Every day.

As far as we know, none of the Maryland General patients has died, so those thousand or so medical errors don't even show up on the radar screen. The IOM study focused only on medical errors with fatal outcomes.

The IOM report should horrify us all. The report said that these errors are caused by "systems problems" that go undetected and uncorrected by hospitals. This is certainly the case at Maryland General; the problems went undetected, or ignored, by the hospital for an extended period of time. But given the IOM report, I believe we can assume that Maryland General's problems are not unique in the industry.

How can this be happening in a country that arguably provides the best health care in the world? I suggest that what we are seeing is the direct result of a 30-year experiment in self-regulation by the hospital industry.

I believe that the Maryland General experience is merely a symptom of a system failure, and I believe it calls into question the legitimacy and adequacy of the entire regulatory process. I have said publicly that the system is broken and needs overhaul; I mean just that. In the case of Maryland General Hospital, the system was not equipped to address the problems at the hospital or its lab. The federal and state regulatory agencies, which bear ultimate responsibility for ensuring quality health care, do not have the regulatory tools they need to provide any credible assurance of quality. Let me explain.

Federal law, and a comparable state law, grant what is known as “deemed status” to any laboratory accredited by the College of American Pathologists (CAP) or the Joint Commission on Accreditation of Health Care Organizations (JCAHO). Accredited facilities are “deemed” to be in compliance with all applicable federal and state regulations and thus are exempt from routine federal and state surveys. In Maryland this legislation was passed about 30 years ago, and embodied the logical-sounding idea that no one is better equipped to regulate doctors and hospitals than doctors and hospitals themselves. So we passed the baton to private entities like the Joint Commission, which answers not to government, and not to the public, but to the American Hospital Association and the American College of Surgeons.

We depend on these accreditation organizations to conduct their own periodic surveys, and to provide us with assurance that their high standards of quality are being met -- that patients can feel safe in a deemed facility. Patient safety is ultimately a government regulatory responsibility, but we have subcontracted it out. The federal government, and many state governments, have abdicated – have turned over their authority to private-sector organizations, which have, in my view, uncomfortably close ties to the industry they survey.

Accreditation surveys are generally announced in advance – and even if unannounced they are fairly predictable. The surveys are collegial in nature and leisurely in execution, and they focus almost entirely on process instead of outcome. This is like saying a business is doing fine as long as its books appear to be in order.

By way of contrast, in Maryland we regulate nursing homes by looking first at outcomes, not process, and it is our consistent experience that bad outcomes are a very good indicator of systemic problems in a facility. We do care about process, but we try to care more about people. When it comes to regulating hospitals, though, our ability to care about either is less than ideal.

Deeming limits the ability of government to exercise its inherent regulatory authority. Even though hospitals operate under licenses granted by the state, we have no authority to routinely inspect those facilities. We can only conduct surveys in response to specific complaints, and when those surveys do turn up problems, our ability to mandate corrective action is limited. The corrective process is slow, and it is based on the assumption that once a hospital knows of a problem, it will fix that problem even without the expectation of follow-up surveys.

There is also the issue of disclosure, of transparency. Those hundred thousand deaths a year are not spread evenly among all hospitals; there are good hospitals and not-so-good hospitals, but the public has very little chance to know which is which. Survey reports by the private-sector accrediting organizations are not routinely disclosed to the general public – in theory some of the reports are public, but actual disclosure requires the consent of the facility. The public has no consistent and reliable way to evaluate hospitals before choosing one.

In contrast, the surveys we conduct at nursing homes and other long-term care facilities are periodic, unannounced, comprehensive, and public. The results of our surveys are published on our web site. As a regulatory agency we can't guarantee that a good facility today won't have problems tomorrow, but at least we give the public the chance to look at track records before they pick a facility. Equally important, the reports help the public – and the legislature – judge how well we are doing our job, and to hold us accountable.

When it comes to hospital laboratories, though, there are at least four different agencies or organizations involved in quality oversight – the state and federal governments and at least two accrediting organizations – which means among other things that when something does go wrong, accountability is spread so thin as to be meaningless. Today you will hear lots of people explain how someone else dropped the

ball. Let me say this as plainly as I can: we all dropped the ball. We all are responsible. We all should be held to account for this.

At Maryland General, as early as November 2002, the state and federal agencies identified potentially serious problems. There was no follow-up to ensure corrective action. The hospital was supposed to notify the accrediting organization and alert it to the federal investigation and deficiencies. This also did not happen. There was no direct or indirect sharing of information between the government and private survey agencies. In April, 2003, the College of American Pathologists conducted its routine inspection and even though its surveyors identified problems similar to those identified by us in 2002, it granted the laboratory accreditation "with Distinction." And the deficiencies went on and on, and were not fixed. It was only in January of this year, after a strongly worded complaint reached both us and the local newspaper, that the hospital – and its gaggle of regulatory and accrediting agencies – began to address the problem.

The current system is frightening. It is cumbersome; it is bureaucratic. Even if there were good communication between all the agencies, there are too many of them. We are hindered by laws that prevent the discovery, and slow the correction of problems. If one hundred thousand patients are dying in hospitals each year because of medical errors, it is occurring at least in part because of a system that for all intents and purposes allows the hospital industry to regulate itself, without adequate oversight.

This is a system that is legislative in origin and will require legislative corrections, at both the federal and state level. If there is anything good we can say about the Maryland General situation, it is that it makes a powerful wake-up call. We have a problem, and now we know it. There is nothing to be gained by playing blame games; we all are to blame for this problem, and it is up to all of us to work together to fix it.