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Good afternoon. I'm Mike Harsh and I'm Vice President and Chief Technology Officer for GE Healthcare, the $17 billion diagnostics, healthcare IT, and life sciences division of the General Electric Company that touches billions of lives every day around the world through life saving technologies. It's a pleasure to be here. Thank you to Senator Kohl and Senator Grassley for hosting this program and for your leadership in advancing American healthcare.

I have led R&D efforts at GE Healthcare in Milwaukee, Wisconsin, Senator Kohl's home state, and at the GE Global Research Center, the world's first corporate R&D center that was established in 1900 near Albany, New York.

In addition, I'm a member of the College of Fellows of the American Institute for Medical and Biological Engineering.

My 34 years of seeing healthcare innovation up close and its impact on patients, healthcare providers and society as a whole, provides the foundation for my comments today in this important forum on the challenges, promise, and potential of aging in America.

- **Where are we today and how far have we come in the last five decades?**

The medical technology that today helps clinicians diagnose aging-related conditions faster and earlier has come a long way since it first was invented more than 100 years ago. Developments in IT, imaging and biology mean that we are moving from a medical paradigm of "see-and-treat disease" to one of "predict-and-prevent" that will dramatically change how physicians are able to address the increasingly complex needs of a globally aging population.

Surprising himself and changing medicine forever, Willhelm Roentgen, experimenting with cathode-ray tubes, noticed light passing through solid objects. This was a yet-to-be-defined phenomena. Hence he called it "X-ray," which he named after the mathematical symbol X for the unknown quantity. The year was 1896. You may have seen that iconic image from what's called the "first X-ray" – the recognizable image of his wife's hand, bones and large ring included.

Only one year later, inventor and GE founder Thomas Edison — along with fellow GE engineer and collaborator Elihu Thomson — increased the X-ray tube's power and made the fluoroscope the world's first commercially-available X-ray. For the first time, physicians could identify bone fractures and locate foreign objects in the body, providing an unprecedented

window into the human body and impacting the course of treatment for patients. A new field of medicine was born: radiology.

Over the next seven decades, medical imaging continued to evolve, with more advanced technology and clearer images. In 1932 Irving Langmuir won the Nobel Prize in Chemistry, specifically for his work in surface chemistry, an invention that led to early coronary artery imaging, again revolutionizing physicians' ability to see inside the body.

Several technological breakthroughs followed, such as the introduction of sonar-based ultrasound imaging; contrast agents; and a new diagnostic approach in women's health: mammography. Emile Gabby — known around the world as the father of mammography — brought about revolutionary X-ray tube design that made it possible to image soft tissue with unprecedented resolution, which led to the creation and commercialization of the first mammography unit signaling a breakthrough in women's healthcare.

In the early 1960s, we saw a superconducting magnet built that paved the way for modern magnetic resonance imaging (MRI) scanners, and a decade after that, GE's Ivar Giaever won the Nobel Prize in Physics for his work in discovering the properties of electrons in superconductors, work that spearheaded discoveries in MR.

In 1975 and 1976, diagnostic imaging took yet another leap forward as the first concepts were developed for full body computed tomography (CT) system that captured X-ray images in less than five seconds, 60 times faster than previous technologies.

In the 1980s, MRI enabled physicians to see organs in real-time, helping diagnose abnormalities and guide and monitor therapies. Innovators took existing technology and incorporated new technology to push the limits of performance and capabilities to even greater heights.

Today, X-ray images are produced with incredible speed and accuracy, having transformed from the grainy view of Roentgen's wife's hand to startlingly clear images of blood flow in the brain.

Ultrasound technology provides detailed images for patients old and young. Today some models even fit in a physician's pocket and deliver ultrasound at 1/100th of all the cost. In this day and age of talking cell phones with GPS units, we can still marvel at this technology that even can allow physicians to guide needle placement in IV lines in elderly patients, preventing the need for unnecessary placement procedures and creating more cost efficiency. Ultrasound also holds great potential for primary care and home care in the not too distant future in developed markets such as the U.S., enabling physicians to understand more about their patients in the home or clinic setting.

As the 21st century has dawned, governments are urging healthcare systems to be more productive and technology must align with the new realities of healthcare, providing patient, diagnostic and economic value. Access, quality and outcomes must drive the purpose of healthcare innovation.

Specifically, clinicians are demanding that technology reduce the overall cost burden of delivering care. Technology must help deliver higher quality, portable and efficient healthcare to an increased number of individuals, thus increasing access while lowering costs. For example, the ability to monitor the effectiveness of the clot-busting drug TPA on strokes can not only help monitor treatment but do it cost-effectively.

In addition, the wealth of clinical and patient data now afforded through electronic health records, electronic medical records, and clinical databases that house treatment protocols from expert clinicians means solutions must be developed to efficiently document, store and share that data safely and broadly through flexible and portable healthcare IT.

As diagnostics and therapies shift to the molecular level, molecular diagnostics will enable earlier, more precise disease detection and allow physicians to understand more about each individual patient. Life sciences capabilities will enable the next generation of bio-therapies, which increasingly will be delivered in tandem with diagnostics.

A few examples illustrate this opportunity. By combining the incredible power of imaging with molecular biology and pathology, we can help move treatment forward, particularly in cancer, to custom-tailored, individualized approaches, critical to improving outcomes and cost containment. We are moving from a healthcare paradigm where we "see and treat" existing disease, to the ability to detect disease at the molecular level before physical symptoms emerge, and to treat that disease at a much earlier stage when it is much less costly to address and more advantageous to the patient's quality of life.

In neurodegenerative disease, molecular agents for in-vivo and in-vitro testing will help determine the pathology behind early cognitive impairment, leading to earlier diagnoses and treatments in Alzheimer's and Parkinson's disease. With the advent of disease modifying drugs, this brings the opportunity to improve people's quality of life as they age. This has particular significance for a population that is living longer and increasingly at risk of memory loss and impairment from neurological conditions such as Alzheimer's and dementia.

Additionally, it's now possible to use cells in the process of drug discovery to speed the time to market and do toxicity tests in vitro on cells in a petri dish rather than on animals or humans in trials. Moreover, the ability to image a cell as a virus attacks to determine vectors for disease treatment is fast coming on the horizon.

It has been 116 years since that first grainy X-ray. With continued advances in medical imaging, molecular diagnostics and health IT, it can be a bright future in which physicians predict, detect, treat and manage disease earlier and more precisely than ever. We at GE share the commitment of everyone in this room to helping increase quality of life for patients and their families.

- **Where do you project we will be in the next two decades?**

Looking ahead, and taking into account how technology has evolved in the last century, here are some possible directions medicine may take:

- Health monitoring will be a part of everyone's life. Just like the oil light on our car warns that the oil is low, we will have more "early warning" systems to alert us to changes in our bodies, at a stage when disease is typically easier to treat, even through lifestyle changes.
- Health care delivery will be broadened with remote robotic surgeries, people will visit portals for both diagnosis and treatment rather than doctors' offices, pharmacies or hospitals of today, providing connection with medical professionals regardless of location
- Regenerative medicine will become a reality and allow for new organs and body parts to be created
- Wireless technology and interconnectability will become more ubiquitous: Personal user interfaces (future smartphones or personal communications devices) direct sensory connections (machine/brain interface), and image-guided surgery will proliferate
- Understanding of biological systems will present a daunting *informatics* and *computational* challenge. These will be the rate limiting factor in the biomedical technology advances of the next 50 years.
- Reversing the course of disease, repairing tissue and reconstructing organs with cell-based therapies, tissue engineering, and artificial blood
- Patient empowerment and cost pressures will lead to decentralization of healthcare delivery. Technologies that enable healthcare delivery at the point of care and in the primary care setting will become increasingly important.
- Specialized centers will evolve for the delivery of more routine diagnostics and treatment. Hospitals will be devoted to the diagnosis and treatment of complex disorders by teams of physicians focused on outcomes. Medical education will have to be drastically altered to allow these changes in medical practice to take place.
- Access to very large databases and decision support tools running on advanced computing platforms will play a major role in evidence-based medicine and comparative medicine in the next 50 years
- Diagnosis and treatment will no longer be distinct in most situations. Most diagnostic modalities will become portals for delivering therapy at the point of diagnosis.
- Technology improvements will enable better care for the elderly, and the very old. Centenarians are the fastest growing demographic segment in many countries, and this will extend to many more countries over the next 50 years.

- **What two or three things, if changed, would put us onto a better path and what would the future hold?**

1) Improve medical device market authorization processes

Effective regulation of medical devices is necessary for ensuring patient safety and protecting public health.

GE Healthcare believes that improving certain aspects of the medical device market authorization processes will enable the U.S. Food & Drug Administration (FDA) to successfully maintain the delicate balance between upholding patient safety and fostering the development of innovative medical devices that can significantly improve the lives of countless American seniors as well as help set standards globally.

Improvements such as better training and consistency among reviewers could help the timeliness of device clearance/approval, and protect public health.

Effective reforms that lead to a stronger more consistent FDA will go a long way in ensuring that America's seniors, as well as all Americans, have earlier access to cutting edge technology and that America continues to be a leader in healthcare technology innovation.

2) Move from "sick care" to truly preventive healthcare

The challenge we face is to transform our approach to health from one of disease treatment to one based on prevention, prediction and pre-symptomatic detection, with a long-term care paradigm focused on keeping patients out of hospitals and clinics and in the home care setting. This change, which is now technologically within reach, would save lives and reduce healthcare costs and enable seniors to lead longer, healthier lives contributing to society and the economy.

The World Health Organization has stated that 80% of heart disease, stroke and diabetes are preventable; 40% of cancers could be avoided by lifestyle changes. It also states that focusing on the common underlying risk factors common to most cardiovascular disease averted 14 million cardiovascular disease deaths between 1970 and 2000 in the United States. Prevention works.

Prevention, combined with prediction and early diagnosis enabled by the convergence of bioscience, diagnostics and IT, means that it is already possible to diagnose diseases undetectable in the 1980s. Health professionals currently have access to an array of technological advances, which they could not even dream of 10 years ago.

We do not have to wait for technological advances over a 20-year period; we simply need to apply the technologies and information systems already available. Accelerated take up of innovations that enable patient stratification, earlier diagnosis and treatment and care in the home, would transform the way health and medicine are delivered and help realize the much-needed transition from curative medicine to a new, predictive medicine.

Stratified screening followed by disease management, whether medical, nutritional, pharmaceutical or behavioral, requires the early identification of disease or risk of disease. Early management of a suite of chronic conditions that affect seniors, like rheumatic and

musculoskeletal disease, dementia, obesity, osteoporosis, cardiovascular disease and diabetes, would lead to earlier interventions which would drive better outcomes, and longer, healthier more productive lives for seniors, as well as generate improvements in the health economy and extend people's working lives. Changing our approach to healthcare from reactive to preventive combined with a move from institutional to community or home based care for long-term chronic conditions, would reduce hospitalizations, be more sustainable and efficient, and benefit not just patients, but the healthcare system as a whole.

Here are some additional facts regarding the chronic disease burden and the need for early diagnosis and preventive healthcare:

The aging and chronically ill are key cost drivers for the American healthcare system. Hospital stays and readmissions are on the rise.

Technology will enable the move from costly acute care in the future to the clinic setting initially and to the home setting ultimately. Home health monitoring of the elderly will transform disease management.

Dementia/Neurological conditions

The impact on society by the growing population of patients with dementia cannot be underestimated. The worldwide prevalence of dementia will increase by 85% over the next 20 years and more than triple by the year 2050. The current dementia population of 35.6 million people will nearly double to 65.7 million by 2020 and to 115.4 million by 2050 (ADI World Alzheimer Report 2010: The Global Economic Impact of Dementia estimated).

In the United States in 2011, 5.4 million Americans are living with Alzheimer's disease – 5.2 million aged 65 and over; 200,000 with younger-onset Alzheimer's. By 2050, approximately 16 million Americans will have the disease.

Dementia-related costs, currently estimated at $600 billion, will increase by 85% by 2030, a figure based solely on the predicted growth of the worldwide dementia population. In the United States in 2011, the cost of caring for those with Alzheimer's to American society will total an estimated $183 billion. This is an $11 billion increase over last year, a rate of increase more than four times inflation.

Diagnosis will undoubtedly shift from identification of signs and symptoms of neuronal failure to the non-invasive detection of specific biomarkers underlying the pathological process (Clark et al., 2008).

Cancer

The elderly are the most common group of patients in oncology practice today. With at least 60% of all cancers being diagnosed in patients older than 65 years, cancer in the aging patient and its treatment must be considered a first-line health problem.

According to data from the Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute, in the United States alone the estimated prevalence of people living with cancer as of January 2008 reached almost 12 million and of these, close to 8.5 million were aged 60 years or older. Although there is a paucity of trials on this population group, age should not be a barrier for adequate treatment in healthy elderly patients, especially in those with long life expectancy and good health status.

Furthermore, 60% of cancers are globally cured or become a chronic condition. This advanced prognosis has its toll not only in the expectancy of treatment but also in subsequent follow-up and post-treatment adverse effects that can be generated.

Chronic/cardiovascular disease

More than 130 million Americans – 45% of the population - have at least one chronic disease and this figure is expected to grow to about 165 million - or about 50% of the population - by 2025.

Chronic diseases are the leading cause of death and disability in the United States, responsible for 70% of all deaths, 81% of hospital admissions, 91% of all prescriptions filled and 76% of all physician visits.

The U.S. Centers for Disease Control estimates that eliminating three risk factors – poor diet, inactivity, and smoking – would prevent 80% of heart disease and stroke, 80% of type 2 diabetes and 40% of cancers.

Conclusion

The future of healthcare technology holds tremendous promise for increasing patient access to earlier diagnosis and treatment of disease, improving healthcare quality and decreasing healthcare cost.

All of us, hopefully, will experience the aging process, and healthcare innovation increasingly makes possible an unprecedented quality of life for seniors in which living old can be living well, and mean taking an active part in one's health.

We all know America was built on a premise of what might be possible – a notion that spurs great achievement. So it goes for healthcare technology and its role in helping people live healthier lives.

Thank you for allowing me to be a part of celebrating the 50-year achievements of the Senate Special Committee on Aging. If I may paraphrase Albert Einstein, "Imagination is more important than knowledge. For knowledge is limited to all we now know while imagination embraces the entire world, and all there ever will be to know."

Here's to long, healthy lives and the ability to dream of what might be possible.

Thank you for your time today.