Testimony Before the Senate Special Committee on Aging
Hearing on Technology and Prescription Drug Safety
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Good afternoon. Mr. Chairman and Members of the Special Committee on Aging, thank you for the opportunity to speak with you this afternoon regarding technology and prescription drug safety. I am Peter A. Klein, a pharmacist and Vice President of Business Development for En-Vision America. En-Vision America is a privately held company that was founded in 1996 to develop and market technologies aimed at assisting the Visually Impaired to live a more independent lifestyle. Our most recent invention has been developed into a commercially available product known as the ScripTalk™ Talking Prescription Label System. The ScripTalk™ System is a cost effective method that promises to enhance the Safety of millions of Senior Citizens as well as a staggering number of Americans afflicted by other conditions or situations that prevent them from reading or understanding the directions that appear on their prescription labels.

Currently, there are over **120 million** Americans who have difficulty reading or understanding the instructions of their prescription medications. In many cases, even identifying the contents of the prescription package is impossible. The small print and look-alike packaging of medicine vials can lead to confusion, non-compliance, and ingestion errors. The repercussions of such adverse events are immense and increase healthcare costs through additional hospitalizations, doctor office visits and changes to or addition of drug therapies.

En-Vision America set out to develop a technology that would allow the visually impaired to safely manage their own medication regimen. The result is the ScripTalk™ Talking Prescription Label System, which combines radio frequency identification technology with advanced voice synthesizer capability to deliver a cost effective solution for those unable to read or understand their prescription instructions.

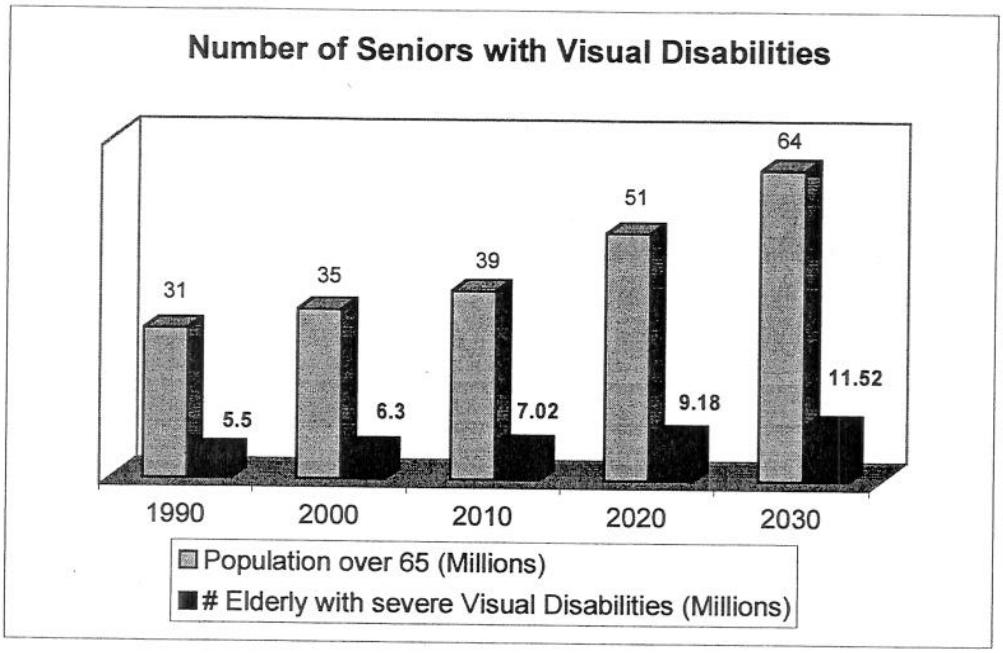
Medication errors have been in the forefront of the news lately. The seriousness of this issue has been articulated by Institute of Medicine (IOM) reports that state up to 2 million people are hospitalized from side effects or reactions to prescription drugs. The IOM survey, however, does not consider statistics related to poor therapeutic outcomes as a result of ***non-compliance***. A non-compliant patient does not achieve the expected benefit of their drug therapies, and their conditions may not improve or even worsen because they did not take enough medication or they did not take it at the proper interval, or worse yet, they overmedicated themselves.

Compliance cannot occur for up to 42% of United States Citizens due to their inability to read, translate, or comprehend the instructions and warnings that appear on their prescription containers. The ScripTalk™ Talking Prescription Label System eliminates this barrier to compliance by actually reading the text of a prescription label aloud to the user.

Seniors with Severe Visual Impairment

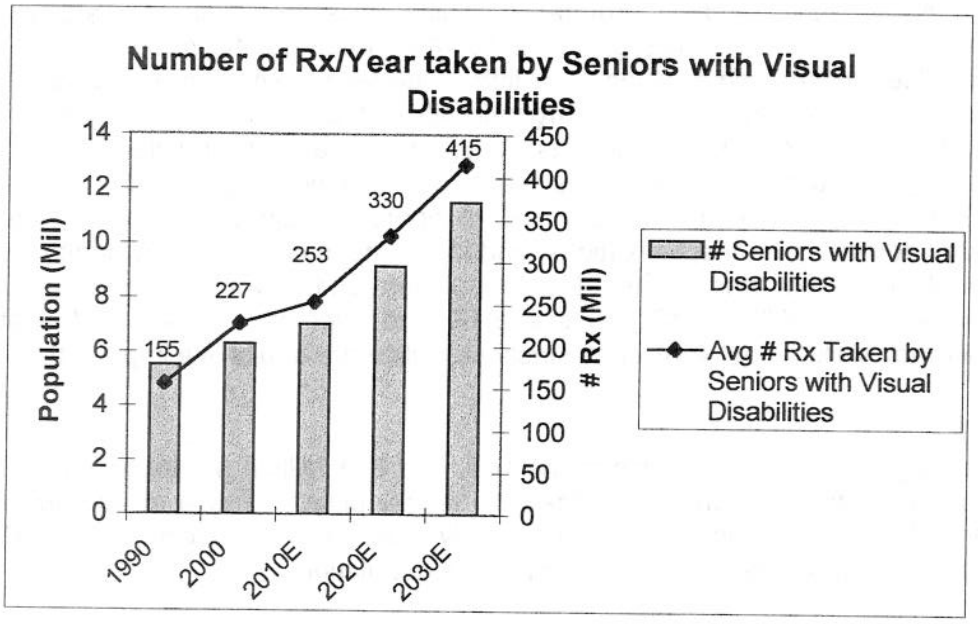
The United States Census Bureau reports that at least 18% of Americans over the age of 65 have a functional limitation seeing words and letters or are unable to see words or letters. There are currently more than 35 million Americans over the age of 65, and approximately 6.3 million may not be able to safely read the directions that appear on their prescription labels.

Exhibit 1 demonstrates the current population, along with well-known projections that depict "The Graying of America".



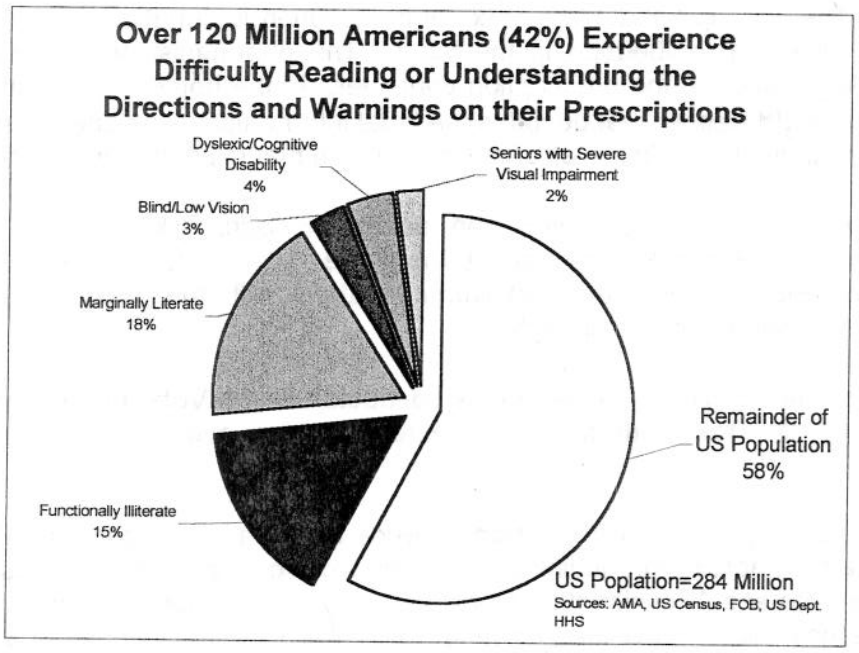
According to several Prescription utilization reporting agencies, Seniors over the age of 65 consume, on the average, 36 filled prescriptions annually. Therefore, in the year 2000, Seniors experiencing a visual impairment consumed over 227 million prescriptions. (See *Exhibit 2)* This means that 7% of the prescriptions dispensed in the US were for only 2% of the population, who may not have been able to read the instructions or warnings on the label. This alarming statistic illustrates the need for technology that enables this population to self-medicate.

Exhibit 2 examines the total number of Prescriptions taken by this Visually Disabled Senior population, based on recently reported statistics.



Others who would benefit from ScripTalk™

Seniors with visual impairment are not the only group who could benefit from the use of the ScripTalk™ System. **Exhibit 3** Illustrates other Segments of the population who would also benefit from ScripTalk™:



Health Illiteracy in the U.S.

Studies sponsored by the AMA have concluded that 90 million people in the U.S. have difficulty comprehending medical information, which limits their ability to care for their own medical problems. Of this group, 21% (40 million to 44 million people) are functionally illiterate (reading at or below a fifth grade level), while an additional 27% of adults (50 million people) are only marginally literate (having difficulty with reading comprehension and/or computational skills). These Americans are unable to read and/or understand prescription medication labels and auxiliary warning labels. Low health literacy skills cost the US health care system approximately $73 billion annually in unnecessary doctor visits, hospitalizations, and longer hospital stays. Low health literacy is particularly common among the older population and low-income people. Some studies indicate that 66% of US adults age 60 and over have either inadequate or marginal literacy skills; about 45% of all functionally illiterate adults live in poverty.

The Blind

There are roughly 8.8 million people in the U.S. and 80+ Million people worldwide that have visual disabilities and are categorized as "legally blind". Only a small percentage (less than 1%) of this population can actually read Braille, which renders Braille prescription labeling useless for the majority of the population.

Reading and Comprehension Difficulties

It is estimated that approximately 11 million people (4% of the US population) are severely affected by dyslexia (10% of the population "show some sign" of dyslexia).

How ScripTalk Works

When a patient using a ScripTalk™ reader submits a prescription, the pharmacy software prints and programs a Talking Label using a dedicated, small-footprint Talking Label printer. The Talking Label stores textual prescription information in an electronic format onto a microchip embedded in the label. The pharmacist or technician then places the Talking Label on the prescription container. In the home, the patient uses a hand-held ScripTalk™ Reader that decodes the label information using speech synthesis technology. The patient then *hears* all of the information that is printed on the label.

By simply moving the prescription within an inch of the ScripTalk™ reader, pertinent information such as, the name of the patient; the name of the drug; the dosage; general instructions; warnings; prescription (Rx) Number; along with the doctor's name and phone number are converted into speech.

A clinical trial of the ScripTalk™ system was conducted at the Veterans Administration Hospital in Hines, IL. The study began in September 2000 and concluded March 15, 2001.

Based on information provided to En-Vision America during a meeting in early April, we anticipate that a favorable report outlining the benefits of ScripTalk™ will be presented to the appropriate Veterans Administration officials. It is our understanding that the VA will then determine how the product may be made available to visually impaired Veterans. The Hines VA Pharmacy Chief who was involved in the initial Study has indicated his

interest in planning another Study to determine the usefulness of the product for marginally literate Veterans.

We at En-Vision America are confident that this technology will be of great benefit to the Elderly, visually impaired and functionally illiterate users. We are working diligently to create opportunities to make this technology available to as many Americans as possible. We appreciate the support of the Veterans Administration who recognized the need for such a technology within that Health System. Their support has been vital in helping us develop and refine the ScripTalk™ functionality.

Thank you so much for providing the opportunity to present information on our technology to the Special Committee.