

Exhibit Number: 4

HB 222

“To Err Is Human”

The following exhibit has several pages of text from a Report, which lays out a comprehensive strategy for addressing a serious problem in health care. This report exceeds the 10-page limit therefore it cannot be scanned. A small portion has been scanned to aid in your research for information. The exhibit is on file at the Montana Historical Society and can be viewed there.

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Executive Summary

The knowledgeable health reporter for the Boston Globe, Betsy Lehman, died from an overdose during chemotherapy. Willie King had the wrong leg amputated. Ben Kolb was eight years old when he died during "minor" surgery due to a drug mix-up.¹

These horrific cases that make the headlines are just the tip of the iceberg. Two large studies, one conducted in Colorado and Utah and the other in New York, found that adverse events occurred in 2.9 and 3.7 percent of hospitalizations, respectively.² In Colorado and Utah hospitals, 8.8 percent of adverse events led to death, as compared with 13.6 percent in New York hospitals. In both of these studies, over half of these adverse events resulted from medical errors and could have been prevented.

When extrapolated to the over 33.6 million admissions to U.S. hospitals in 1997, the results of the study in Colorado and Utah imply that at least 44,000 Americans die each year as a result of medical errors.³ The results of the New York Study suggest the number may be as high as 98,000.⁴ Even when using the lower estimate, deaths due to medical errors exceed the number attributable to the 8th leading cause of death.⁵ More people die in a given year as a result of medical errors than from motor vehicle accidents (43,458), breast cancer (42,297), or AIDS (16,516).⁶

Total national costs (lost income, lost household production, disability and health care costs) of preventable adverse events (medical errors resulting in injury) are estimated to be between \$17 billion and \$29 billion, of which health care costs represent over one-half.⁷

In terms of lives lost, patient safety is as important an issue as worker safety. Every year, over 6,000 Americans die from workplace injuries.⁸ Medication errors alone, occurring either in or out of the hospital, are estimated to account for over 7,000 deaths annually.⁹

Medication-related errors occur frequently in hospitals and although not all result in actual harm, those that do, are costly. One recent study conducted at two prestigious teaching hospitals, found that about two out of every 100 admissions experienced a preventable adverse drug event, resulting in average increased hospital costs of \$4,700 per admission or about \$2.8 million annually for a 700-bed teaching hospital.¹⁰ If these findings are generalizable, the increased hospital costs alone of preventable adverse drug events affecting inpatients are about \$2 billion for the nation as a whole.

These figures offer only a very modest estimate of the magnitude of the problem since hospital patients represent only a small proportion of the total population at risk, and direct hospital costs are only a fraction of total costs. More care and increasingly complex care is provided in ambulatory settings. Outpatient surgical centers, physician offices and clinics serve thousands of patients daily. Home care requires patients and their families to use complicated equipment and perform follow-up care. Retail pharmacies play a major role in filling prescriptions for patients and educating them about their use. Other institutional settings, such as nursing homes, provide a broad array of services to vulnerable populations. Although many of the available studies have focused on the hospital setting, medical errors present a problem in any setting, not just hospitals.

Errors are also costly in terms of opportunity costs. Dollars spent on having to repeat diagnostic tests or counteract adverse drug events are dollars unavailable for other purposes. Purchasers and patients pay for errors when insurance costs and copayments are inflated by services that would not have been necessary had proper care been provided. It is impossible for the nation to achieve the greatest value possible from the hundreds of millions of dollars spent on medical care if the care contains errors.

But not all the costs can be directly measured. Errors are also costly in terms of loss of trust in the system by patients and diminished satisfaction by both patients and health professionals. Patients who experience a longer hospital stay or disability as a result of errors pay with physical and psychological discomfort. Health care professionals pay with loss of morale and frustration at not being able to provide the best care possible. Employers and society, in general, pay in terms of lost worker productivity, reduced school attendance by children, and lower levels of population health status.

Yet silence surrounds this issue. For the most part, consumers believe they are protected. Media coverage has been limited to reporting of anecdotal cases. Licensure and accreditation confer, in the eyes of the public, a "Good Housekeeping Seal of Approval." Yet, licensing and accreditation processes have focused only limited attention on the issue, and even these minimal efforts have confronted some resistance from health care organizations and providers. Providers also perceive the medical liability system as a serious impediment to systematic efforts to uncover and learn from errors.¹¹

The decentralized and fragmented nature of the health care delivery system (some would say "nonsystem") also contributes to unsafe conditions for pa-

tients, and serves as an impediment to efforts to improve safety. Even within hospitals and large medical groups, there are rigidly-defined areas of specialization and influence. For example, when patients see multiple providers in different settings, none of whom have access to complete information, it is easier for something to go wrong than when care is better coordinated. At the same time, the provision of care to patients by a collection of loosely affiliated organizations and providers makes it difficult to implement improved clinical information systems capable of providing timely access to complete patient information. Unsafe care is one of the prices we pay for not having organized systems of care with clear lines of accountability.

Lastly, the context in which health care is purchased further exacerbates these problems. Group purchasers have made few demands for improvements in safety.¹² Most third party payment systems provide little incentive for a health care organization to improve safety, nor do they recognize and reward safety or quality.

The goal of this report is to break this cycle of inaction. The status quo is not acceptable and cannot be tolerated any longer. Despite the cost pressures, liability constraints, resistance to change and other seemingly insurmountable barriers, it is simply not acceptable for patients to be harmed by the same health care system that is supposed to offer healing and comfort. "First do no harm" is an often quoted term from Hippocrates.¹³ Everyone working in health care is familiar with the term. At a very minimum, the health system needs to offer that assurance and security to the public.

A comprehensive approach to improving patient safety is needed. This approach cannot focus on a single solution since there is no "magic bullet" that will solve this problem, and indeed, no single recommendation in this report should be considered as *the* answer. Rather, large, complex problems require thoughtful, multifaceted responses. The combined goal of the recommendations is for the external environment to create sufficient pressure to make errors costly to health care organizations and providers, so they are compelled to take action to improve safety. At the same time, there is a need to enhance knowledge and tools to improve safety and break down legal and cultural barriers that impede safety improvement. Given current knowledge about the magnitude of the problem, the committee believes it would be irresponsible to expect anything less than a 50 percent reduction in errors over five years.

In this report, safety is defined as freedom from accidental injury. This definition recognizes that this is the primary safety goal from the patient's perspective. Error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. According to noted expert James Reason, errors depend on two kinds of failures: either the correct action does not proceed as intended (an error of execution) or the original intended action is not correct, (an error of planning).¹⁴ Errors can happen in all stages in the process of care, from diagnosis, to treatment, to preventive care.

Not all errors result in harm. Errors that do result in injury are sometimes called preventable adverse events. An adverse event is an injury resulting from a medical intervention, or in other words, it is not due to the underlying condition

of the patient. While all adverse events result from medical management, not all are preventable (i.e., not all are attributable to errors). For example, if a patient has surgery and dies from pneumonia he or she got postoperatively, it is an adverse event. If analysis of the case reveals that the patient got pneumonia because of poor hand washing or instrument cleaning techniques by staff, the adverse event was preventable (attributable to an error of execution). But the analysis may conclude that no error occurred and the patient would be presumed to have had a difficult surgery and recovery (not a preventable adverse event).

Much can be learned from the analysis of errors. All adverse events resulting in serious injury or death should be evaluated to assess whether improvements in the delivery system can be made to reduce the likelihood of similar events occurring in the future. Errors that do not result in harm also represent an important opportunity to identify system improvements having the potential to prevent adverse events.

Preventing errors means designing the health care system at all levels to make it safer. Building safety into processes of care is a more effective way to reduce errors than blaming individuals (some experts, such as Deming, believe improving processes is the *only* way to improve quality¹⁵). The focus must shift from blaming individuals for past errors to a focus on preventing future errors by designing safety into the system. This does not mean that individuals can be careless. People must still be vigilant and held responsible for their actions. But when an error occurs, blaming an individual does little to make the system safer and prevent someone else from committing the same error.

Health care is a decade or more behind other high-risk industries in its attention to ensuring basic safety. Aviation has focused extensively on building safe systems and has been doing so since World War II. Between 1990 and 1994, the U.S. airline fatality rate was less than one-third the rate experienced in mid century.¹⁶ In 1998, there were no deaths in the United States in commercial aviation. In health care, preventable injuries from care have been estimated to affect between three to four percent of hospital patients.¹⁷ Although health care may never achieve aviation's impressive record, there is clearly room for improvement.

To err is human, but errors can be prevented. Safety is a critical first step in improving quality of care. The Harvard Medical Practice Study, a seminal research study on this issue, was published almost ten years ago; other studies have corroborated its findings. Yet few tangible actions to improve patient safety can be found. Must we wait another decade to be safe in our health system?

RECOMMENDATIONS

The IOM Quality of Health Care in America Committee was formed in June 1998 to develop a strategy that will result in a threshold improvement in quality over the next ten years. This report addresses issues related to patient safety, a subset of overall quality-related concerns, and lays out a national

agenda for reducing errors in health care and improving patient safety. Although it is a national agenda, many activities are aimed at prompting responses at the state and local levels and within health care organizations and professional groups.

The committee believes that although there is still much to learn about the types of errors committed in health care and why they occur, enough is known today to recognize that a serious concern exists for patients. Whether a person is sick or just trying to stay healthy, they should not have to worry about being harmed by the health system itself. This report is a call to action to make health care safer for patients.

The committee believes that a major force for improving patient safety is the intrinsic motivation of health care providers, shaped by professional ethics, norms and expectations. But the interaction between factors in the external environment and factors inside health care organizations can also prompt the changes needed to improve patient safety. Factors in the external environment include availability of knowledge and tools to improve safety, strong and visible professional leadership, legislative and regulatory initiatives, and actions of purchasers and consumers to demand safety improvements. Factors inside health care organizations include strong leadership for safety, an organizational culture that encourages recognition and learning from errors, and an effective patient safety program.

In developing its recommendations, the committee seeks to strike a balance between regulatory and market-based initiatives, and between the roles of professionals and organizations. No single action represents a complete answer, nor can any single group or sector offer a complete fix to the problem. However, different groups can, and should, make significant contributions to the solution. The committee recognizes that a number of groups are already working on improving patient safety, such as the National Patient Safety Foundation and the Anesthesia Patient Safety Foundation.

The recommendations contained in this report lay out a four-tiered approach:

- establishing a national focus to create leadership, research, tools and protocols to enhance the knowledge base about safety;
- identifying and learning from errors through the immediate and strong mandatory reporting efforts, as well as the encouragement of voluntary efforts, both with the aim of making sure the system continues to be made safer for patients;
- raising standards and expectations for improvements in safety through the actions of oversight organizations, group purchasers, and professional groups; and
- creating safety systems inside health care organizations through the implementation of safe practices at the delivery level. This level is the ultimate target of all the recommendations.