This is to certify that the
thesis entitled

DESIGNING A SENIOR FRIENDLY AND
CHILD-RESISTANT OTC/PHARMACEUTICAL SOLID ORAL
MEDICATION/VITAMIN SUPPLEMENTAL
ORGANIZER/DISPENSER PACKAGE

presented by

AMY SUZANNE HOUGHTALING

has been accepted towards fulfillment
of the requirements for the

M.S. degree in Packaging

Harold Haugh
Major Professor's Signature

30 April, 2004
Date

*MSU is an Affirmative Action/Equal Opportunity Institution*

# DESIGNING A SENIOR FRIENDLY AND CHILD-RESISTANT OTC/PHARMACEUTICAL SOLID ORAL MEDICATION/VITAMIN SUPPLEMENTAL ORGANIZER/DISPENSER PACKAGE

By

Amy Suzanne Houghtaling

A THESIS

Submitted to
Michigan State University
In partial fulfillment of the requirements
For the degree of

MASTER OF SCIENCE

School of Packaging

2004

# DESIGNING A SENIOR FRIENDLY AND CHILD-RESISTANT OTC/PHARMACEUTICAL SOLID ORAL MEDICATION/VITAMIN SUPPLEMENTAL ORGANIZER/DISPENSER PACKAGE

By

Amy Suzanne Houghtaling

According to the U.S. Consumer Product Safety Commission, more than 600,000 older Americans are treated each year in hospital emergency rooms for injuries acquired at home. Approximately 10 to 25 percent of these injuries are caused by medication noncompliance (Smith, 1989).

There is evidence that suggests medication noncompliance is partially attributable to reduced cognition and hand dexterity, which is more common with the elderly population. However, people of all ages and abilities experience difficulty in using packages, such as child-resistant packages.

For this research, a solid oral pharmaceutical/OTC dispenser/organizer package was designed that requires minimal hand dexterity, while remaining child resistant. This newly designed package dispenses daily medications with the use of two fingers on the same hand.

A nonworking prototype of the package designed for this research was evaluated using 100 test subjects, individuals with and without disabilities, to obtain data that would be useful for the package research and development process.

By designing a package that is easy to use for people with and without disabilities, medication compliance can be improved.

For my wonderful husband Kevin, our son Tylor,

my parents Robert L. and Elise A. Berger,

my siblings Wendi, Noah, Jared, and Molly

and my grandmother Dorothy Berger (1912 – 2000),

with love.

# ACKNOWLEDGEMENTS

"Behind every initiative and every accomplishment there is a team of people dedicated to the success of the student and their research." – Author unknown

During my years of study, there has been much support from many people, including family, friends, professors and people in the packaging industry. Many people have influenced my work in a very positive way. My sincere thanks go to all of them.

Professor Harold A. Hughes, Ph.D., my major professor, was happy to provide me with the guidance, resources, and tools I needed during the process of this research, which included a visit to the 3D Media Center on the campus of the University of Michigan, Ann Arbor, Michigan, to see, first hand, the technology of rapid prototyping, a process used for the creation of prototypes. His open-mindedness allowed me to explore creativity and imagination in package design.

Professor Laura Bix, Ph.D., a valuable committee member, provided excellent resources and guidance on human factors, as well as enabling my package design to obtain needed protection by putting me in contact with Mr. Bradley Shaw and Mrs. Janyth Sherman at the Michigan State University Office of Intellectual Property. Dr. Bix also directed me towards invaluable package testing resources, such as Ellen Weaver and Paula Rehner of the Capital Area Center for Independent Living.

My thanks also go to rheumatologist Dr. Robert C. Shephard, M.D. and his friendly office personnel for providing me with many arthritic test subjects.

Professor Hugh Lockhart, Ph.D., another valuable committee member, also has my gratitude. His knowledge of pharmaceutical packaging has proven to be an invaluable part of my research. He extended my mind to the many regulations involved in packaging and the product being packaged.

Professor David Zachary Hambrick, PhD., from the Department of Psychology, also a valuable committee member, provided me with guidance, resources, insight, and humor that augmented and increased my knowledge of cognition, such as the cognitive skills that influence package use and medication compliance.

Mr. Javier De La Fuente, an industrial designer and fellow packaging student, provided his expertise for the mechanical development of my package; from the making of the package model to the three-dimensional computer generation of my package design. He has been a very important part of my research.

Professor Bruce Harte, Ph.D., Professor Susan Selke, Ph.D., Professor Robert LeMoreaux, PhD., as well as the rest of the packaging faculty and staff, provided guidance, resources and friendship, as well as broadened my knowledge of packaging and the packaging industry through courses and assistantship opportunities.

I would also like to thank fellow students and friends Napawan Kositruangchai, Krittika Tanprasert, Hsin-yen Chung, Uruchaya Sonchaeng, Dario Martino and other friends in the School of Packaging for their friendship.

My deepest gratitude goes to my husband, Kevin, our son Tylor, as well as to my parents Robert L. and Ann E. Berger, sisters and brothers, Wendi, Noah, Jared and Molly, and their families, whose love, enthusiasm and support enabled me to pursue and to complete my research and education.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

## Introduction

Two major functions of packaging are utility and communication. Package utility includes package usefulness and ease of use, whereas package communication provides information that leads to the purchase of a product, and promotes safe and economical use of a package and/or the packaged product. These functions are important for all products. When a package is difficult to open, problems ranging from frustration to severe injury and medication noncompliance can occur.

The utility and communication functions influence medication compliance. Medication compliance is the act of taking the correct dose of the correct medication at the correct time. Medicines can only help if they are taken as prescribed.

Problems with package utility and communication happen because most packages are designed for people with normal physical and psychological abilities, including people with normal hand dexterity, adequate vision, and no serious physical disabilities.

Injuries, frustration, and medication noncompliance can happen to anyone, especially within the aging population. Because modern medicine, science, and technology, in this country, has brought the majority of infectious disease epidemics under control, people born in this country can expect to live about 78 years (Arias & Smith, 2003). Life expectancy in the United States has risen by 18.5 years since 1930, when it was about 59 years (Minino & Smith, 2001). This increased life expectancy will consequently result in a greater portion of our population being inflicted with degenerative diseases, such as arthritis, osteoporosis, diabetes, hypertension, heart

disease, incontinence and physical frailty. These conditions are becoming increasingly our largest healthcare problem (Spirduso, 1995).

As the population ages a rise in medication noncompliance will increase. Studies have shown that medication non-compliance causes 125,000 deaths annually in the U.S. (Smith, 1989). It leads to 10 to 25 percent of hospital and nursing home admissions, and is becoming an international epidemic. It is, in the words of The New York Times, the world's "other drug problem" (Zuger, 1998).

Legislation specific to packaging that protects children from accidental poisonings and protects all users from product tampering, is administered by the Food and Drug Administration (FDA). Label legibility is also regulated by the FDA to help people read and understand the provided information.

Legislation has improved the usability of certain products for individuals with disabilities, but does not include package design. Public Law 104-104, The Telecommunications Act of 1996, requires telecommunication manufacturers and service providers to ensure that equipment is designed, developed, and fabricated to be accessible to, and usable by, individuals with disabilities, if this is readily achievable. Existing legislation, which aids people with disabilities, may lead to legislation that promotes consumer-friendly packaging.

Many companies use consumer friendly packaging because people associate consumer-friendly packaging with product quality. These companies design product/package systems to keep loyal customers and to attract more consumers (McMath & Forbes, 1998).

The purpose of the project discussed in this thesis was to design a child-resistant, solid oral, pharmaceutical/over-the-counter/vitamin supplemental organizer/dispenser (CRMOD) package that is universally designed. For a package to be considered "universally designed", it must be useful for healthy adults, as well as for adults with abilities that are affected by the effects of aging and disability.

Applying universal design to a package requires the careful consideration of human factors and ergonomics. Ergonomics, generally defined as the study of human beings and their interaction with products, environments, and equipment in performing tasks and activities, can be used to improve the utility and communication of packages, making packages easier to use and understand. Ergonomics, the design of products to be user friendly, can enable a person to encode (read), comprehend, and comply with the instructions given (Bix, 2001 and Rousseau et al, 1998).

Based on the above information, the objective of the project was to design and evaluate a CRMOD package. Testing was performed to determine if the techniques for using the new package are easy to learn and understand.

The research presented in this document also includes specific human and package interactions that occur while using pharmaceutical/over-the-counter (OTC) medication/dietary supplement packaging, with an emphasis towards the abilities of the elderly population.

The fundamental hypothesis of this research was that, by manipulating specific packaging components of a CRMOD package, a more consumer-friendly and child-resistant package will result.

## Chapter 1: Literature Review

### *Why Design a Consumer-Friendly and Child-Resistant Pharmaceutical/OTC Organizer/Dispenser Package?*

Designing a consumer-friendly and child-resistant solid oral pharmaceutical multi-compartmental organizer and dispenser (CRMOD) package that is universal, as well as reusable, will be beneficial. Although many people with decreased hand dexterity experience difficulty when using packages, there are many people with normal hand dexterity that also experience difficulty with packages (Ibberson, 2000).

Difficulties with package opening, closing, and reading and comprehending instructions, are common. These problems occur because many packages are designed for people with normal physical strength and eyesight.

> Consumer frustration, injuries, and death have occurred as a result of difficulties with package use. When people can't open a package they become frustrated. This frustration often results in people not taking their medications, or they take measures of opening the package into their own hands. Very often, people will try to open the package using inappropriate tools, such as opening packages using knives. These tools often result in accidents. It has been reported that packaging related accidents involving knives account for 6% of all the reported accidents (Ibberson, 2000).

Many people of all ages are taking dietary supplements for overall health, as well as to supplement their exercise regime. According to Mediamark Research, Inc., 10.8% of the 193,462,000 adults studied used calcium supplements, with garlic and multi-vitamins following at around 7.5% (Mediamark Research, 1997). Because the population is growing, and because studies continue to indicate the benefits of taking vitamins, it is predicted that more people will be using them.

***Why Design a Consumer-Friendly and Child-Resistant Pharmaceutical/OTC Organizer/Dispenser Package for the Aging Population?***

*Medication Noncompliance*

As the population ages, the effects of medication noncompliance are expected to affect more people. Medication compliance, which is the taking of the correct medication, in the correct quantity, at the correct time, is a major problem in U.S. healthcare today. This is evident from the number of people who are hospitalized or die each year because of medication noncompliance, and is especially severe in the elderly population. Liability and insurance costs, which result in the loss of money to the economy, are also affected by medication noncompliance.

> Almost 50% of the 1.8 billion prescription medications, dispensed annually, are not taken correctly by patients. One researcher has estimated that only one-third of all patients take all their prescribed medicine, while one-third take only some, and an astonishing one-third take none at all. In Oregon, nearly 10% of all hospital admissions have been reported to be the result of pharmaceutical noncompliance. The U. S. Chamber of Commerce estimated, in 1984, that medication noncompliance caused a $13 – 15 billion loss to the economy due to increased use of medical resources, unnecessary physician visits, therapeutic failure and prolonged illness (Smith, 1989 and Lockhart, 2002).

Health conditions that must be treated with medications become more common when people age. These health conditions, when coupled with the side effects of some medications, can negatively affect the body. This phenomenon is the focus of Pharmacokinetics. Pharmacokinetics is the study of the action of drugs in the body, including the processes of absorption, transformation, distribution to tissues, duration of action and elimination.

*Disability*

A person is considered to have a disability if he or she has difficulty performing certain functions (seeing, hearing, talking, walking, climbing stairs, and lifting and

carrying), or has difficulty performing activities of daily living, or has difficulty with certain social roles (doing school work for children, working at a job or around the house for adults). A person who is unable to do one or more activities or uses an assistive device to get around, or who needs assistance from another person to perform basic activities, is considered to have a severe disability (U.S. Department of Commerce, 1997).

Many people do not admit, or believe, they have a disability. For those that do admit to having a disability, about in 1 in 5 Americans ages 5 and over, 47.9% of the total population, have some form of disability, and 1 in 10 have a severe disability (United States Department of Commerce, 1997). And, with the population aging, as well as the likelihood of disability increasing with age, the growth in the number of people with disabilities can be expected to accelerate in the coming decades.

> About 9 million people of all ages have disabilities so severe that they require personal assistance. Disability occurs with any age, sex, or race. Even among children aged 6 to 14, for instance, 1 in 8 had some form of disability. Nevertheless, the likelihood of having a disability increases with age – half of seniors aged 65 and older have a disability (U.S. Census Bureau, 2002).

The health of many older Americans is threatened by chronic conditions. Statistics for the most prevalent chronic conditions, since 1995, state that 88% of Americans aged 65 and over have at least one chronic health condition, such as arthritis, hypertension, heart disease, or cancer (King & Buchner, 1998).

*Child Safety*

Even though special packaging is now required for use with 30 household substances by the Consumer Product Safety Commission (CPSC), child poisonings still occur. Public Law 91-601, the Poison Prevention Packaging Act, which was passed by

Congress in 1970, seeks to protect small children by requiring that dangerous household substances be sold in special packages that are child-resistant (CPSC, 2003).

The CPSC estimates over 900 children's lives have been saved since the law was passed (CPSC, 2003). However, there are still thousands of serious accidental poisonings occurring every year in the United States. About 30 fatalities from poisoning of children under the age of five occur each year (Bush, 2003). Some of these accidents occur because the child-resistant feature has been disabled by an adult to avoid difficulties with child-resistant features, or because of accidental failure to enable the child-resistant feature.

Child poisonings are expected to increase proportionately with the aging population growth. In the United States, approximately five to six percent of grandchildren, and ten percent of grandparents, live in grandparent-grandchild households at any given time (Pebley & Rudkin, 1999). Many poisonings occur when children visiting grandparents explore the medicine cabinet or grandmother's purse.

*Physical and Cognitive Changes Associated with Aging*

Apart from life, aging is one of the few experiences shared by every human. Although all people age, they do so in different ways and at different rates. Some people live longer and have a higher quality of life than others. Gerontology is the study of these differences, their causes, and the factors that amplify or attenuate them (Spirduso, 1995).

Chronological age is the amount of time between birth and date of observation. The physical dimension of age and meaning of time depend on the biological, psychological, and social significance attached to it. Biological processes that occur in

youth are thought of as developmental, whereas time-related changes that lead to disability and dysfunction are thought of as aging, or senescence (Spirduso 1995).

Aging is a process, or group of processes, occurring in living organisms that, with the passage of time, lead to a loss of adaptability, functional impairment, and eventually death.

Aging is classified as normal (primary or universal) aging and secondary aging. Normal aging is associated with the loss of vision, hearing, strength, and cognition, which are independent of disease. Secondary aging is accelerated aging that occurs as a result of disease or environmental factors. Hearing, vision, and cognition are important for communication, whereas physical strength is important for physical ability (Spirduso, 1995).

*Age-Related Changes in Audition (Hearing)*

Hearing is crucial for humans, since most of the time we relate to each other through verbal communication. Hearing loss is thought by many to be the most devastating handicap of all, frequently resulting in withdrawal from interactions with society and meaningful people such as family and friends. Subtle changes in hearing usually begin in the 40s and progress gradually with age. It has been estimated that 55 percent of those over age 65 have some hearing loss, while by age 80, 66 percent have serious hearing problems (Saxon, 1987).

Changes in audition occur with primary and secondary aging. Specific aging changes in audition include the pinna losing some of its original flexibility. The pinna also becomes larger and wider. Hairs in the external ear canal become stiffer. Decreased flexibility of the tympanic membrane reduces the acoustic reflex, which is a protective mechanism that contracts in response to loud noises (Saxon, 1987). (Figure 1)

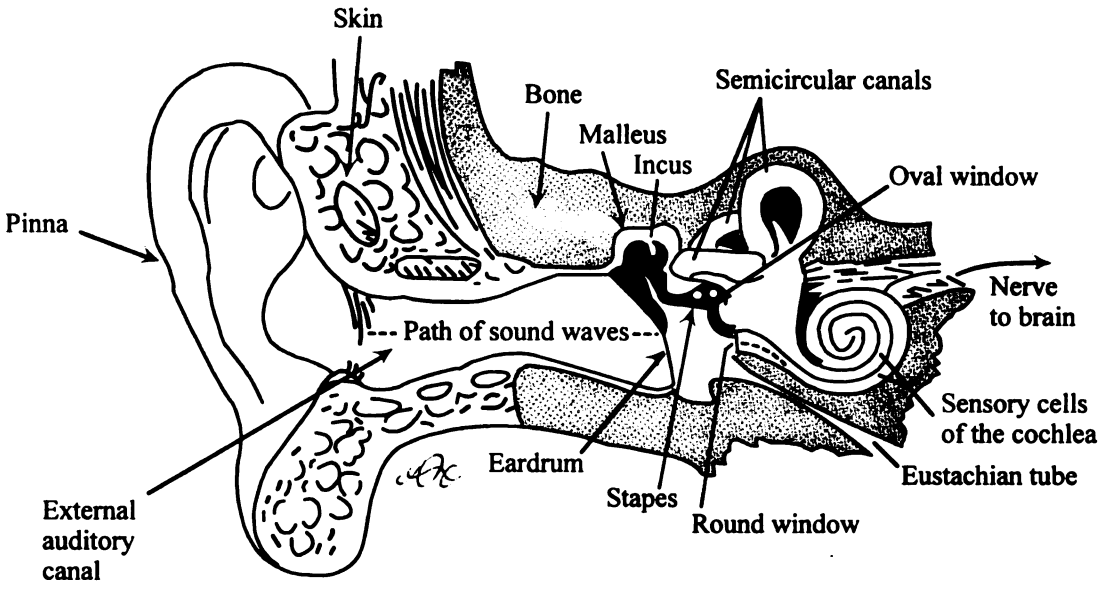



Figure 1 – Structure of the Human Ear

Presbycusis, the loss of hair cells in the cochlea, eventually produces hearing impairment. This age related auditory loss occurs gradually, with the perception of high frequency sounds usually being affected first. Later changes may involve middle and low frequency ranges as well. In our culture, men tend to show hearing loss earlier than women. If the speculation that more males than females have been exposed to high level occupational noise is correct, sex differences in auditory loss could be primarily due to environmental exposure, rather than to inherent sex-related differences. Speech intelligibility is especially affected (Saxon, 1987).

An important bit of information is that those that have been affected by hearing loss are reluctant to admit it. Therefore, oral instructions might be only partially understood. Loss of this function increases the importance of label reading comprehension.

Hearing changes can also affect the ability to hear a package noise, such as the snap of a child-resistant lock being engaged.

*Age-Related Changes in Vision*

Aging adults have a decrease in visual acuity. This is because several changes occur in the eye as a result of aging. (Figure 2)

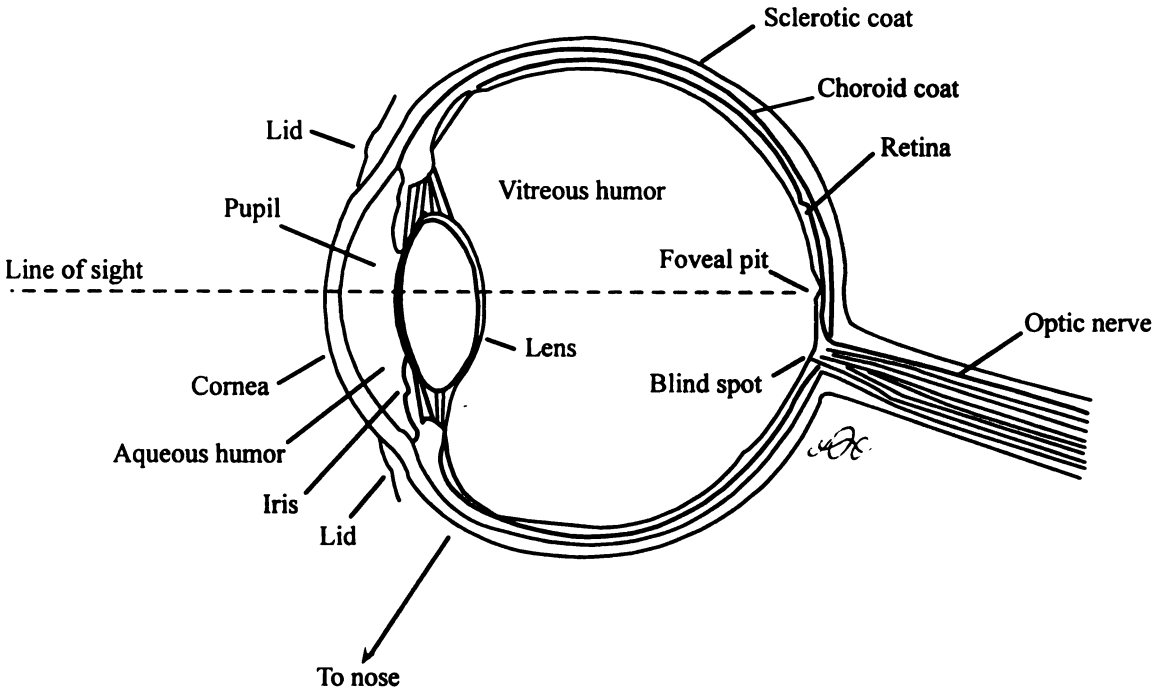



Figure 2 – Structure of the Human Eye

With advancing age, the cornea flattens somewhat, causing reduced refractive ability. There is also a tendency toward corneal astigmatism due to subtle changes in the shape of the cornea in the older eye. With time, a grayish-yellow ring tends to form along the iris-sclera border (arcus senilus). Another age-related change in the iris is that some fading of the color occurs, which results in eyes of older individuals not appearing as lustrous as the eyes of younger individuals (Saxon, 1987).

The pupil size decreases with age. It is estimated that reduced pupil size and the yellowing of the lens, with age, may result in a 60-year-old individual's retina receiving only approximately 30 percent as much light as the retina of a 20-year-old. Lens

changes with age have several effects on the efficiency of the visual system (Saxon, 1987).

The vitreous humor becomes less gel-like and more liquid-like with age. It also becomes less transparent and causes light rays to scatter as they pass throughout the vitreous humor to the retina causing blurred vision and opacities known as "floaters", which are loose cells casting shadows on the retina (Saxon, 1987).

The retina, referred to as an extension of the brain, has decreased blood flow with age, as well as some loss of rods and cones. Light and dark adaptation decrease with age. There is a higher threshold of sensitivity with age so that more light is needed to adequately stimulate visual receptors. Visual threshold refers to the minimum amount of light that will stimulate the rods or cones and trigger nerve impulses to the brain (Saxon, 1987).

The final visual change of significance for visual coping and adaptive behaviors is a decrease in visual acuity (sharpness of vision). Visual acuity decreases with age. Visual acuity is poor in children, improves in young adulthood, and begins to decline gradually at about age 40. Changes in the lens, pupil size, composition of the vitreous humor and ability to shift from near vision to far vision serve to decrease the sharpness of visual images as we grow older (Visual Expert, 2002).

The decrease in visual acuity with age presents a need for better legibility, which begins with the sizes and fonts used. To effectively notice and decode (read) printed label information, consumers must physically perceive the text using their vision (Rousseu, 1998 and Bix, 2001).

*Age-Related Changes in Grip Strength*

Bone and muscle mass develop together during youth, and decline together during aging (Spirduso, 1995). Beginning in the mid-20s, the rate of bone formation begins to fail to keep pace with resorption, in which bone loss occurs. By age 90 some women have lost 90% of their cancellous bone mass, whereas for men it is usually 10% to 25%. This loss of bone is related to hormonal changes that occur as the body ages (Spirduso, 1995).

Bones are linked together at articulations (joints) by ligaments, tendons, and connective tissue. The attachment is also supported by the muscles that cross the joint. A smooth, rubbery covering of hyaline cartilage covers the ends of the bones so they can move with relatively little friction. This cartilage also absorbs shock when the two bones are pressed together by muscular action using external forces. Joint flexibility is described by the extent to which the linked bones can be moved before being stopped by bony structures or tight ligaments (Salvendy, 1997). (Figure 3)

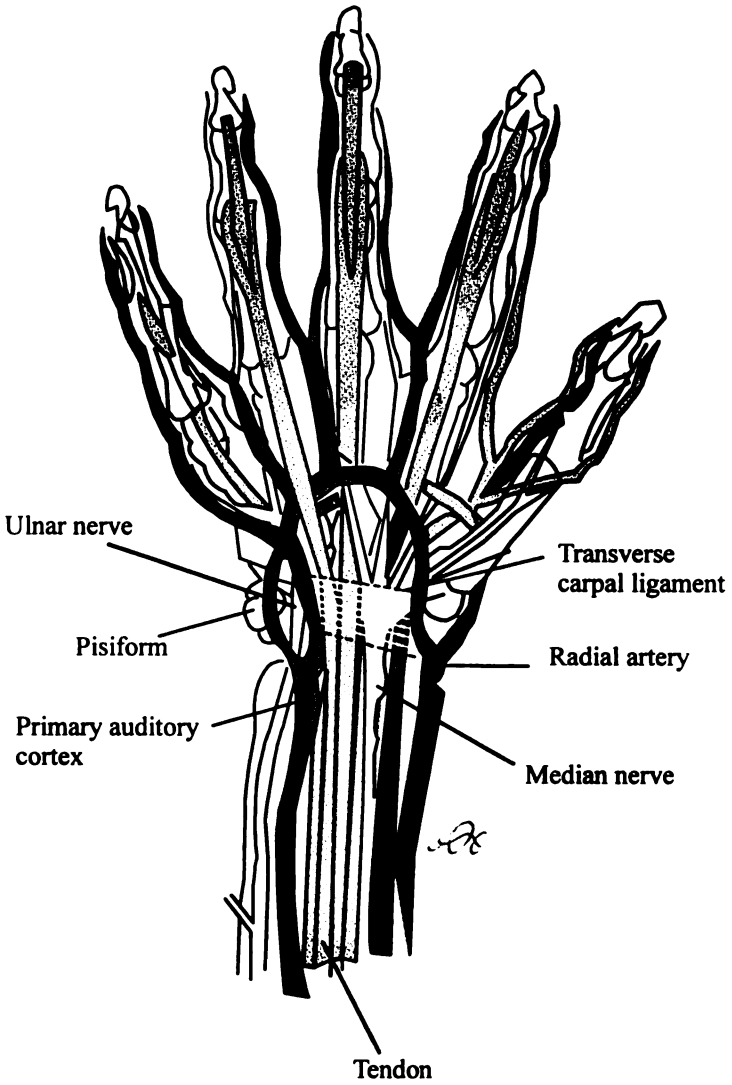



Figure 3 – Structure of the Human Hand

Adults lose a significant amount of flexibility as they age, and these losses can be measured when individuals, themselves, actively move the limb through the range of motion or when the clinician passively moves the limb (Spirduso, 1995).

Exercise contributes significantly to joint stability and flexibility. Resistive exercises enhance the tensile strength of tendons and ligaments, and flexibility exercises maintain suppleness of tendons, ligaments, and muscles, thus promoting full range of

joint motion. Stretching exercises are important for middle-aged and older people (Spirduso, 1995).

Chronic diseases, such as osteoporosis and osteoarthritis, cause significant disability in the elderly. These diseases affect nearly 80% of adults over the age of 65 (roughly 6 million people) (Spriduso, 1995). Nearly all older adults suffer from some degree of osteoarthritis, and this may limit hand strength and the ability to manipulate fingers. Several researchers have found that older adults have difficulty opening containers with child-resistant closures (Fisk & Rogers, 1997).

It has been found that grip strength is related to aging. A study was done to find changes in grip strength on 847 males within ages 20 to 100 using a grip dynamometer, which measures the maximum amount of strength that an individual can produce in gripping. This study showed that grip strength loss with age differed greatly among the population. Most people lost strength, but some did not. Some older subjects lost less strength over a 10-year period than did the middle aged and young subjects, while 29% of the middle aged subjects, and 15% of the older subjects, lost no strength at all. According to Table 1, the average grip strength for a 50 year old is 100 kg and begins to decline from there. An average of 95 kg is the grip strength for a 60 year-old, whereas average grip strength of 85 kg is had by a 70 year-old. A grip strength average for an 80-year old is 70 kg (Spirduso, 1995).

Table 1 – Age and Corresponding Average Grip Strength (Spirduso, 1995)

| Age, Years | Average Grip Strength | |
|---|---|---|
| | lbs | kg |
| 20 | 47 | 103 |
| 30 | 48 | 105 |
| 40 | 47 | 104 |
| 50 | 45 | 100 |
| 60 | 44 | 97 |
| 70 | 39 | 85 |
| 80 | 33 | 72 |

*Age-Related Changes in Cognition*

Understanding the cognition involved in using products and packages is important to prevent an increase of the effects of noncompliance, such as hospitalization and death. This emphasis on cognition, as it relates to safety, can eliminate difficulties experienced while using child-resistant packaging (Better Packages, 2004).

Memory impairments affect more than one-third of men and women ages 85 and older (Federal Interagency Forum on Aging-Related Statistics, 2000).

> In order to accurately adhere to a complicated regimen, an older adult has to comprehend instructions on each medication, use working memory to integrate those instructions into a daily plan, use long-term memory to remember what the plan is, and, finally, engage prospective memory to remember to take the medication (Park & Schwarz, 2000).

There are mechanisms that have been hypothesized to account for age differences in cognition, which include the speed at which information is processed, memory, reasoning performance, inhibitory function, and spatial visualization. Each of these mechanisms can be thought of as a type of cognitive or processing resource, and one author has suggested that combinations of these mechanisms may be an even better estimate of cognitive resource than any single measure (Park & Schwarz, 2000).

Salthouse suggests that the fundamental mechanism that accounts for age-related differences in performance is the decreased speed of performing mental operations. He collected a large amount of evidence that indicates nearly all age-related differences on almost any kind of cognitive task, ranging from memory to reasoning, can be explained by the rate at which the individual makes quick comparisons on perceptual speed tasks (Park & Schwarz, 2000).

> Perceptual speed tasks are simple paper-and-pencil measurements that require the individual make rapid perceptual same-different judgments about pairs of digit or letter strings or two similar symbols. Speed of processing is measured by the number of comparisons correctly made in a fixed period of time. The important mechanism responsible for the relationship between speed of processing and cognition is the limited time mechanism, which suggests that the time to perform later operations is greatly restricted. Older adults' performance will differ substantially from younger adults on tasks such as working memory, recall, and reasoning slowing even though these tasks do not necessarily appear to have a speed component (Park & Schwarz, 2000).

*What is Cognition?*

Cognition can be thought of in terms of functions of the brain, such as memory, association, comparison, abstract reasoning (verbal and quantitative), spatial ability and manipulation, and synthesis. The process of cognitive attention (mental energy), working memory, information processing speed, psychomotor ability, and perception support the cognitive functions and processes interact to enable individuals to make decisions and behave intelligently. Tests have been developed with the hope of assessing the application of brain functions to psychological and social function. However, much is yet to be learned (Spirduso, 1995).

*Mechanisms of Cognition and the Brain*

Mechanisms of cognition are controlled by the brain. The brain, as illustrated in Figure 4, has three major regions: the hindbrain, the midbrain, and the forebrain (Neath & Suprenant, 2003).

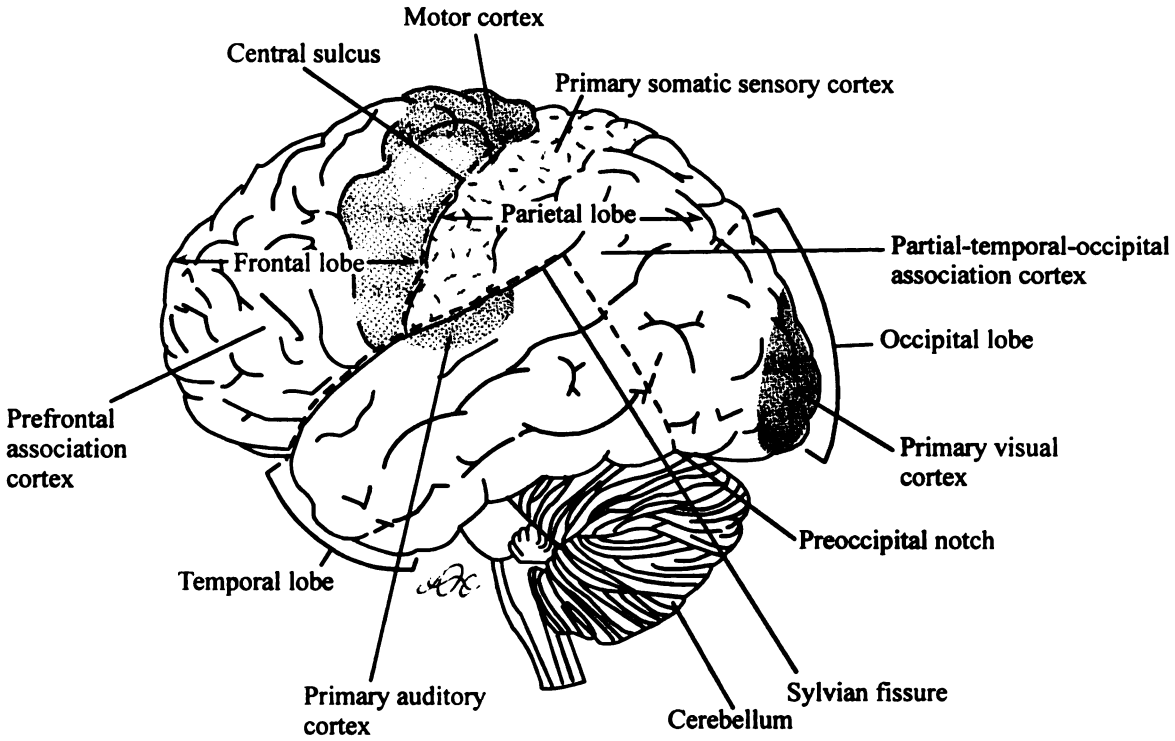



Figure 4 – Structure of the Human Brain

The hindbrain, including the cerebellum, is responsible for the coordination of movement and regulates basic body functions. The midbrain, which is located between the hindbrain and the forebrain, is involved in reflexive responses. Also included in the midbrain are dopamine-releasing neurons that control smooth motor-skill movement. The forebrain is associated with complex thought and cognition (Neath & Suprenant, 2003).

The thalamus, the hypothalamus, and the limbic system are part of the forebrain. The thalamus can be thought of as a sensory relay station. Structures that surround the

thalamus are the amygdale, the septum, and the hippocampus. The amygdale is an evaluation system that contributes to feelings of fear and anger. Damage to the amygdale impairs the evaluation of stimuli. The hippocampus has been identified as an important structure for memory (Neath & Suprenant, 2003).

The frontal lobe is responsible for motor control and contains an area called the motor cortex, which controls the precision of motor control. Frontal lobes are important for a number of memory functions (Neath & Suprenant, 2003).

Memory is not the function of any single structure, but is a part of local operations carried out in all cortical areas where the information to be remembered is processed and perceived. Memory, a mechanism that is part of cognition, enables the use, or retrieval, of information that was previously decoded and processed. Memory can be divided into five major categories. These are procedural memory, the perceptual representational system, primary procedural memory, which includes short-term memory and working memory, episodic memory and semantic memory (long-term memory).

Procedural memory is responsible for learning associative relations, simple relations, simple conditioning, and motor and cognitive skills.

Primary procedural memory is for the learning and retention of a wide assortment of motor and cognitive skills, such as playing the piano, driving a car, solving a jigsaw puzzle, and reading. These abilities have a large automatic component associated with them, and typically do not involve the conscious recollection of the initial learning episode (Park & Schwarz, 2000).

Short-term memory is a memory store that holds information for a short period of time. Information within this store is forgotten over time if the information is not rehearsed (Neath & Suprenant, 2003).

Working memory is the ability to hold some information in mind while you're doing something else (Hambrick, 2003). Working memory capacity, the extent to which a person can control and sustain attention during interference and distraction, varies among individuals.

The speed of performing mental operations, such as those involved in working memory, affects free and cued recall. Free recall is a task in which individuals recall a list of items in any order. Cued recall is when individuals recall previously presented items with a cue.

*Cognitive Processes in Using Products/Packages*

Using products or packages involves a decision process. The decision process involves three phases:

- Assembling all possible information about alternatives
- Analyzing the possible courses of action and outcomes
- Selecting the best alternative

In the case of using pharmaceutical/OTC packages, the decision process also includes the awareness that a medication needs to be taken.

Along with the awareness that a medication should be consumed, it is also important the medication being taken is the correct medication that is taken in the correct amount and at correct time. Poor short-term memories, especially in people with

diseases that alter memory, impaired visual acuity, and reduced physical strength, negatively affect medication compliance.

Cognition is an important aspect of package use that can improve medication compliance.

> "Visual acuity and cognition are the most important human functions of opening a senior friendly and child-resistant package. People need to get away from designing packages that require strength because the elderly tend to have deceased dexterity. Designing a package that requires the cognitive abilities to open a package using two or three steps is beneficial for keeping young children out of packages." (Fuller, 2002)

*Cognitive Change Theories*

Lifespan development consists of dual processes of gains and losses. Two of the theories used to explain the effects of normal aging on memory are the disuse view and the multiple systems view.

The disuse view of age-related declines has been termed the "use it or lose it" view. The analogy is to muscles, where exercise increases performance, and lack of exercise induces atrophy, or physical and psychological degeneration and weakening.

The multiple systems view states that memory can be broken down into a number of functionally different memory systems, including episodic, semantic, and procedural memory, with episodic memory being the last system to develop and the first system to be impaired (Neath & Suprenant, 2003).

Age differences will be small or nonexistent for tasks that require the use of semantic memory, but are greatly affected for tasks that use episodic memory. It has been suggested that the "process" is affected rather than the system.

*Problems with Cognitive Claims*

Although there is statistical evidence for physical aliments, such as for the proportion of elderly people with arthritis, it is not as easy to provide definitive evidence for decreases in cognition, even though there is a great deal of scientific evidence indicating that mental processes become less efficient during the process of aging. This is because adults compensate for losses by using acquired knowledge. There is strong evidence that indicates growth of knowledge and experience helps to compensate for decreases in cognition, making decreases in cognition more difficult to measure (Hambrick, 2003).

Stereotyping, preconceived or oversimplified generalizations about an entire group of people without regard for individual differences, has an impact on performance. Even when stereotypes are positive they can lead to discrimination. Stereotypes make cognition difficult to study because people tend to live up to how others perceive them. Stereotypes suggest that elderly individuals are slower at performing many tasks and have poorer memories than when they were younger.

*Prevention of Age-Related Cognitive Declines*

Exercise plays a large role in health. Exercise has been proposed to directly affect major areas of brain function:

- cerebrovascular function
- cerebral neurotransmitter balance
- cerebral neurotransmitter function
- neurotransmitter balance
- neurotransmitter function
- neuroendocrine tone

Exercise maintains cerebralvascular integrity by increasing oxygen transport, which reduces hypoxia (lack of oxygen) in active brain regions. Cerebral hypoxia is common among older people in poor health. Oxygen is essential for the metabolism of glucose, the brain's fuel, and it also is a critical ingredient for the metabolism of norepinephrine, and serotonin (Spirduso, 1995). With regular exercise, these types of diseases can be postponed or prevented.

### *Guidelines for Consumer-Friendly Package Design*

Utility and communication functions of packaging play a large role in ease, and hindrance, of product use. Difficulty with using a package can occur with people of all physical and psychological abilities. To increase consumer-friendliness with products and packages it is important that utility and communication functions, based on physiological and psychological abilities, be understood and implemented. Universal Design and the science of human factors engineering are ways to improve these functions.

#### *Universal Design*

Universal Design includes seven principles that may be applied to guide the design process and to educate both designers and consumers about the characteristics of more usable products and environments, but not all of the principles may be relevant to all designs. The seven principles that are depicted in Table 2 include equitable use, flexibility in use, simple and intuitive use, perceptual information, tolerance of error, low physical effort, as well as size and space for approach and use.

Table 2 – Universal Design Principles (Betty, Rose, et al, 1997)

| Universal Design Principles | | |
|---|---|---|
| Principle Number | Title | Description |
| 1 | Equitable Use | The design is useful and marketable to people with diverse abilities |
| 2 | Flexibility in Use | The design accommodates a wide range of individual preferences and abilities |
| 3 | Simple and Intuitive Use | Use of the design is easy to understand, regardless of the user's experience, knowledge, language skills, or current concentration level |
| 4 | Perceptual Information | The design communicates necessary information effectively to the user, regardless of ambient conditions or the user's sensory abilities |
| 5 | Tolerance for Error | The design minimizes hazards and the adverse consequences of accidental or unintended actions |
| 6 | Low Physical Effort | The design can be used efficiently and comfortably and with a minimum of fatigue |
| 7 | Size and Space for Approach and Use | Appropriate size and space is provided for approach, reach, manipulation, and use regardless of user's body size, posture, or mobility |

The principles of Universal Design address only universally usable design, while the practice of design involves more than consideration for usability. Designers must also incorporate other considerations such as economics, engineering, cultural, gender, and environmental concerns in their design processes. The Universal Design principles offer designers guidance to better integrate features that meet the needs of as many users as possible (Rose, Betty, et al, 1997).

*Human Factors*

The science of human factors, synonymous with ergonomics, is a collection of human properties and interactions with products, environments, and equipment in

performing tasks and activities. The term "human factor" encompasses both physiological and psychological, and covers most factors affecting human performance (Salvendy, 1997).

Throughout history, human factors knowledge has been implemented to make equipment easier to use. Applying human factors to packaging and products has and will continue to make packaging and products more consumer-friendly.

Human factors, first used in the 1940s, provides information that should be used when designing for humans. However, before the identifying title of human factors existed, much work in this area had already been accomplished. Charles Babbage, in his 1932 book "Economy of Machinery and Manufacture", described methods for making worker's jobs easier and more economical, which was based on the principle of "division of labor" earlier formulated by Adam Smith in his "Wealth of Nations", in 1776 (Burgess, 1986).

Human factors has largely proven its worth in military and space flight applications. It has been making a major impact in civilian and industrial applications. Ergonomics is cost effective and improves compatibility of the machines, products, and packages with their users, which can be seen in reduced human error and increased productivity (Burgess, 1986).

*History of Human Factors*

The science of human factors is also known as human engineering. The U.S. Navy used the term human factors; whereas the other branches of the U.S. military used the term human engineering. During World War II, new and complex war machines were required, and the concept that machines, not personnel, win wars, gave way to efficient man-machine relationships. Before long, many scientific disciplines were

being consulted. These disciplines included psychology, engineering, anthropometry, and physiology. The Department of Defense issued human engineering standards for the design of military equipment for the Army and human factors information for the Air Force and the Navy. This work was based on 90% of the adult males acceptable for certain segments of military service (Tilley, 1993).

By the 1960s, a systematic gathering of data was ongoing, and the U.S. Department of Health, Education, and Welfare published "Weight, Height, and Selected Body Dimensions of Adults". In the 1970s, the Society of Automotive Engineers made a very useful survey of children, from two-month-old infants to eighteen-year-old youths. In the 1980s, the elderly were measured when it became evident that they were becoming a large segment of the population (Tilley, 1993).

In 1990, the Americans with Disabilities Act (ADA) became law and prohibited discrimination on the basis of disability. The act provides rules of accessibility and protection for wheelchair occupants, for the blind and visually impaired, and for the deaf and hearing impaired.

In the Telecommunications Act of 1996, Section 255 required telecommunications products and services to be accessible to people with disabilities, requiring the design of products to be compatible with adaptive equipment used by people with disabilities, where readily achievable.

*Human Factors Implementations*

The field known as human factors recognizes that there are capabilities and limitations of the human organism (HO), which include sensory limitations, information processing limitations, and limitations of the effector subsystem (Burgess, 1986). These

capabilities and limitations directly affect the ability of a HO to perform specific tasks, such as the use of prescription or OTC medication packages.

Sensory limitations that include the auditory modality (hearing mechanism), the visual modality (sight mechanism), and other sensory limitations, such as touch and smell, have an influence on a person's ability to make decisions. Cognitive information processing skills used in making decisions include expectancies, objectivity, memory and data processing, emotionalism, boredom and sensitivity to stress (Burgess, 1986).

Capability and limitations of the effector subsystem are affected by body measurements, a human factor study area known as anthropometry. Anthropometric data is useful for designing a machine, or product, based on body size characteristics, in which there are bio-mechanical limitations (strength, response-speed, and tracking capability) and sensory limitation in space perception (Burgess, 1986).

There are many measurement tools involved in gathering data of the body size and its components. Because of this, anthropometry is time-consuming and expensive. The most complete and reliable information has been prepared by the military forces, while civilian data is not complete.

Large samplings, such as 2000 to 4000 men and women, are needed because a large sample produces greater accuracy. Several types of measurements are taken and then plotted on a graph, with the measurements on the horizontal axis increasing towards the right from the zero point. The frequency of occurrences is plotted vertically on the axis, increasing toward the top from the zero point. A smooth curve averaging a dimension will appear bell-shaped (Gaussian or normal distribution curve). In this case, the mean, median, and mode coincide. The mean is the arithmetical average of values,

the median is the middle number of the values, and the mode is the most commonly occurring value and the highest point on the curve. Figure 5 is a typical frequency distribution curve representing height.

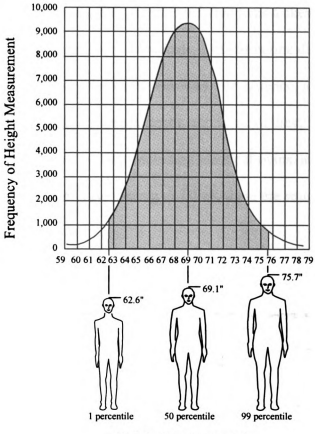



Figure 5 – Height Frequency Distribution Curve (Tilley, 1993)

*Problems with Human Factors*

Because of the variability of people, it is often a problem when designers choose a "single percentile model", where it is assumed that many people can fit into the chosen percentile. Using the 5$^{th}$ or 95$^{th}$ percentile does not represent actual users. Because of this, a range of percentiles, such as 5$^{th}$ to 95$^{th}$ percentiles, would fit more of the actual users.

At times a smooth curve averaging a particular height dimension will not be a normal distribution curve. If weight or flesh measurements (for example, hip width, buttock depth, or abdominal depth) are plotted, the resulting curve is not symmetrical; the peak of the curve is off center. This curve is referred to as a skewed curve, in which case the mean, median, and mode do not coincide. Data from one dimension do not necessarily correlate with those of other dimensions. For instance, a small woman may have a small or large hip width or buttock depth, and so on (Tilley, 1993).

No two people are exactly alike, including identical twins, and this diversity poses a problem for the designer. According to Tilley, there are roughly three categories of human variability. (Table 3)

Table 3 – Human Variability Categories (Tilley, 1993)

| Category | Definition |
|---|---|
| Intra-individual: | Sizes change during adult life. Some changes are due to aging and/or nutrition; others are caused by movement and/or the environment. The face and body are usually asymmetrical. This may be the reason some people do not like photographs of themselves; they are accustomed to seeing themselves in the mirror, which reverses the image. |
| Inter-individual | There are big differences due to sex, ethnic and racial membership. Differences include skin color, eye and hair color, body proportions, and other features. |
| Secular variability | Changes occur from generation to generation for various reasons. However, the pace of these changes is relatively slow. |

Accurate human factors data for the last decade is difficult to assess because of the immigration of many shorter people. It has been said that the U.S. population "has the most diverse ethnic and racial mix of any country in the world." However, it does not represent the world population.

> Japanese women that are smaller than the Japanese 15th percentile would not even be included in a U.S. study, because the 1st percentile Japanese woman is 2.3" (58 mm) shorter than the 1st percentile American woman. American and Canadian farmers are taller than the 99th percentile U.S. male. This particular group's 95th percentile stature of 75.6" (1920 mm) coincides with the 99th percentile U.S. population stature (Tilley, 1993).

It is difficult to accommodate the entire world population, so excluding a percentage of very small and very tall people is necessary.

It is not customary to design for everyone. The few at either end of the normal curve may be so extreme that an encompassing design could become too large, or too expensive, to produce. The military chose to exclude 5% at the small end and 5% at the large end, thus accommodating 90% of the measured population in the Military Standards. The 5% value is called the 5th percentile, and the 95% value is called the 95th percentile. Any other percentile values may be chosen by using a population percentile conversion table for estimating various percentiles (Tilley, 1993). (Appendix 1)

Measurements can also vary depending on posture. Height varies between a straight or rigid posture as much as 0.2" to 0.8" (5 to 20 mm). There is a loss in height due to relaxing into a slumped position (Tilley, 1993). These anthropometrical values are based on data from Human Scale 1/2/3, 1974; NASA, 1978; and U.S. Department of Health, Education, and Welfare, 1966 and 1979. Infant to youth 18 years of age was adapted from SAE, 1975 and 1977 (Tilley, 1993).

Chronological age serves only as an index for biological, psychological, and sociological changes that occur, and older adults are not a homogeneous population. There are much greater individual differences among the elderly and aging populations, beginning at age 60. These differences increase with age, especially with people over

age 80. Data, for a distinct population of the elderly, exists for people of ages 65 to 79, but is not available for people 80 to 90 years of age.

Making use of guidelines and standards, including the Safe Medical Devices Act of 1990, as well as human factors, and ANSI standards, can help. Developing participant groups for usability testing is also recommended, and can be accomplished by looking to community support groups. Taking a systems approach to design requires the designer to look beyond the design of the equipment to the system in which it must function, the environment.

*Human Factors - Economy of motion*

Five kinds of motion are listed below in order of increasing effort, exertion, and time of operation:

1. Finger
2. Finger and wrist.
3. Finger, wrist, and forearm.
4. Finger, wrist, forearm, and upper arm
5. Finger, wrist, forearm, upper arm, and body

Because hand strength is reduced 16% – 40% by age 65, a result of arthritis and normal loss of strength, it is important that package use should require minimal strength. Gripping mechanisms, such as triggers and handle shapes and sizes, are important to reduce needed strength. In theory, human factors data can be consulted to find the range of strength, as well as motion, which is most comfortable for the desired percentage user (Tilley, 1993).

Grip strength, as a function of grip opening and hand anthropometry, is an important concern when opening packages. Figure 6 shows grip strength capacity as a function of the separation distance of grip opening. This figure indicates that there is a very narrow range of grip openings that can maximize grip strength. If the grip opening

deviates from this ideal range, by as little as an inch, the grip strength is dramatically reduced. This trend is also due to a length-strength relationship with the forearm muscles.

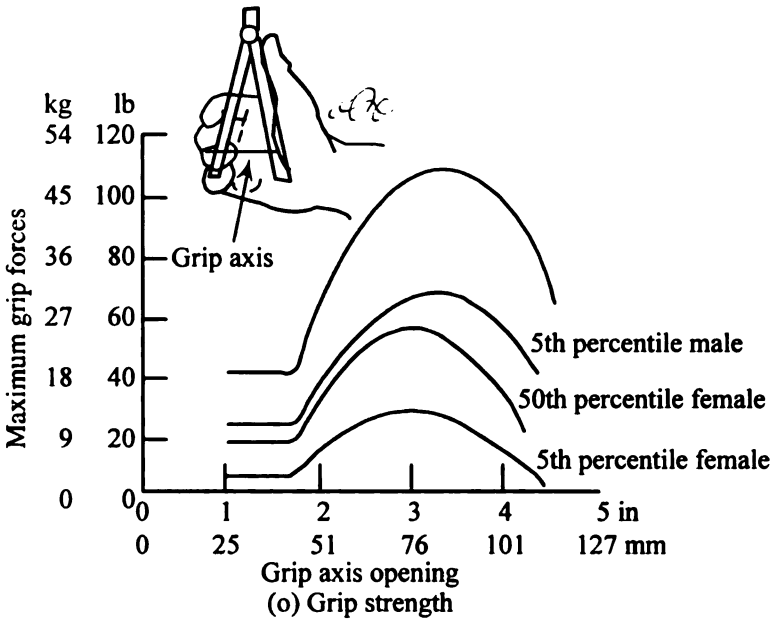



Figure 6 – Grip as it Relates to Distance (Salvendy, 1997)

The use of a larger diameter continuous thread closure, as well as the use of less turns and torque, can be helpful. These components can be compared to high torque and rotary knob specifications. A high-torque knob is a rugged valve knob with a palm grip or five-finger grasp of 1.5" (22 mm) min – 1" (25.4 mm) max. Finger notches help. A Skirt length of 0.5" (13 mm) min – 1" (25.4 mm) max should be used. Torque may range from 0 to 5.2 oz (f) – IN (0.037 N · m). (Figures 7 and 8)

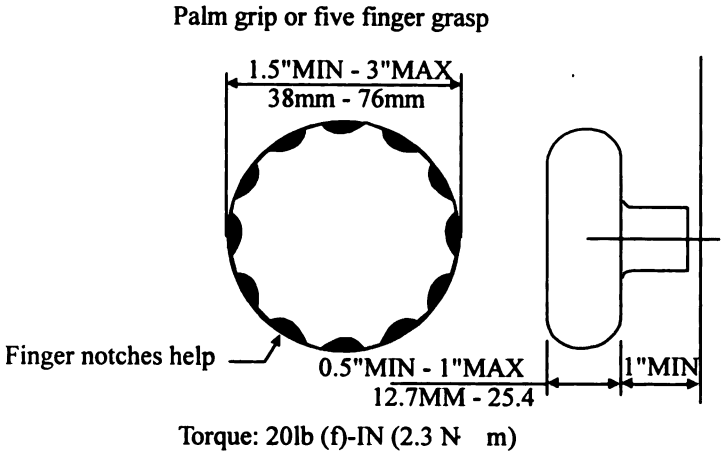



Figure 7 – High Torque (Tilley, 1993)

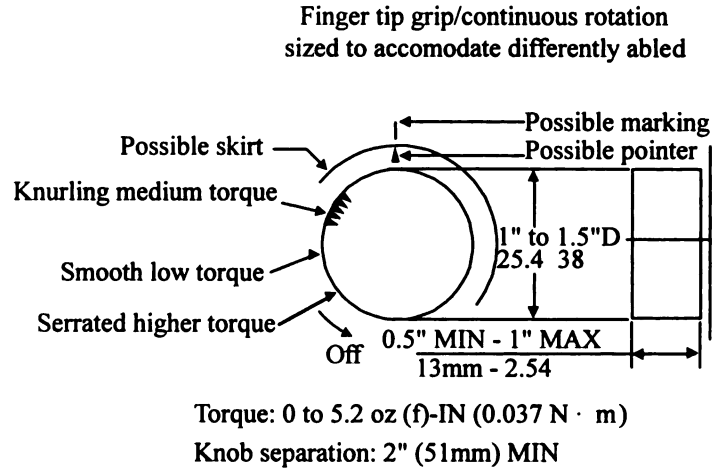



Figure 8 – Rotary Knobs (Tilley, 1993)

For packages with handles, information used for triggers and hand tools are useful. Dimensions of the hand grip can vary depending on the force to be exerted as long as the minimums are preserved. There are many variations are possible that can be used for trigger design. (Figure 9)

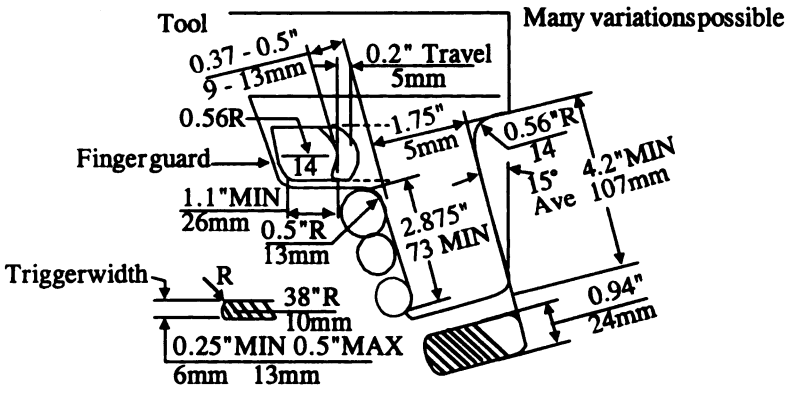



Figure 9 – Triggers and Tool Grip (Tilley, 1993)

*Communication*

Pictorial symbols become important when language barriers, or simply not reading instructions, prevent effective communication. According to Kenneth Fuller, more women read directions than men do. A simple and intuitive package design may include informative icons, which are visual representations of objects, scenes, or people, printed on a surface. Icons can be used to cue recall and may provide a quick reference on how to use a package (Fuller, 2002).

Symbols must be easily read and interpreted as a common language, and promote common understanding. Pictorial symbols represent common meanings within a variety of cultural backgrounds. However, a symbol alone may not be sufficient for symbol understanding. Pictorial symbols may carry vivid emotional, cultural, national and religious meanings. Standardization of some pictorial symbols has already been adopted for international use. Standard International ski trail markings, for example, have been in use for a number of years (Burgess, 1986).

Because people don't generally take their medications in perfectly lighted conditions, it is important to use an effective contrast of colors to enable differentiation of drug identification and warning differentiation. There is evidence that suggests

symbol recognition decreases with age because of changes in visual acuity. The benefit of symbols can only happen if they are seen and understood (Burgess, 1986).

Color is an important factor in communication. Color-coded symbols are an effective way to improve the comprehension of what is being said. It was found that identification and reading time was slowed down by not matching words with colors (Burgess, 1986). Warren (1974) studied the association between word meanings and color and found that they are strongly associated. For example, when asked to identify the color associated with various descriptive adjectives, strong associations were indicated (Burgess, 1986). (Table 4)

Table 4 – Color Associated with Descriptive Adjectives (Burgess, 1986)

| Color | Red | Yellow | Green | White |
|---|---|---|---|---|
| Descriptive Adjective | Stop<br>Alarm<br>Critical<br>Failure<br>Major<br>disable | Minor<br>Standby | Active<br>Enable<br>Manual<br>On<br>Run | Clear |

Restricting the number of colors for instructions and warnings is useful in communicating smoothly, and without confusion.

Arrangement of instructions and pertinent identification, as well as warning information, is important because the HO has been known to be easily confused, and to miss significant signals. Less confusion and increased reliability result when convenient and reliable reading configurations are presented.

## Chapter 2: Design and Development Process

Special packaging, packaging that is child-resistant, has prevented many child poisonings. Recent amendments to packaging, under the direction of the CPSC, require child-resistant packaging to be easier to use for the elderly and the handicapped.

Implementing ease of entry into a child-resistant pill organizer package for the elderly and the handicapped, as well as for people without compromised abilities, would make it easier for people to store their dietary supplements and solid oral medication in organizers and increase medication compliance, as well as to prevent child poisonings. The use of a pill organizer is beneficial if several medications are used daily. Filling a pillbox takes a few extra moments, once a week, but reduces the chance of medication errors (Wong & Norman, 1987).

*Inspiration*

The idea for the design of a child-resistant solid oral pharmaceutical/OTC medication/vitamin supplemental (CRMOD) package came from existing solid oral medication/dietary supplement organizer packages. These packages come in many forms, but usually have several compartments in which to organize medications and vitamin supplements for daily, or several times a day, doses. Some are child-resistant and some are not child-resistant.

Although these packages have increased medication compliance, there are shortcomings. These shortcomings include hazardous substances being removed from child-resistant containers and placed into organizers that are not child-resistant. (Figure 10) Accidental child poisonings have resulted.

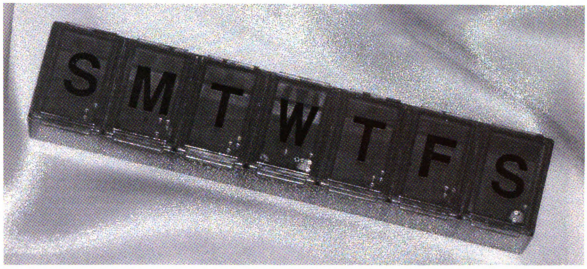



Figure 10 – Non Child-Resistant Daily Dose Organizer

Two child-resistant organizers are shown in Figures 11 and 12. To access the contents of the child-resistant organizer shown in Figure 11, the user must first press and hold a button located at the upper right hand side of the package, unlocking the sliding covers of the compartments, and then slide the covers open to access the compartments and their contents. To access the contents of the child-resistant organizer shown in Figure 12, the user must also first press and hold a button on the side of the organizer to unlock the flip top covers of the individual compartments. Once unlocked, the flip top covers may be opened. If the user finds these difficult to use, frustration and medication noncompliance can occur.

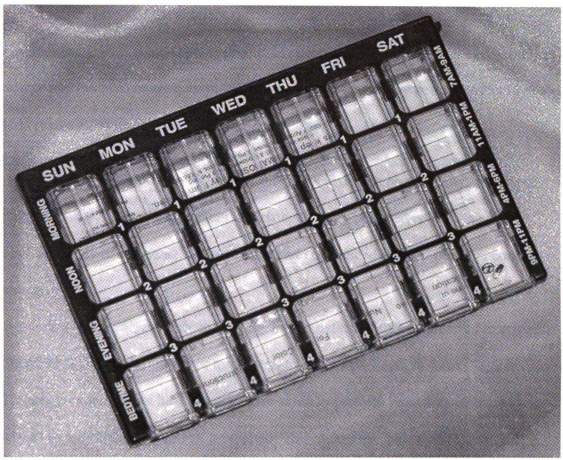



Figure 11 – Child-Resistant Daily Multi-dose Organizer

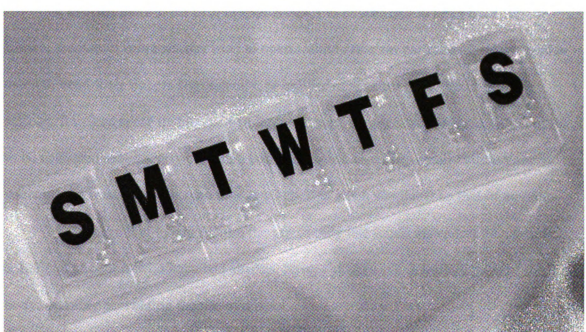



Figure 12 – Child-Resistant Daily Dose Organizer

After review of the available packages, including an analysis of shortcomings, it was decided that a CRMOD package should be designed that is easy to use by the elderly and individuals with disabilities and can also be used by people without reduced hand dexterity or disabilities.

*Package Design Development*

The most important objective of the package design process was to improve package utility, while providing child-resistance. Both parameters were studied simultaneously to enable a "child-resistant and consumer-friendly" package concept to emerge.

For this package, both utility and child-resistant features were used that required cognitive skills involving two or three steps to use the package. In theory, children ages five and younger do not have the cognitive skills to perform two or more sequential actions to access the contents of a package. This makes the two or three steps for package opening beneficial in keeping children under the age of five out of packages.

It is often painful for people with arthritis to extend and to bend their fingers. Hence, the two or more actions used to open a child-resistant package must not require users to bend their fingers significantly, or require much strength to perform these actions. It makes sense that by using a large distance between two buttons, which must to be activated sequentially to open a package, would also keep small children out of packages because the hand span of a small child is much smaller than that of an adult.

A package that would require the use of only one hand, instead of two, will be beneficial to people who have had strokes. Severe strokes can debilitate parts of the body, possibly preventing the use of a hand.

Because many people lead busy lives, the size of the organizer is also important. The organizer would need to be easy to transport. This feature, along with one hand operation, would be an added convenience.

Therefore, the goal was to design a convenient child-resistant package that would dispense a daily dose of medication/dietary supplements that would also reduce the amount of work for the user in hand dexterity and finger bending, and would fit into a purse or a bag.

*Sketches*

With the previously discussed factors in mind, the package design process began. After much thought and sketching, the new package idea was born. (Figure 13 and Appendix 3)

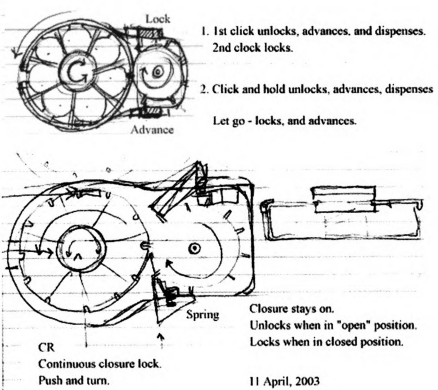



Figure 13 – Sketch of Package

*Package Design Illustration*

The sketch of the package, which contained most of the working mechanisms, was computer generated, using Adobe Illustrator 6.0. At this stage, the working mechanisms, which were the two buttons used for the child-resistant feature, the eight-compartment "cam-wheel" that would hold the daily dosage, the advancing gears to advance the cam-wheel, and dispensing and refilling features were fine-tuned. (Figure 14)

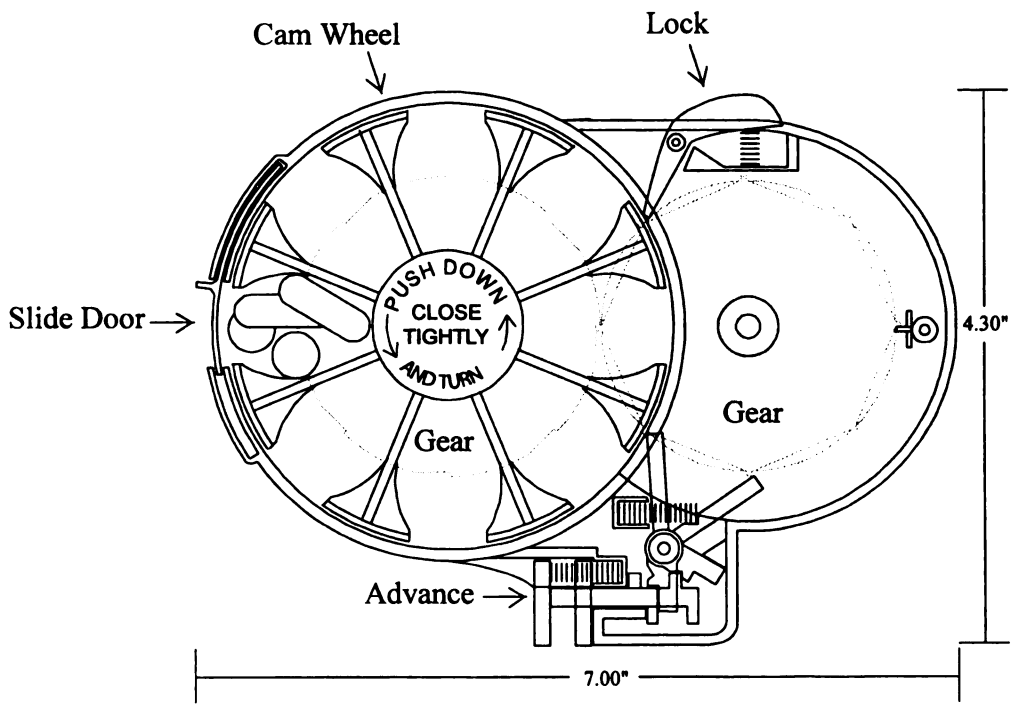



Figure 14 – Initial Package Drawing

*Model*

The package design illustration was then used to proceed to the next stage, the production of a model. This model was created to see if the mechanisms worked, as well as for ergonomic testing. (Figure 15)

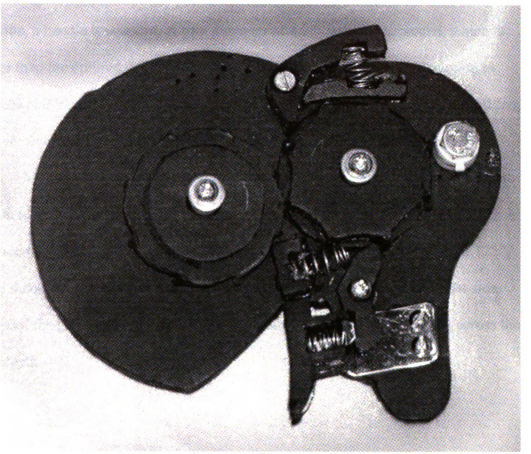


Figure 15 – Package Model

Hunt Foam Board, 3/16" thickness, which is a soft, three-layered board with a black foam layer in the center and black outer layers of paper, was used to make the package parts. Package parts were cut from the foam board using an X-ACTO® knife. The package parts were then assembled using machine screws, hex and lock nuts, nylon fasteners, springs, and stainless steel sheet metal.

After evaluation of the assembled model, it was decided that the package needed ergonomic and mechanical changes. Ergonomically, the package was difficult to hold the way it was intended to be held because there was no handle. Using human factors information, based on $5^{th}$ percentile, as well as for the reduced abilities of people with arthritis, a handle was added. A grip diameter of 4.25" was implemented, which is larger than the optimal 0.875" – 1.25" handle grip diameter, with the intention to prevent children under the age of five from accessing the package contents. Children that are five years of age have a hand grip diameter of .60" – .85" (Tilley, 1993).

Mechanically, the gears would not mesh together to enable the gears to turn simultaneously, and the ratchet that advanced the gears would not move the gears as intended. Gears with 48 teeth, a 1.25" outer diameter and inner diameter of 1.125", were made. A ratchet, with a curved tip on one side and straight on the other side, replaced the previous ratchet to enable a smoother transition of the ratchet across the gear teeth.

Once the non-working model was finished, the original Adobe Illustrator 6.0 drawing was updated to reflect these changes. (Figure 16)

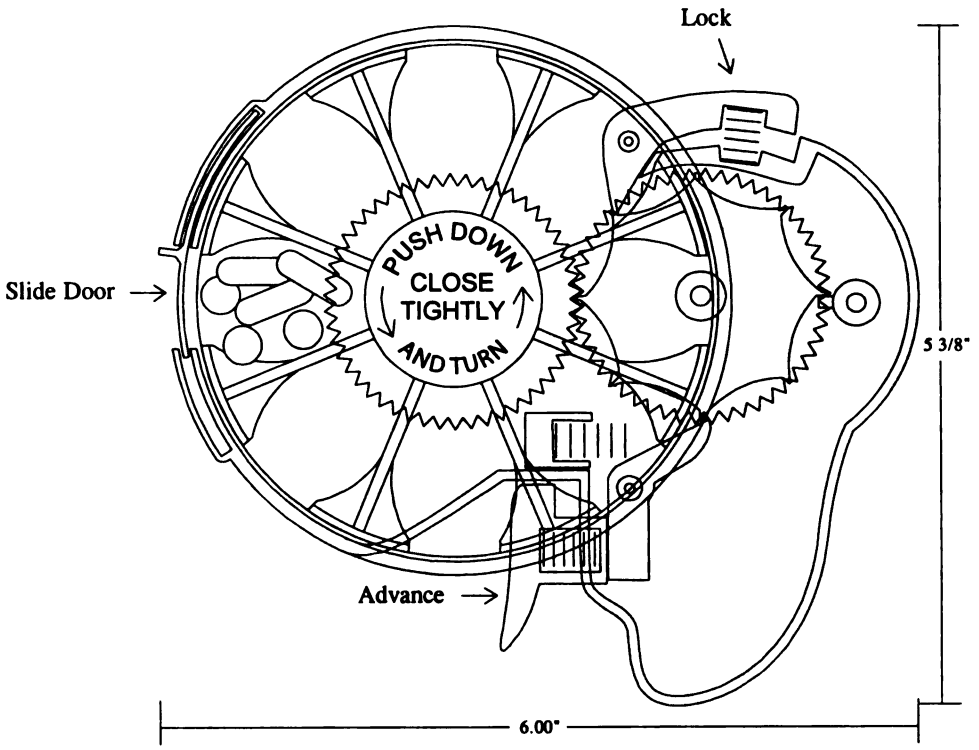



Figure 16 – Organizer Dispenser Package Final Illustration

*Nonworking Prototype*

After the non-working model was complete, the next step in the package development began, which was to make a prototype. Using Rhino 3.0, a three-dimensional (3D) drafting program that is used by many animators and industrial designers, the package was drawn as a 3D image. This was accomplished by importing the updated Adobe Illustrator 6.0 file directly into Rhino 3.0. From the imported drawing, individual two-dimensional (2D) drawings were extruded into 3D images.

Boolean unions, differences, and intersections were also used during this process. A Boolean union occurs when two or more 3D images, that were created separately, are overlapped and combined into a single image. The newly formed image takes the form of the two images put together. A Boolean difference occurs when two or more 3D images, created separately, are overlapped and combined into one image. The resulting image takes the form of one of the first image minus the second image, leaving a void in the first image where the second image once was. A Boolean intersection is where two or more 3D images, created separately, are overlapped and combined into one image. The resulting image subtracts all parts of the images except for the parts of the images that overlap.

After the parts were drawn, clearance between objects was added to allow for part movement, such as the gear and button openings that rotate on posts. This clearance measured approximately 0.0625". The clearance was added to accommodate the thickness of the epoxy coatings, which is added to strengthen the manufactured package parts used in rapid prototyping. (Figures 17, 18, 19, and 20)

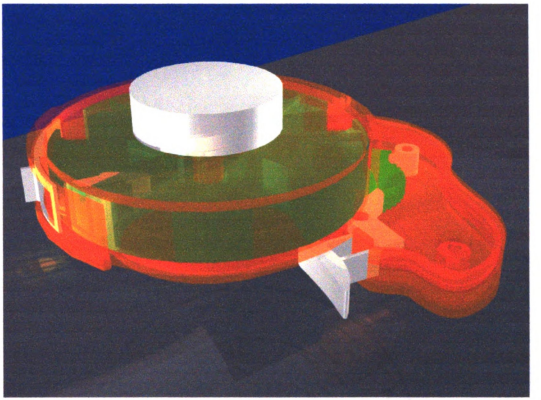


Figure 17 – Rhino 3.0 Rendering of Package Prototype

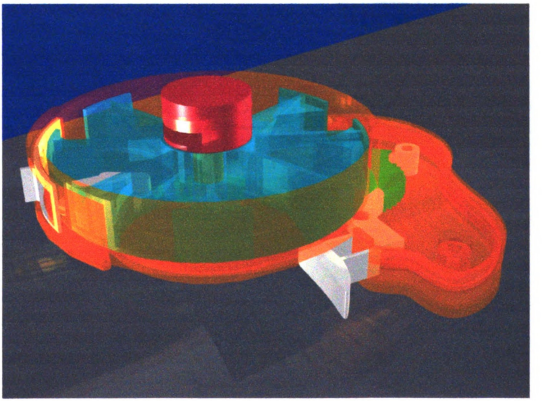


Figure 18 – Rhino 3.0 Rendering of Package Prototype Open

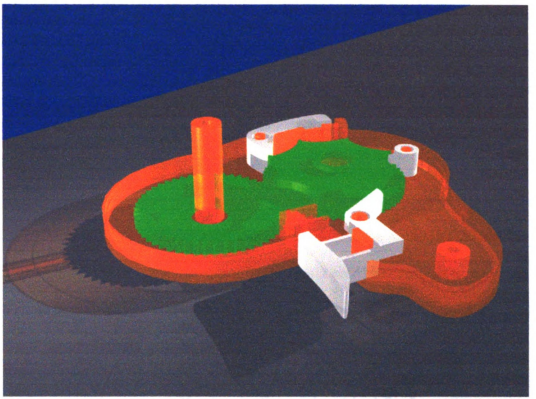


Figure 19 – Rhino 3.0 Rendering of Package Prototype Gears

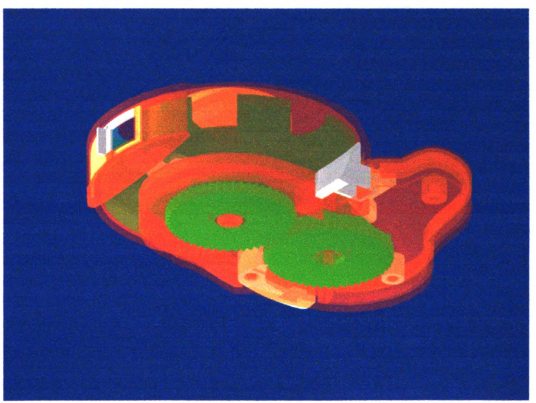


Figure 20 – Rhino 3.0 Rendering of Package Prototype Bottom View

Once the package part drawings were complete, they were saved and exported individually into a stereolithography, .STL, binary format and then electronically sent to the University of Michigan's 3D Media Center in Ann Arbor, Michigan, to be printed, or manufactured. The 3D non-working prototype parts were produced on the ZPrinter 310 System using ZP102, a plaster based powder. (Appendix 2)

The first printing resulted in a non-working prototype that needed more clearance between parts, and structural changes to some of the parts. The second printing of this package produced prototype parts that could be constructed successfully, after some modification, performed with sandpaper. Two copies of this package were produced; one for testing and another for display. (Figure 21)

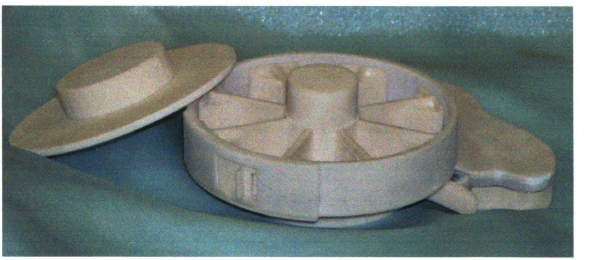


Figure 21 – Nonworking Prototype

*New Package Features*

This package was designed to enable consumer-friendly access to medications or vitamin supplements for people with decreased hand dexterity, such as arthritis, while preventing small children from accessing the contents of the package.

*How Package Works*

Package dimensions are 7.0" x 4.3" x 2.0" (length, width, height). The package features eight "daily" compartments, each having the capacity to hold several different sized solid oral medications and vitamins. The compartments are pie shaped, forming the cam-wheel, which rotates in a counter-clockwise motion. This motion is manually controlled by the user, who simply grasps the handle of the package, with either hand, and pushes first the top button to unlock the locked gear, with an index finger or chin (Gleason, 2003) and while still holding down the top button, compresses the bottom button to advance the unlocked gear, which advances the cam wheel one step to the next day.

To access contents of the compartments, as well as to prevent the contents from spilling out of the dispensing opening, a slide door that is not child-resistant, and which is manually opened or closed by the user, is provided.

Eight compartments, instead of seven, are provided for mechanical symmetry, child-resistance, and as a reminder to refill the compartments for the upcoming seven days. Because the sliding door is not child-resistant, an empty compartment should be kept in front of the sliding door when the package is not in use.

To refill the package, a typical continuous thread child-resistant closure that is imbedded into a transparent cover to protect the contents of the compartments is removed. The closure is simply pushed down and turned counter-clockwise. This

unlocks the closure, which can then be pulled up and removed to expose the compartments. Once refilling is complete, the clear lid and closure is simply placed on top of the exposed compartments, pushed down, and twisted clockwise to return to the original locked position (Appendix 4).

*Child-Resistant Feature*

Two actions must take place to access the contents of this pill organizer. The lock on the advance wheel must be disengaged before the wheel can be cycled into position for the next day. This child-resistant feature would make it difficult for a child aged five and younger to access the contents of the package. A child would need the cognitive abilities to determine that the top button, which locks and unlocks the package, and the bottom button, which advances the cam-wheel, must be operated sequentially to access the package contents. Also, because the handle grip distance between the two buttons, that are required to unlock and advance the compartments, is greater than the handle grip capacity of a toddler or young child's hand, .60" - .85" (Tilley, 1993), small children will be prevented from unlocking and rotating the cam-wheel to get to the next day's medication dose.

*Intangibilities*

The package itself, when seen in the store, will have the feeling of a beautiful, sterile, package that is fun to watch when it is being advanced to the next day. A commercial version of the unit should be transparent to enable viewing of the components inside, such as the gears and levers involved in advancing the wheel to the next day. However, this may inspire small children to try to use the package.

Amber was chosen as the color of the transparent outer plastic of the package to block ultraviolet rays that could cause the medication inside the package to decompose.

## Chapter 3: Materials and Methods

Consumer input during the design process is important for the success of any product. Improvements in graphics and prototyping technology have enabled the realistic depiction of how a product might look when manufactured (Fisk & Rogers, 1997).

*Package Prototype*

A prototype can be a mock-up, model or actual working version of a technological device or process. Prototypes are used to generate engineering information that will help design or perfect the final product/process (UMaine, 2004).

Before a prototype was made for testing purposes, a model was created to determine if the working mechanisms would work, and to evaluate the package ergonomics. (Figure 22)

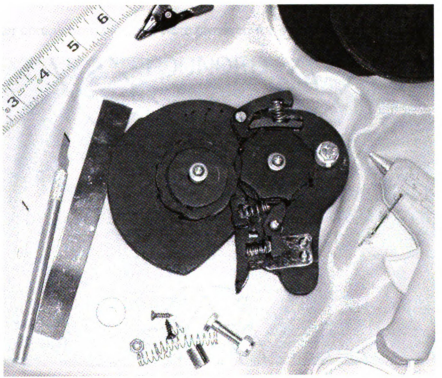


Figure 22 – Model Creation

Changes were made to the drawing that corrected the now apparent problems of the model. Then, the prototype parts were printed. (Figure 23)

Figure 23 – Manufactured Package Parts

After completion, the parts were prepared for prototype assembly. (Figure 24)

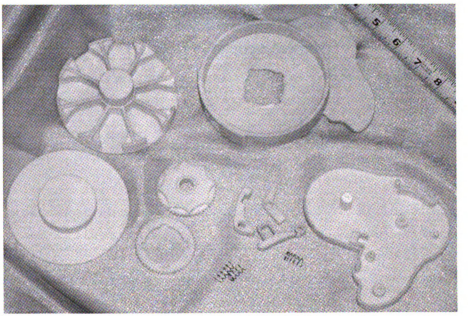


Figure 24 – Unassembled Prototype Parts

To prepare the parts for assembly a very fine sand paper was used to smooth rough surfaces and to further increase clearance between parts, such as the top and bottom cover of the package, so that they fit together nicely.

When all parts were prepared, the prototype was assembled. (Figures 25 and 26)

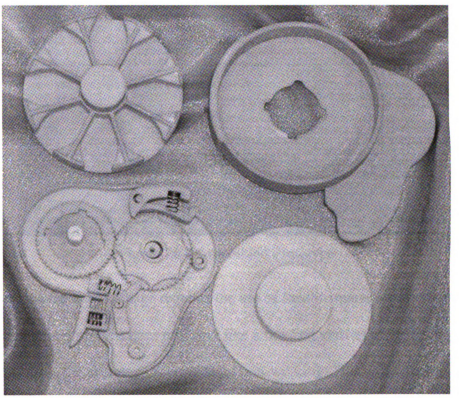


Figure 25 – Prototype Assembly

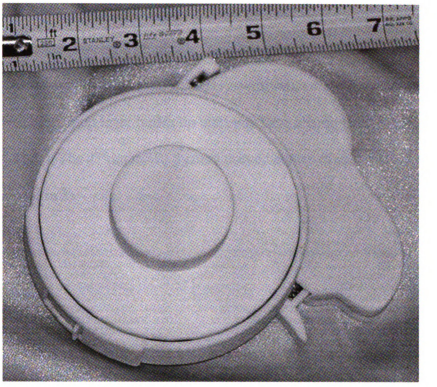



Figure 26 – Assembled Prototype

Because the new package requires the use of flexible materials for some of the working parts, the prototype does not work like a finished version of the package would. Therefore, the prototype is considered non-working. This non-working prototype was created to determine package usage comfort, such as holding the package in your hand, as well as button placement. Consumer understanding of how the package works was also tested.

*Rapid Prototyping Technology*

Rapid prototyping, a new technology that prints 3D objects quickly and accurately, was used to manufacture the non-working prototype of this package.

The technology of rapid prototyping is one method used for creating 3D objects in three dimensions. Just as you can currently print out a drawing in 2D, rapid prototyping allows you to print an object. It works by taking a computer model and

slicing it into thousands of very thin layers. Each of these layers can be laid down, one at a time, by a device printing with plastic (which is often called "Fused-Deposition Modeling" (FDM) or with thin layers of paper, metal foil, ceramic, or various other materials. Over time, each layer builds up until you have a completed model (Z Corporation, 2003). The ZPrinter 310 System printed copies of each part of the new package. (Appendix 2)

## Chapter 4: Test Procedure

To prove that the package would provide people an easier way to adhere to their medication regime, the package was tested on people, including individuals with disabilities. The test procedure presented in this chapter consisted of subject orientation and the collection of subject-related information.

### *Subject Orientation*

Testing was performed in various locations, representing realistic conditions where people might actually take their medications. Subjects were tested in homes, retirement centers, physician offices and group gatherings because medications are rarely taken under optimal, and controlled, conditions.

Before testing began, subjects were provided with an overview of the package, the reason for the development of the package, and the components of the package that enable the package to be easier to use.

> "This is a non-working prototype of a newly developed automatic pill organizer/dispenser that was developed to make medication taking easier for everyone, including people with arthritis, and other physical conditions that cause using a pill organizer to be difficult to use. This is only a prototype. The actual manufactured package will be made of a transparent plastic and will be lighter than the prototype. If you choose to participate in this study you will be asked information regarding your age, sex, physical condition affecting your hands, if any, as well as questions about medication packaging that is commonly used. I am also asking for your opinion about comfort and learning aspects of the new package, such, as comfort of the distance between the two buttons that are required to be pressed simultaneously in order to access the next dose, as well as the comfort of holding the package using the package handle. Your opinion of package ease of learning and understanding how to use the package is also needed. If there are any questions or need for clarification during any part of this test, please ask. If there are any suggestions or concerns about this package they are also welcome. This information will be anonymous; your name will not be recorded on the questionnaire. This testing will take no longer than 20 minutes."

To protect the test subjects' rights, subjects were asked to review and sign a written consent form (IRB # 03-830; expiration date October 13, 2004). Before testing began, subjects signed the form, signifying acceptance of the invitation to participate. To further protect the subjects' rights, test subjects also signed a media consent form, signifying their acceptance to allow images, such as photographs or video, to be taken of them during testing.

For the protection of the newly developed package, the Michigan State University Office of Intellectual Property required test subjects to sign a confidential disclosure agreement, in which each receiving party agrees neither to use the confidential information for any purpose other than for evaluation nor to provide the confidential information to any third party other than a signatory to this agreement for a period of five (5) years upon the receipt of the confidential information (Appendix 5). The Michigan State University invention disclosure identification number for this package is MSU 4.1-662-ID03-070.

***Collection of Subject-Related Information***

After the subject signed the consent and confidentiality forms, a closed end questionnaire was used to record general subject-related information, health and medication daily consumption, medication packaging, and new package questions. (Appendix 6)

The general subject-related information section asked about test subject age. An appropriate age range was required to be chosen by the test subjects to categorize the age of the test subject. The gender (sex) information required test subjects to choose one of two options; male or female.

The health and solid oral daily consumption section asked for information about physical condition, and daily medication/vitamin intake. The physical condition section asked test subjects to choose one of two options; normal or secondary. Normal meant test subjects without disease related conditions affecting hand dexterity. Secondary meant disease related conditions affecting hand dexterity. If secondary, test subjects were asked about the physical condition that was affecting their hand dexterity, such as arthritis, stroke, or other. If the test subject checked the "arthritis" box, they would then check the appropriate box for arthritis type, such as osteoarthritis, rheumatoid arthritis, or other. If test subjects checked the "stroke" box, they would then check the appropriate box for stroke severity, such as minor or major paralysis. If the test subject checked the "other" box, they would then write the condition on the provided line. (Appendix 7)

Once health information was collected, test subjects were then asked to provide information about the type of daily medication/vitamins they take, if any. Each test subject was asked to check the appropriate "medication/vitamin" boxes. The box options were solid (such as pills and tablets) or liquid (such as elixirs and spirits). Each test subject was also asked to provide information on how many medications/vitamins they take on a daily basis. (Appendix 7)

The packaging section asked questions about types of containers their medications/vitamins come in, the ease of use of the packages, whether they use pill organizers/dispensers, as well as pill organizer/dispenser preference. (Appendix 7)

The package questions gave test subjects an opportunity to provide their opinions of the newly designed package. Test subjects were asked about the ease of

understanding how to use the package, if the feel of the package handle was comfortable (successful ergonomic design of handle), if the distance of the two buttons was at an adequate distance apart (the distance between the two buttons was comfortable for use with two fingers on one hand), if the two buttons were at a comfortable distance for those with decreased hand dexterity (such as gripping and pinch strength), comfort in knowing the pill organizer/dispenser they use is child-resistant, aid in medication compliance of those with and without hand dexterity problems, and desire of owning and using the newly designed package, if the package is manufactured.

The purpose for asking normal subjects to answer "if the two buttons were at an adequate distance for those with decreased hand dexterity (such as gripping and pinch strength)" was to provide insight into how the normal subjects in this study viewed the abilities of individuals with secondary physical conditions.

The term "medication compliance" was described to each test subject to help them to give their opinions on how this package may increase medication compliance.

The questions were set up as a Likert scale. A Likert scale includes the "statements" in the left-hand column of the chart, and the opinions the test subjects were provided with to choose from were located on the top row of the chart. This was provided to enable test subjects easy response to the "statements", which were strongly agree, agree, neither agree or disagree, disagree, and strongly disagree. Test subjects would simply check the box the best described their opinion of a statement (Trochim, 2002). (Appendix 7) All answers to the questions are unsupported opinions; not facts.

## Chapter 5: Results and Discussion

To determine if the package does make it easier for people to take their medication, specific components of this nonworking package prototype were tested on 100 test subjects, 50 normal and 50 secondary. Results were not tested for statistical significance, but provided useful information that will aid in the research and development of improvements to this package, prior to manufacturing. Demographic information was also collected to aid in the marketing aspects of the manufactured package.

This chapter is divided into two sections. Section one includes test subject age range, gender, and physical condition categories, such as normal and secondary. Section two includes test subject feedback on specific components of the newly designed organizer/dispenser. Test subject solid oral medication/vitamin supplement and quantity use, as well as pharmaceutical/OTC packaging ease of use and preference, were included in the questionnaire.

***Section 1: Test Subject Age Range and Sex, and Physical Condition Categories***

*Test Subject Normal and Secondary Physical Condition*

One-hundred test subjects were interviewed. Fifty normal and 50 secondary male and female test subjects aged 21 years and higher were interviewed. Of the normal test subjects, 56% were male and 44% were female. Of the secondary test subjects, 26% were male and 74% were female. (Figure 27)

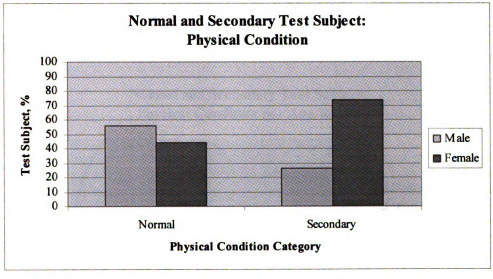



Figure 27 – Normal and Secondary Test Subject: Physical Condition

*Test Subject Physical Condition per Age Range*

Of the normal male test subjects, 82% were aged 21 – 45, 7% were aged 46 – 60, 4% were aged 60 – 77, and 7% were aged 77+. Of the normal female test subjects, 64% were aged 21 – 45, 18% were aged 46 – 60, 14% were aged 60 – 77, and 5% were aged 77+. Of the secondary male test subjects, 15% were aged 21 – 45, 38% were aged 46 – 60, 31% were aged 60 – 77, and 15% were aged 77+. Of the secondary female test subjects, 11% were aged 21 – 45, 41% were aged 46 – 60, 30% were aged 60 – 77, and 19% were aged 77+. (Figure 28)

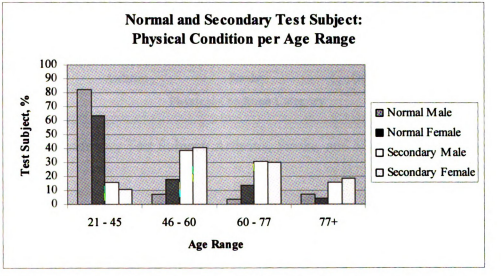



Figure 28 – Normal and Secondary Test Subject: Physical Condition per Age Range

*Secondary Test Subject Physical Condition*

Of the secondary male test subjects, 69% had arthritis and 31% had other physical disabilities. Of the secondary female test subjects, 81% had arthritis, 11% had some type of stroke, and 8% had other physical disabilities. (Figure 29)

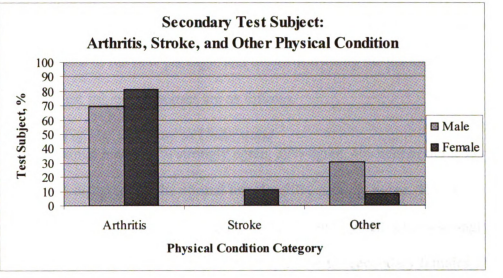



Figure 29 – Secondary Test Subject: Arthritis, Stroke, and other Physical Condition

***Section 2: Test Subject Feedback on Specific Components of the Newly Designed Organizer/Dispenser***

Four aspects of the package were asked about in the questionnaire. These included the comfort of the handle, distance of the two buttons that are required to be pushed simultaneously for normal and secondary people, improvements in medication compliance because of the new package, and desire of owning the package if manufactured. Test subject responses are as follows:

*Package Method of Use was Easy to Understand*

Of the normal males 54% strongly agree, 39% agree, 4% neither agree nor disagree, and 4% disagree. Of the normal females 50% strongly agree, 41% agree, 5% neither agree nor disagree, and 5% disagree. Of the secondary males 62% strongly agree, 31% agree, and 8% neither agree nor disagree. Of the secondary females 38% strongly agree, 46% agree, 11% neither agree nor disagree, 3% disagree, and 3% strongly disagrees. (Figure 30)

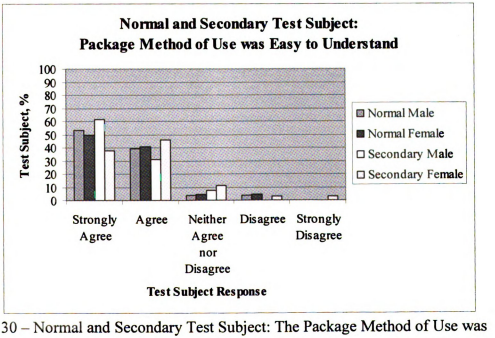



Figure 30 – Normal and Secondary Test Subject: The Package Method of Use was Easy to Understand

*The Feel of the Handle is Comfortable*

Of the normal males, 11% strongly agree, 46% agree, 11% neither agree nor disagree, and 32% disagree. Of the normal females, 5% strongly agree, 64% agree, 5% neither agree nor disagree, 18% disagree, and 9% strongly disagree. Of the secondary males, 31% strongly agree, 46% agree, and 23% disagree. Of the secondary females, 22% strongly agree, 30% agree, 16% neither agree nor disagree, 19% disagree, and 14% strongly disagree. (Figure 31)

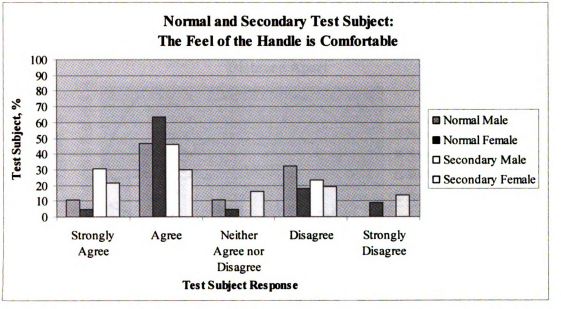



Figure 31 – Normal and Secondary Test Subject: The Feel of the Handle is Comfortable

*The Distance of the Two Buttons are at an Adequate Distance Apart*

Of the normal males, 7% strongly agree, 64% agree, 11% neither agree nor disagree, and18% disagree. Of the normal females, 9% strongly agree, 50% agree, 5% neither agree nor disagree, 32% disagree, and 5% strongly disagrees. Of the secondary males, 31% strongly agree, 31% agree, 15% neither agree nor disagree, 15% disagree, and 8% strongly disagrees. Of the secondary females, 24% strongly agree, 19% agree, 8% neither agree nor disagree, 22% disagree, and 27% strongly disagrees. (Figure 32)

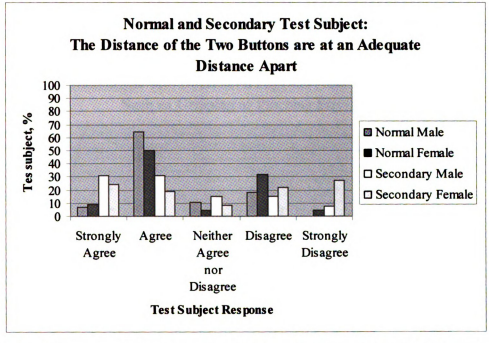



Figure 32 – Normal and Secondary Test Subject: The Distance of the Two Buttons is Adequate

*The Distance of the Buttons is Comfortable for Individuals with Decreased Physical Hand Dexterity, Such as Gripping or Pinching Strength*

Of the normal males, 43% agree, 29% neither agree nor disagree, and 29% disagree. Of the normal females, 9% strongly agree, 41% agree, 23% neither agree nor disagree, 23% disagree, and 5% strongly disagrees. Of the secondary males, 23% strongly agree, 23% agree, 23% neither agree nor disagree, 15% disagree, and 15% strongly disagree. Of the secondary females, 14% strongly agree, 14% agree, 19% neither agree nor disagree, 27% disagree, and 27% strongly disagree. (Figure 33)

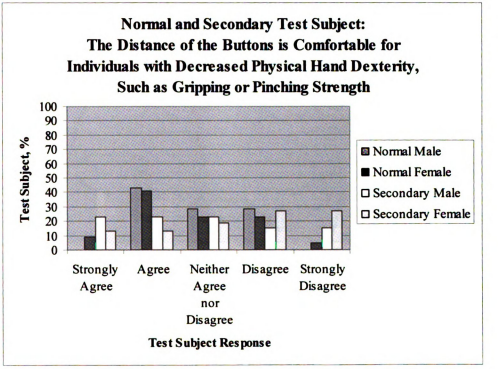



Figure 33 – Normal and Secondary Test Subject: The Distance of the Two Buttons is Comfortable for Individuals with Decreased Physical Hand Dexterity, Such as Gripping or Pinching Strength

*This Package will Aid in Medication Compliance for Both Individuals with or without Physical Hand Dexterity*

Of the normal males, 21% strongly agree, 57% agree, 18% neither agree nor disagree, and 4% disagree. Of the normal females, 41% strongly agree, 45% agree, and 14% neither agree nor disagree. Of the secondary males, 38% strongly agree, 31% agree, 15% neither agree nor disagree, 8% disagree, and 8% strongly disagrees. Of the secondary females, 30% strongly agree, 35% agree, 16% neither agree nor disagree, 8% disagree, and 11% strongly disagrees. (Figure 34)

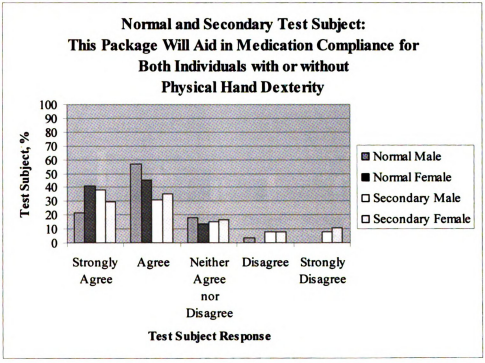



**Figure 34** – Normal and Secondary Test Subject: This Package Will Aid in Medication Compliance for Both Individuals with or without Physical Hand Dexterity

*If Manufactured, I have a Desire to Own and Use This Package*

Of the normal males, 21% strongly agree, 39% agree, 25% neither agree nor disagree, and 14% disagree. Of the normal females, 18% strongly agree, 45% agree, 23% neither agree nor disagree, and 14% disagree. Of the secondary males, 38% strongly agree, 23% agree, 15% neither agree nor disagree, and 23% disagree. Of the secondary females, 22% strongly agree, 27% agree, 16% neither agree nor disagree, 16% disagree, and 19% strongly disagree. (Figure 35)

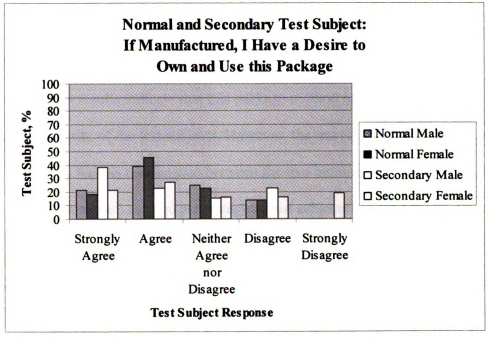



Figure 35 – Normal and Secondary Test Subject: If Manufactured, I have a desire to Own and to use this Package

## Chapter 6: Conclusion and Future Study

For this research, a package was designed to make medication compliance easier for individuals with and without physical ailments. The child-resistant package allows an individual to use only one hand to gain access to medications/vitamin supplements.

Although the data obtained from the questionnaire are unsupported opinions, it does provide insight into the success the package, as well as information on how to improve the package for the package research and development process.

### *Conclusion*

These test results indicate that this package method of use is easy to understand for a strong majority of the test subjects. However, the test results also indicate that the handle design, as well as the distance between the two buttons, will need to be ergonomically improved. A large percentage of test subjects believed the package would aid in medication compliance for individuals with normal and with limited physical hand dexterity. The proportion of test subjects that desire to own and use this package, if it is manufactured, was not overwhelming. However, ergonomic improvements to this package or future acceptance of the unfamiliar package component use, such as the distance between the two buttons that must be pressed to operate the package, might result in greater acceptance.

Whenever possible, designers who are attempting to meet the needs of the elderly and disabled should follow the principles of universal design. However, sometimes the pursuit of a universal solution may compromise function that is critical to the user, in which case, it is not a universal solution. The challenge in these

circumstances is to achieve that function in as attractive and affordable manner as possible. (Fisk, 1997)

### *Suggestions for Future Research*

*Child-Resistance*

Because of the need for child-resistant packaging that is also senior friendly, the hand span of children and adults should be studied and implemented into package design.

Currently, this package cannot claim to be child-resistant; it has not been tested for child-resistance. Prior to manufacturing, child-resistance of this package should be tested using 16 CFR 1700.20, testing procedure for special packaging.

*Solid Oral Requirements*

Only solid forms of medication/vitamin supplements that do not reach their critical point of shelf-life within one week of constant exposure to environmental humidity can be used in this dispenser package to ensure maximum supplemental benefits.

Currently, the package is classified as well closed, meaning that the package protects its contents from extraneous solids and from loss of the contents under the ordinary or customary conditions of handling, shipment, storage and distribution. Perhaps future developments would enable the package to be tightly closed, which is preferred over well closed. According to the United States Pharmacopeia, Chapeter <671> Containers - Permeation, A tightly closed package protects the contents from contamination by liquids, solids, or vapors, from the loss of the article and from efflorescence, deliquescence, or evaporation under ordinary or customary conditions of handling, shipment, storage, and distribution and is capable of a tight package reclosure.

*Increased Independence for Mentally Handicapped Individuals*

This package may be useful for individuals who are mentally handicapped. The transparency of the package would enable the mentally handicapped individual to see the medication inside the package. If the mentally handicapped individual knows that the medication inside the package needs to be taken, and also knows how to access the medication, this package could increase independence for the mentally handicapped individual. A Pharmacy or care taker can refill package for the individual.

*Compliance Packaging*

Currently, the package cannot be considered a compliance package because the individual compartments are not labeled according to day of the week; Sunday, Monday, Tuesday, Wednesday, Thursday, Friday and Saturday. These labels should be used on this package for this package to be considered a compliance package.

## Appendix 1: Human Percentile Conversions

Any percentile value of measurements may be calculated using the population percentile conversion table. (Table 5)

Table 5 – Population Percentile Conversion (Tilley, 1993)

| Percentile | % Included |
|---|---|
| 99.9 = Mean + (3 * SD) | 99.8 |
| 99.5 = Mean + (2.576 * SD) | 99 |
| 99 = Mean + (2.326 * SD) | 98 |
| 97.5 = Mean + (1.95 * SD) | 95 |
| 97 = Mean + (1.88 * SD) | 94 |
| 95 = Mean + (1.65 * SD) | 90 |
| 90 = Mean + (1.28 * SD) | 80 |
| 85 = Mean + (1.04 * SD) | 70 |
| 80 = Mean + (0.84 * SD) | 60 |
| 75 = Mean + (0.67 * SD) | 50 |
| 50 = Mean | |
| 25 = Mean – (0.67 * SD) | 50 |
| 20 = Mean – (0.84 * SD) | 60 |
| 15 = Mean – (1.04 * SD) | 70 |
| 10 = Mean – (1.28 * SD) | 80 |
| 5 = Mean – (1.65 * SD) | 90 |
| 3 = Mean – (1.88 * SD) | 94 |
| 2.5 = Mean – (1.95 * SD) | 95 |
| 1 = Mean – (2.326 * SD) | 98 |
| 0.5 = Mean – (2.576 * SD) | 99 |
| 0.1 = Mean – (3 * SD) | 99.8 |

SD = standard deviation, which can be found by the formula:

$$SD = \sqrt{\frac{\Sigma(d)^2}{N}}$$

Where $\Sigma$ = summation
d = difference between one person's measurements and the arithmetic mean of that measurement
N = number of people in the survey

There is a particular standard deviation for every measurement and every sample. We have chosen to accommodate 98% of the U.S. population, which lies between the 99$^{th}$ percentile and the 1$^{st}$ percentile, for product designs for civilians. Any lower percent excludes a good number of tall operators. If one prefers a different percentile, the standard deviation can be calculated from data on anthropometric diagrams.

For example:

2.32 SD = 99 percentile stature – mean stature

$$SD = \frac{6.5"}{2.326} = 2.8" \text{ (71 mm)}$$

or

2.326 SD = mean stature – 1 percentile stature

$$SD = \frac{6.5"}{2.326} = 2.8" \text{(71 mm)}$$

# Appendix 2: ZPrinter 310 System

The prototype parts were printed using the ZPrinter 310 system. (Figure 36)

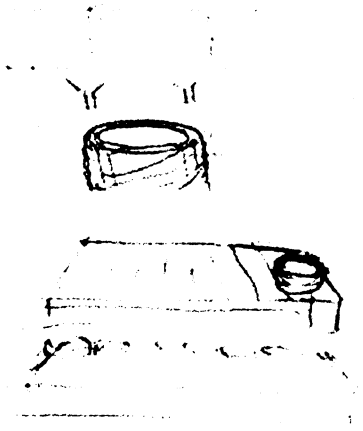
Some of the system specifications and descriptions are provided. (Table 6)

Figure 36 – ZPrinter 310 System

Table 6 – ZPrinter 310 System General Specifications (Zcorporation, 2003)

| Specification | Description |
|---|---|
| Build Volume | 8" * 10" * 8" (203 * 254 * 203 mm) |
| Layer Thickness | User selectable at time of printing; .003" - .010" (.076 - .254 mm) |
| Equipment Dimensions | 29" * 32" * 43" (74 * 81 * 109 cm) |
| Equipment Weight | 250 lbs. (113 kg) |
| System Software | Z Corporation's proprietary software accepts solid models in STL, VRML and PLY file formats as input. ZPrint software features 3D viewing, text labeling, and scaling functionality. The software runs on Microsoft Windows* NT, 2000 Professional and XP Professional. |

## Appendix 3: Sketches



08 April, 2003

Figure 37 – Solid Oral Organizer Sketch

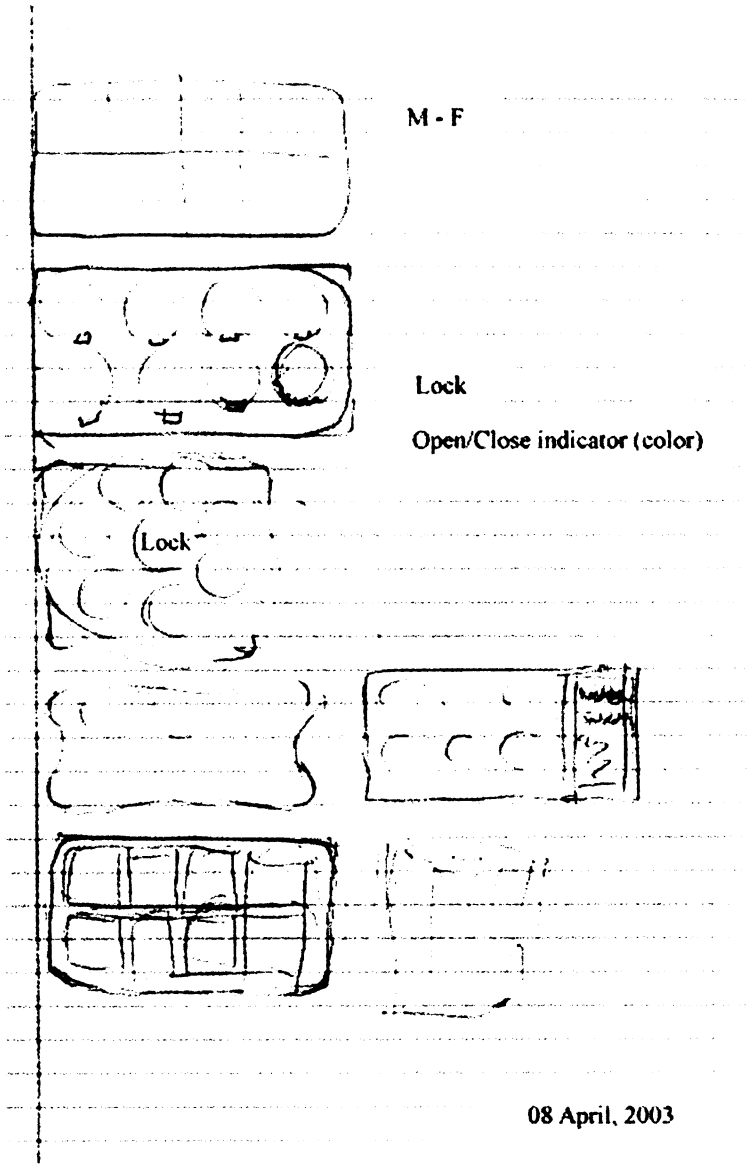



Figure 38 – Solid Oral Organizer Sketch 2

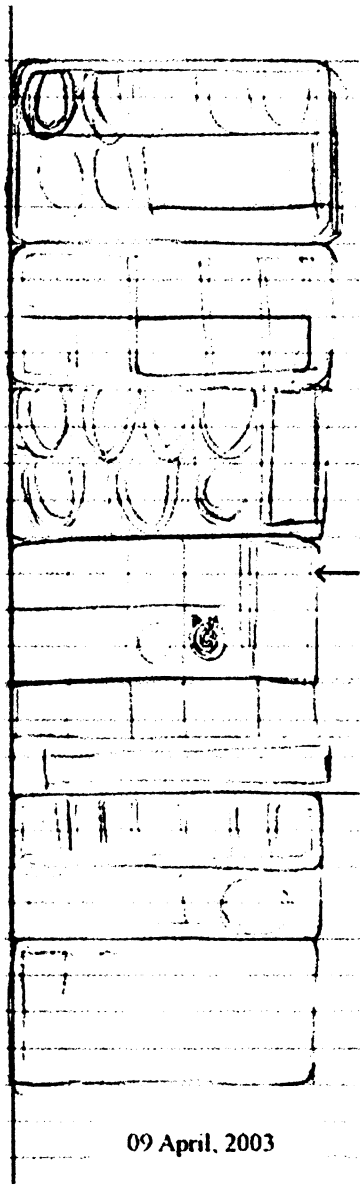



Figure 39 – Solid Oral Organizer Sketch 3

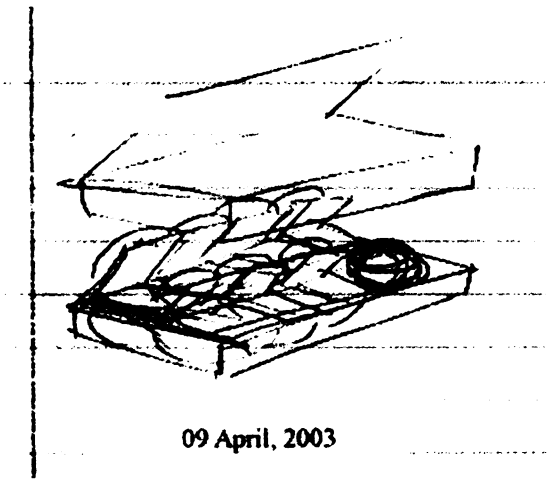



Figure 40 – Solid Oral Organizer Sketch 4

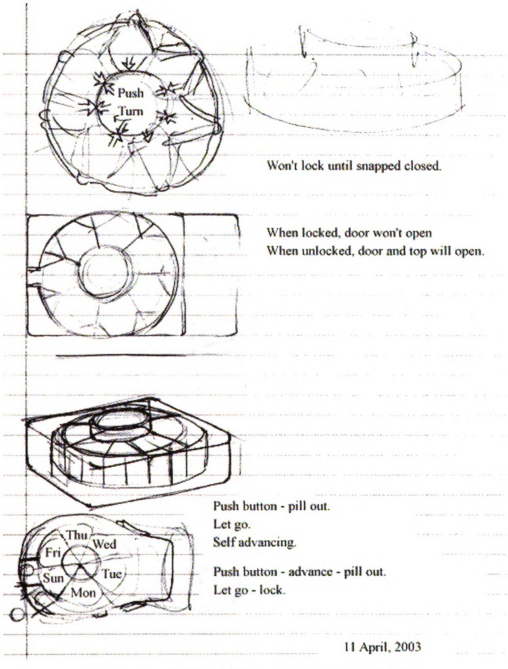



Figure 41 – Solid Oral Organizer/Dispenser Sketch

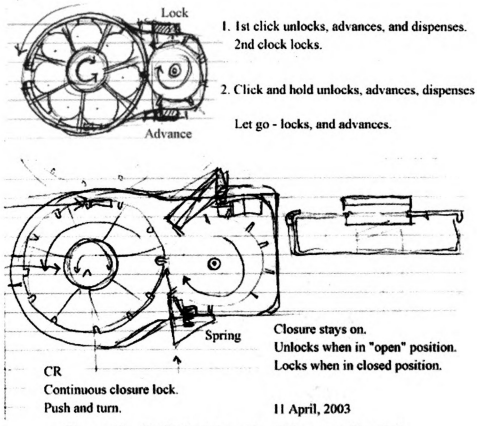



Figure 42 – Solid Oral Organizer/Dispenser Sketch 2

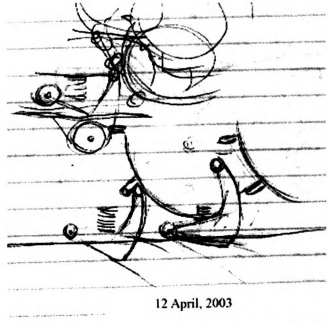



Figure 43 – Solid Oral Organizer/Dispenser Gear and Ratchet Sketch

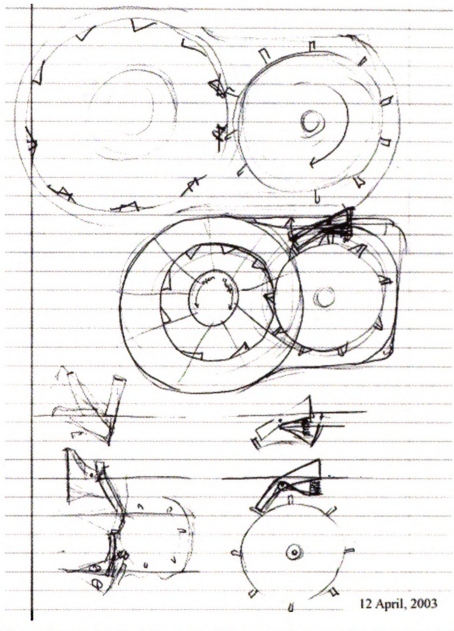
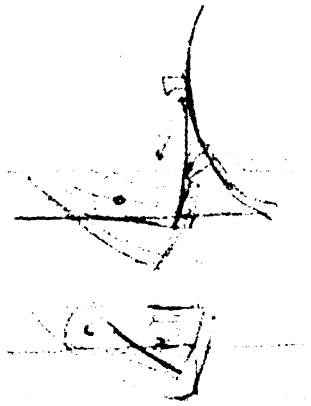



Figure 44 – Solid Oral Organizer/Dispenser Gear and Ratchet Sketch 2



12 April, 2003

Figure 45 – Solid Oral Organizer/Dispenser Gear and Ratchet Sketch 3

## Appendix 4: Package Drawings

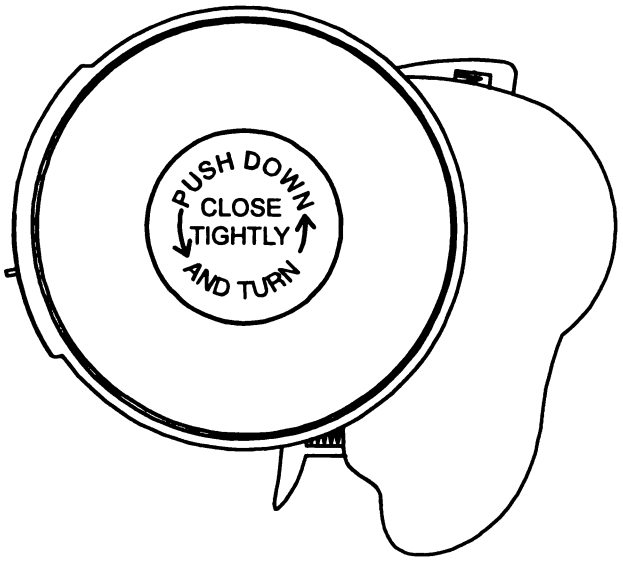



Figure 46 – Top View of Package

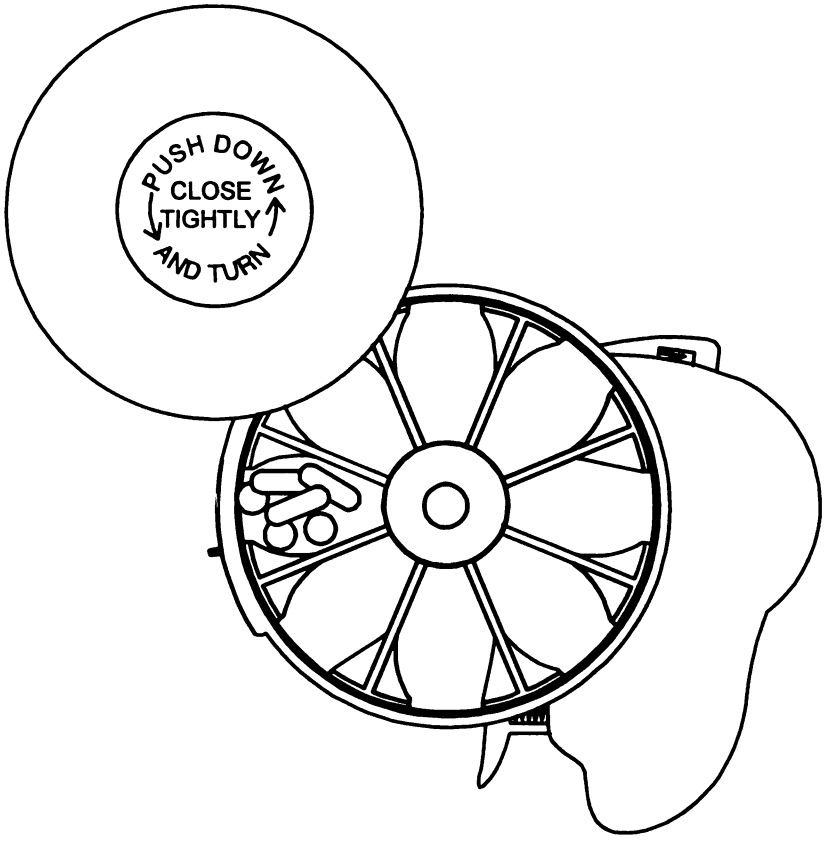



Figure 47 – Top View of Package with Closure and Cover Removed

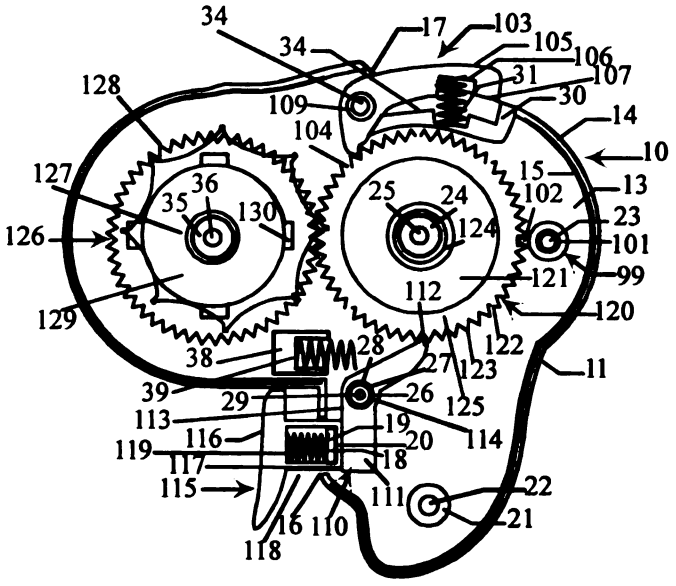



Figure 48 – Top Cross-Section View of Package Second Closing and Advancement Mechanism

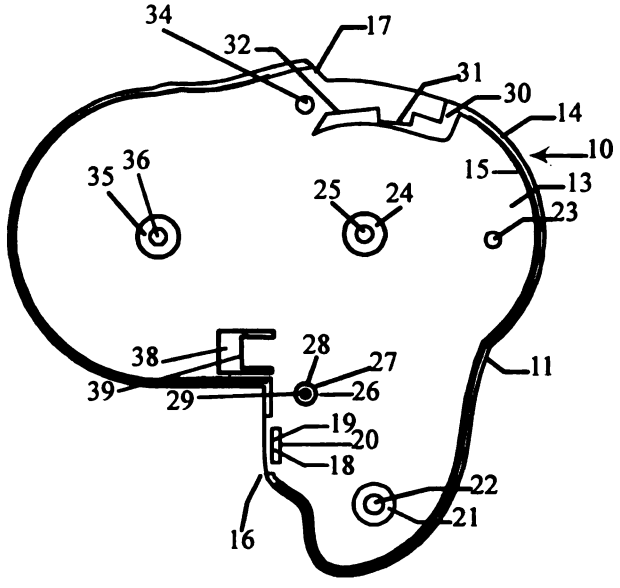



Figure 49 – Top View of Package Second Housing

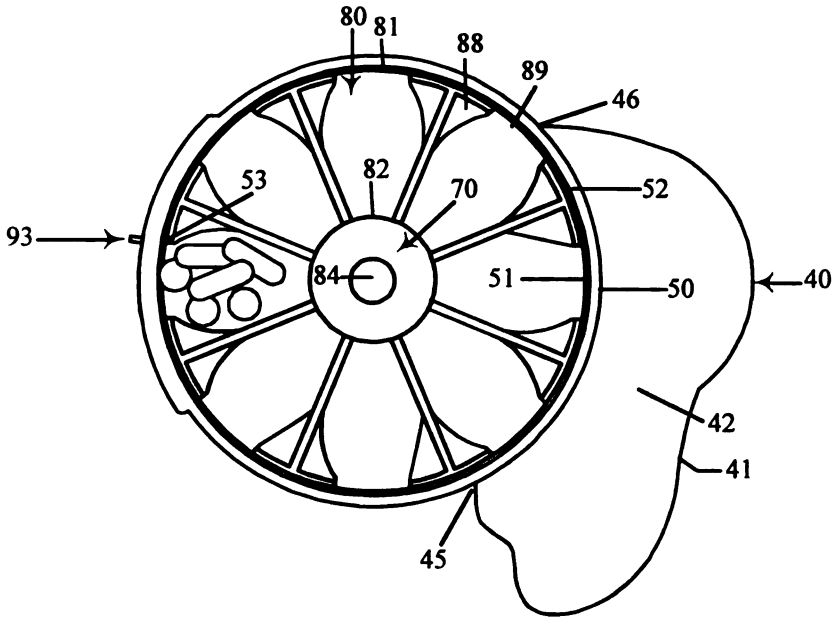



Figure 50 – Top View of Package without Closure and Cover

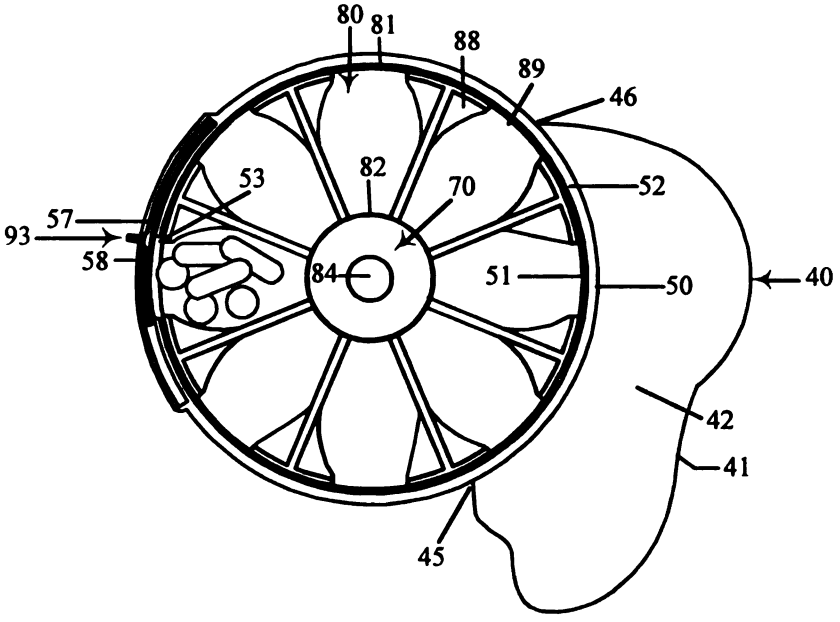



Figure 51 – Top Cross-Sectional View of Package through Circular Wall of First Housing

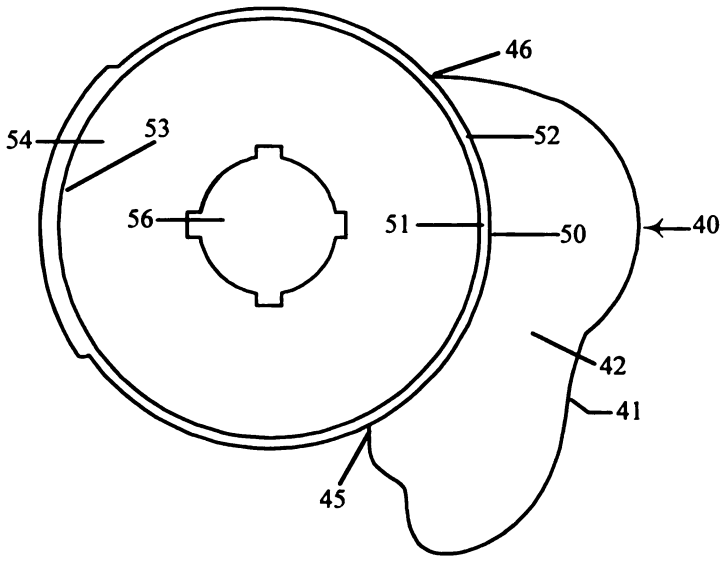



Figure 52 – Top View of Package First Housing

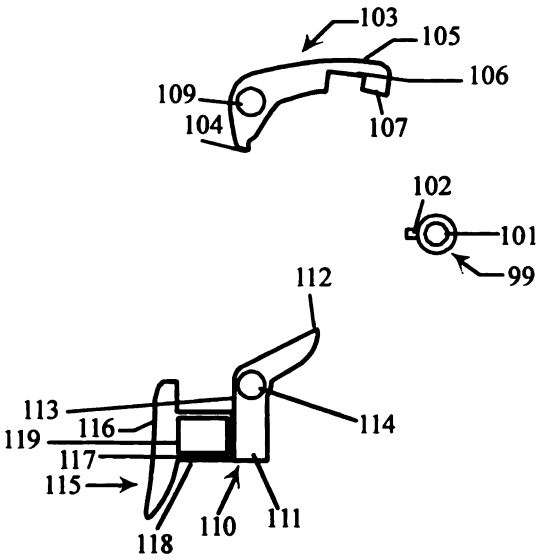



Figure 53 – Top View of Package Lock Release, Trigger, Ratchet, and Break in Relation to One Another

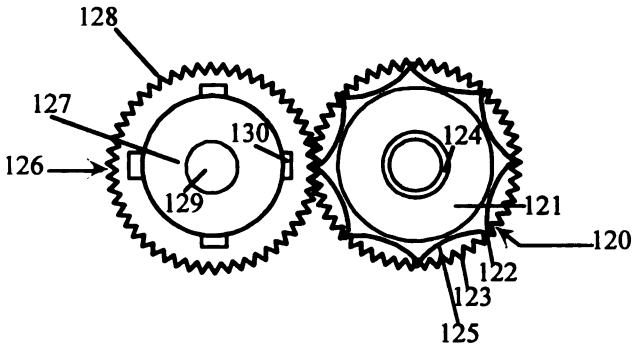



Figure 54 – Top View of Package First Gear and Second Gear in Relation to One Another

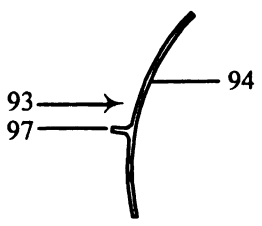



Figure 55 – Top View of Package Sliding Door

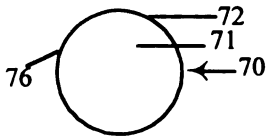



Figure 56 – Top View of Package Wheel Cap

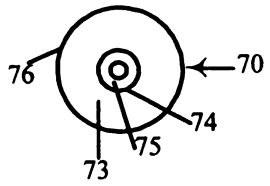



Figure 57 – Bottom View of Package Wheel Cap

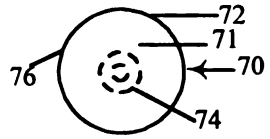



Figure 58 – Top View of Package Wheel Cap 2

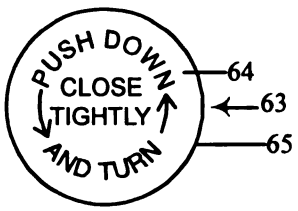



Figure 59 – Top View of Child-Resistant Closure

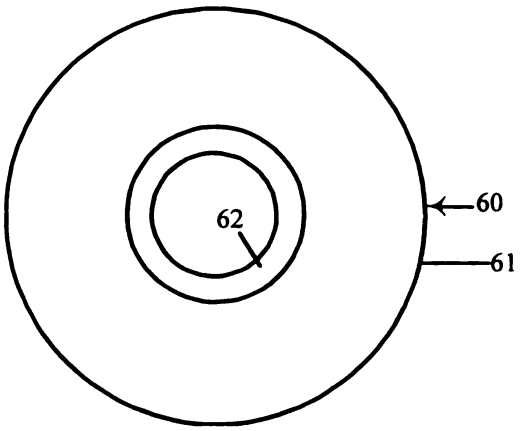



Figure 60 – Top View of Package Clear Cover

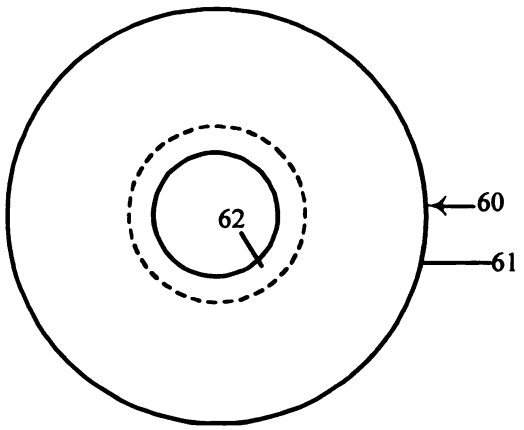



Figure 61 – Bottom View of Package Clear Cover

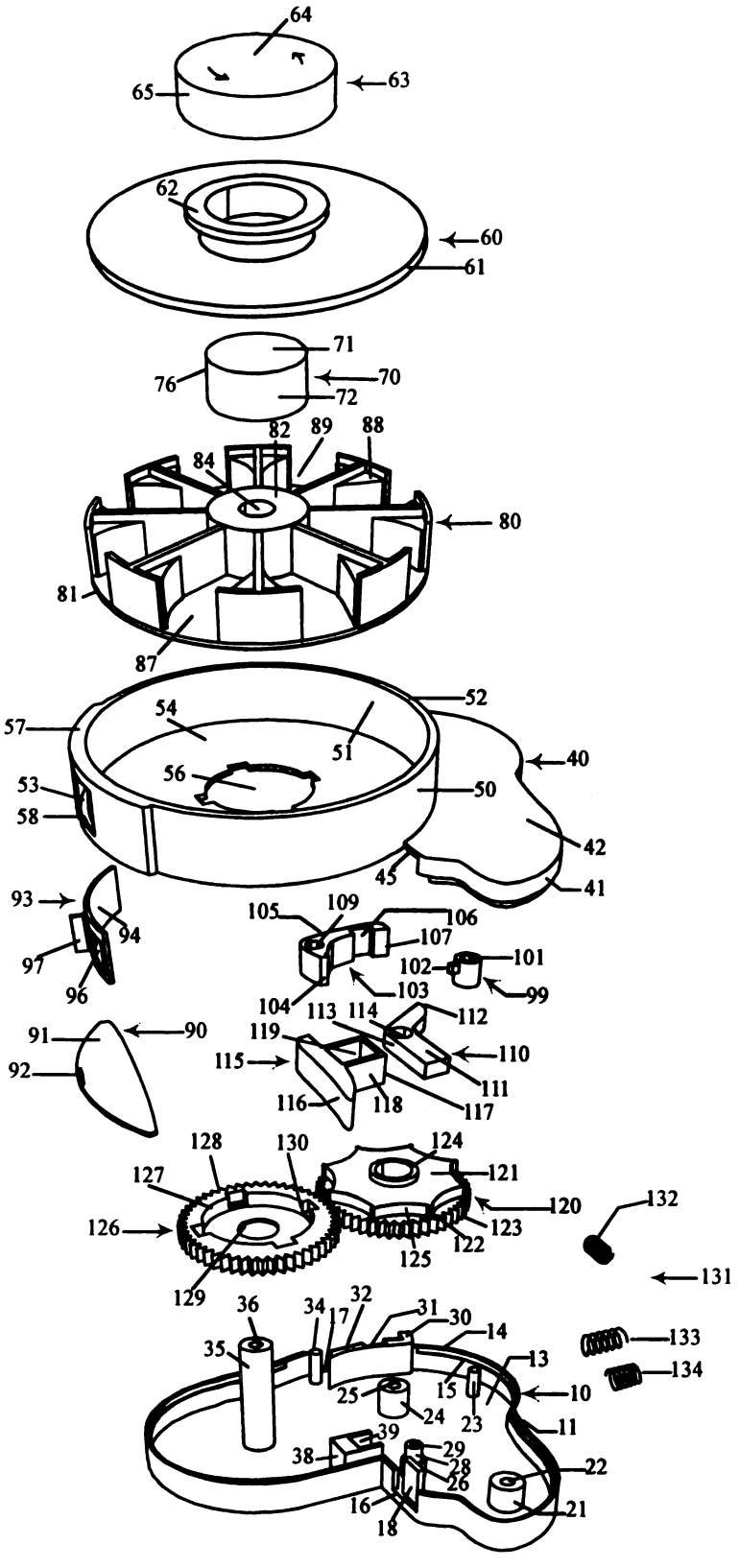



Figure 62 – Top Perspective Exploded View of Package

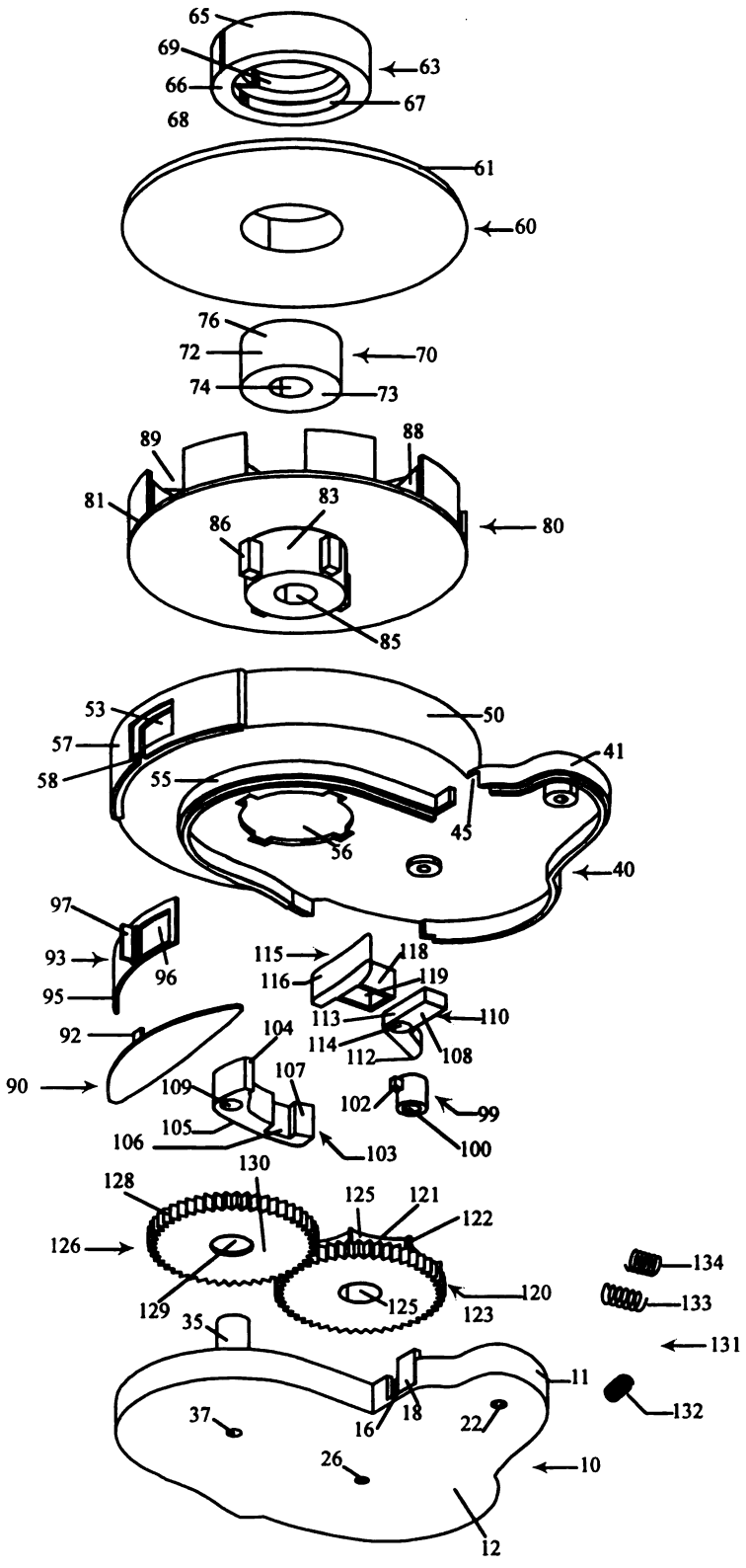



Figure 63 – Bottom Perspective Exploded View of Package

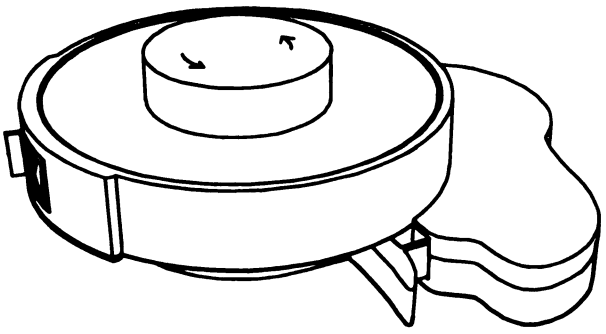


Figure 64 – Top Perspective View of Package

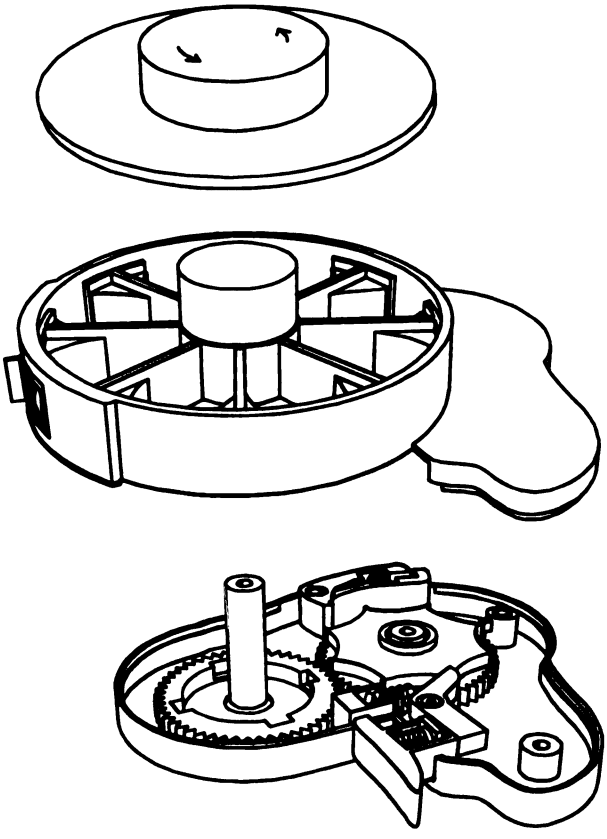


Figure 65 – Top Perspective View of Package with Separated Clear Cover, First Housing, and Second Housing

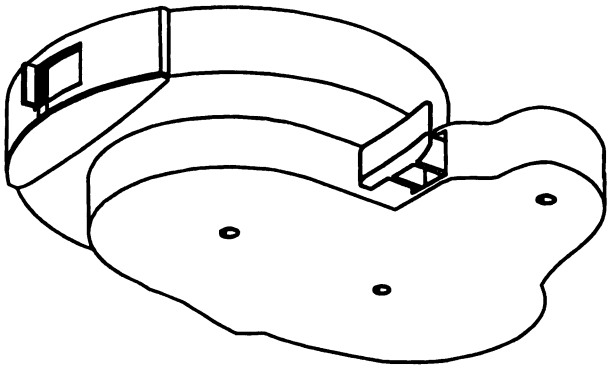


Figure 66 – Bottom Perspective View of Package

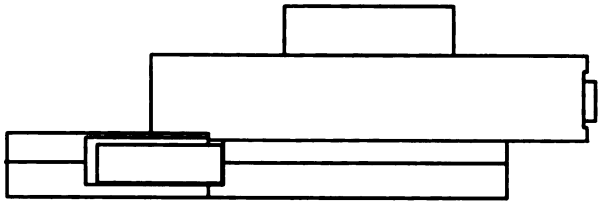


Figure 67 – Back View of Package

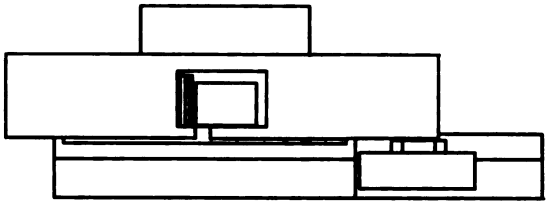


Figure 68 – Front View of Package

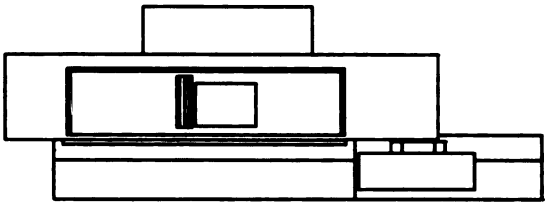


Figure 69 – Front View of Package with Exposed Sliding Door Chamber

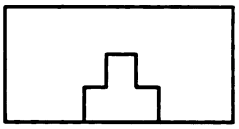


Figure 70 – Side Cross-Sectional View of Package Wheel Cap

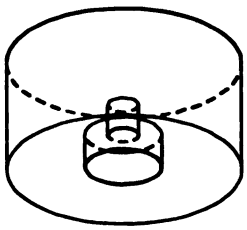


Figure 71 – Bottom Perspective View of Wheel Cap

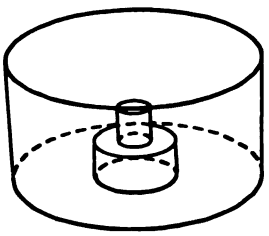


Figure 72 – Top Perspective View of Wheel Cap

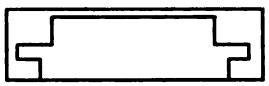


Figure 73 – Side Cross-Sectional View of Package Child-Resistant Closure

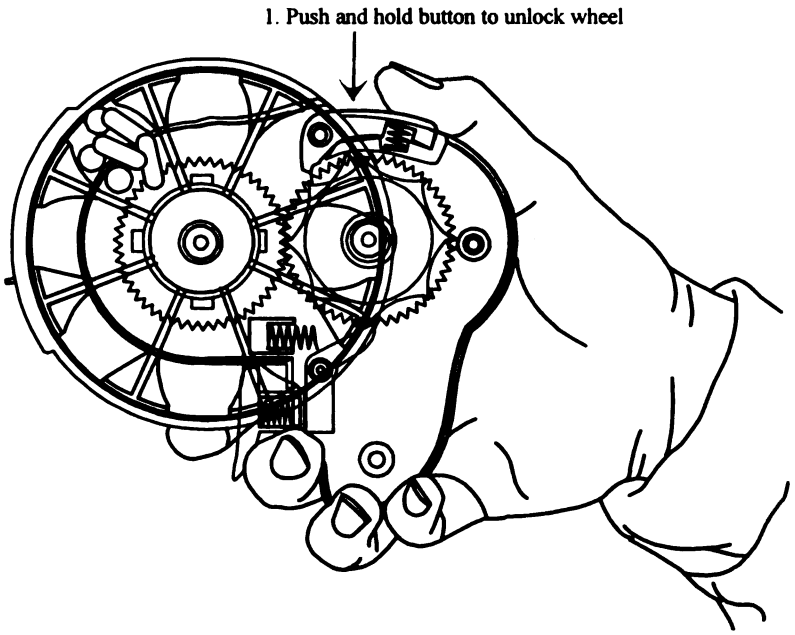



Figure 74 – Top View of Package Inner Workings which Illustrate how to Advance Rotary Wheel with Lock Release in Unlocked Position

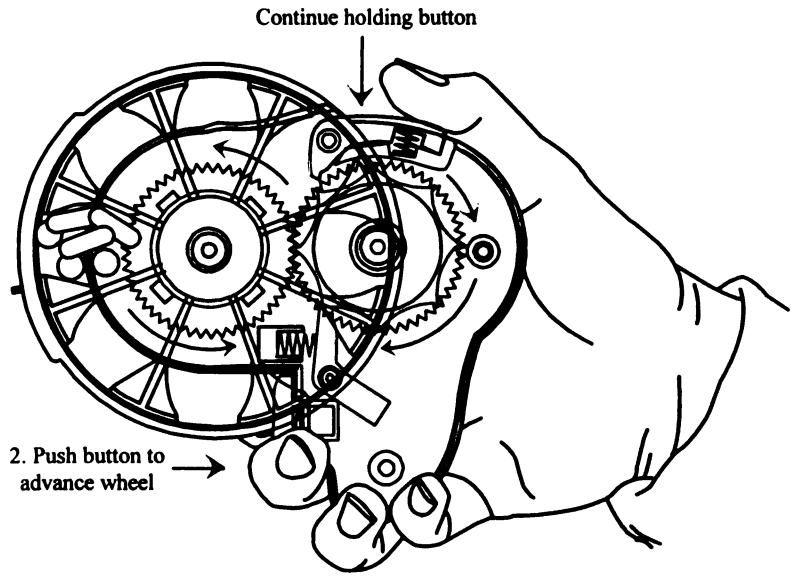



Figure 75 – Top View of Package Inner Workings which Illustrate how to Advance Rotary Wheel by Pulling Trigger

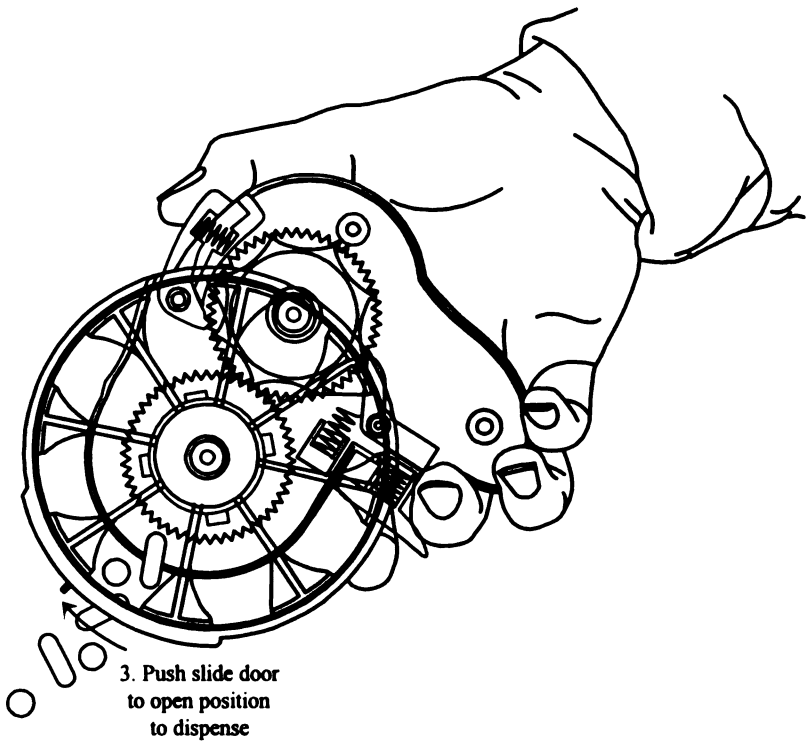



Figure 76 – Top View of Package Inner Workings which Illustrate how to Access the Contents with Rotary Wheel in a Resting Position

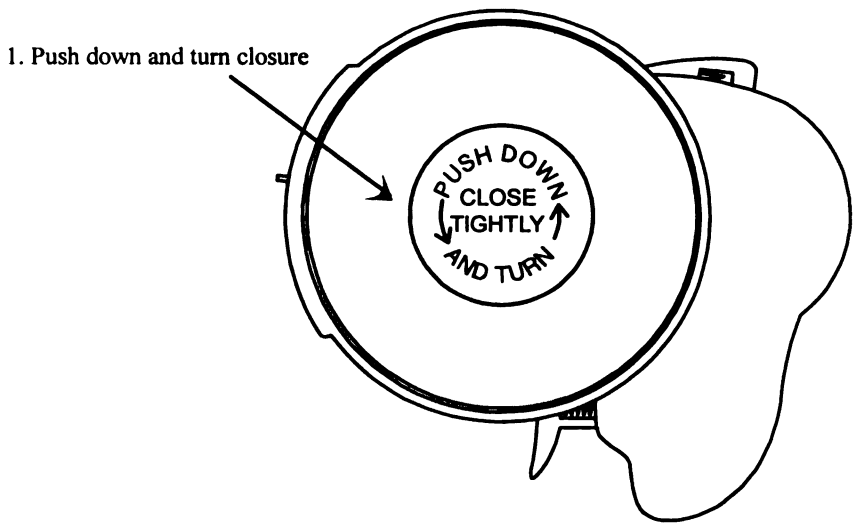



Figure 77 – Top View of Package which Illustrates How to Refill Package by Disengaging Child-Resistant Closure

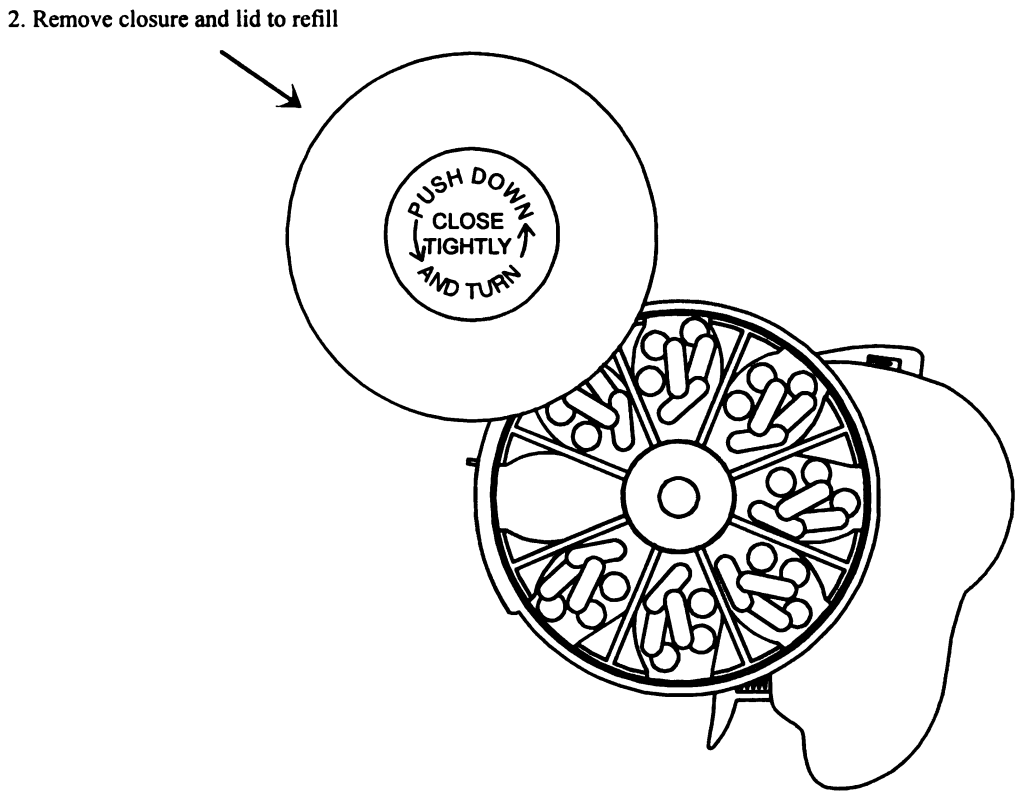



Figure 78 – Top View of Package which Illustrates How to Refill Package by Removing Closure and Cover

Table 7 – Package Part Legend

**10. Second housing**
11. Second housing – edge wall
12. Second housing – bottom surface
13. Second housing – enclosed surface
14. Second housing – side rim
15. Second housing – first housing bottom rim rest
16. Second housing – first opening
17. Second housing – second opening
18. Second housing – third post
19. Second housing – third post top
20. Second housing – third post face
21. Second housing – first screw housing
22. Second housing – first screw housing open threaded circular cavity
23. Second housing – second post
24. Second housing – first axle
25. Second housing – second screw housing
26. Second housing – second screw housing open threaded circular cavity
27. Second housing – fourth post trigger runner top
28. Second housing – fourth post trigger runner
29. Second housing – fourth post
30. Second housing – lock release base
31. Second housing – lock release base open spring cavity
32. Second housing – lock release rest
34. Second housing – first post
35. Second housing – second axle
36. Second housing – second axle screw housing open circular cavity top
37. Second housing – second axle screw housing open circular cavity bottom
38. Second housing – ratchet spring base
39. Second housing – ratchet spring open cavity
**40. First housing**
41. First housing – bottom wall
42. First housing – top face
45. First housing – trigger opening
46. First housing – lock release cavity
50. First housing – circular wall
51. First housing – circular wall inner surface
52. First housing – circular wall outer surface
53. First housing – circular wall opening
54. First housing – enclosed portion of top face
55. First housing – second housing fitment side
56. First housing – circular base open cavity
57. First housing – slide door housing outer side
58. First housing – support plate tab fitment notch

**60. Segment (compartment) cover**
61. Segment cover – edge
62. Segment cover – continuous thread closure engagement
**63. Continuous thread child-resistant closure**
64. Continuous thread child-resistant closure – top surface
65. Continuous thread child-resistant closure – side (gripping surface)
66. Continuous thread child-resistant closure – rim
67. Continuous thread child-resistant closure – circular cavity
68. Continuous thread child-resistant closure – segment cover bead engagement
69. Continuous thread child-resistant closure – wheel cap engagement threads
**70. Wheel cap**
71. Wheel cap – top face
72. Wheel cap – continuous closure engagement threads
73. Wheel cap – bottom face
74. Wheel cap – circular cavity
75. Wheel cap post bed
76. Wheel cap – side
**80. Rotary cam-wheel**
81. Rotary cam-wheel – rim
82. Rotary cam-wheel – wheel cap rest
83. Rotary cam-wheel – circular base
84. Rotary cam-wheel – open circular cavity top
85. Rotary cam-wheel – open circular cavity bottom
86. Rotary cam-wheel – pegs
87. Rotary cam-wheel – segments
88. Rotary cam-wheel – spokes
89. Rotary cam-wheel – wedge shaped pockets (compartments)
**90. Support plate**
91. Support plate – attachment bed
92. Support plate – fitment tab
**93. Sliding door**
94. Sliding door – closed end
95. Sliding door – bottom edge
96. Sliding door – open end
97. Sliding door – tab
**99. Break**
100. Break – circular cavity bottom
101. Break – circular cavity top
102. Break – flexible tooth
**103. Lock release**
104. Lock release – second end
105. Lock release – first end
106. Lock release – open spring cavity
107. Lock release – bottom end
108. Ratchet arm – third end
109. Lock release – hole

**110. Ratchet arm**
111. Ratchet arm – first end
112. Ratchet arm – second end
113. Ratchet arm – base
114. Ratchet arm – circular open cavity
**115. Trigger**
116. Trigger – first side
117. Trigger – second side
118. Trigger – outer side
119. Trigger – open cavity
**120. First gear**
121. First gear – circular cam-wheel
122. First gear – regularly spaced projections of circular cam-wheel
123. First gear – teeth
124. First gear – raised circular cavity ridge
125. First gear – trigger runners
**126. Second gear**
127. Second gear – circular depression
128. Second gear – teeth
129. Second gear – open circular cavity
130. Second gear – circular depression notches
**131. Springs**
132. Springs – lock release
133. Springs – trigger
134. Springs – ratchet

## Appendix 5: Consent and Confidential Agreement Forms

INSTRUCTIONS AND RESEARCH CONSENT FORM

**Determining the Ease of Use of a Newly Developed Child-Resistant OTC/Pharmaceutical Solid Oral Medication/Vitamin Supplemental Organizer/Dispenser Package**

You must be 21 years of age or older and able to use a package without assistance in order to participate in this study.

You are being asked to participate in a study that determines if the newly developed package is easy to handle as well as easy to use for people with and without decreased hand dexterity. The purpose of this study is to:

1. determine if the two buttons that are required to be pressed to use this package are at a comfortable distance apart, as well as package feel.
2. determine if the use of the new package is easy to learn and to understand

Before testing begins you will be asked to sign a confidential disclosure agreement, in which each receiving party agrees neither to use the Confidential Information for any purpose other than evaluation nor to provide the Confidential Information to any third party other than a signatory to this agreement for a period of five (5) years upon the receipt of the confidential information. You will also be asked to sign a form granting permission for photographs to be taken of you during your participation in this research.

In exchange for your participation in this study you will receive a choice of one (1) of the following snack items:

1. Nature Valley Crunchy Granola Bars – Oats 'N Honey Net Wt 1.5oz (42g)
2. Combos Snacks – Cheddar Cheese Cracker Net Wt 1.70oz (48.2g)

During the course of the study you will be asked to watch a 3D animation of the new package being used, to gain understanding of how the package works; what happens when the two buttons are pushed to dispense of solid oral medication/vitamin supplemental package. You will also be asked to handle a non-working prototype of the new package for the determination of your comfort when handling and using the new package. Then you will be asked to answer as many questions on questionnaire, as accurately as possible. At anytime during this test you may request to view the 3D animation and handle the new package non-working prototype, again, to help you answer the questions. There are 17 questions to answer on the questionnaire.

If you have any questions at any time please ask. The entire session will last approximately 20 minutes.

There are minimal possible risks of participating in this research.

If you have any questions or comments regarding this study, please contact Dr. Harold Hughes, Professor of Packaging at Michigan State University at 517-353-6462 or harold@msu.edu.

You are free to discontinue your participation in this study at any time without penalty.

If you choose to discontinue your participation you will still receive one (1) of the snack items listed above.

The results of this study will be treated in strict confidence in that your name will not be associated with any of your responses. Your privacy will be protected to the maximum extent of the law.

You are aware that your participation in this study does not guarantee any beneficial results to you, except that your participation in this research will provide society with a package that people with disabilities can access.

If you have any questions or concerns regarding your rights as a study participant, or are dissatisfied at any time with any aspect of your study, you may contact – anonymously if you wish – Peter Vasilenko, PhD., Chair of the University Committee Involving Human Subjects (UCRIHS) by phone: (517) 355-2180, fax: (517) 432-4503, e-mail: uchris@msu.edu, or regular mail: 202 Olds Hall, East Lansing, MI 48824.

I voluntarily agree to participate in the study determining the comfort and use of the new package.

Signature: _____

Date: _____

You will be provided with a copy of your signed consent form.

UCRIHS APPROVAL FOR THIS project EXPIRES:

OCT 1 3 2004

SUBMIT RENEWAL APPLICATION ONE MONTH PRIOR TO ABOVE DATE TO CONTINUE

MEDIA CONSENT FORM

**Determining the Ease of Use of a Newly Developed Child-Resistant OTC/Pharmaceutical Solid Oral Medication/Vitamin Supplemental Organizer/Dispenser Package**

Photos and/or video will be taken, with your permission, during your participation in this testing. This media will be used for a slide show that will be shown, with music, prior to thesis defense presentation, or during thesis defense, only. Your privacy will be protected to the maximum extent of the law.

You may decide not to have your picture taken at any time during your participation without penalty.

If you have any questions or comments regarding this study, please contact Dr. Harold Hughes, Professor of Packaging at Michigan State University at 517-353-6462 or harold@msu.edu.

If you have any questions or concerns regarding your rights as a study participant, or are dissatisfied at any time with any aspect of your study, you may contact – anonymously if you wish – Peter Vasilenko, PhD., Chair of the University Committee Involving Human Subjects (UCRIHS) by phone: (517) 355-2180, fax: (517) 432-4503, e-mail: uchris@msu.edu, or regular mail: 202 Olds Hall, East Lansing, MI 48824.

I voluntarily agree to participate have media, such as those gathered by camera and video, use of the new package.

Signature: _____

Date: _____

You will be provided with a copy of your signed media consent form.

**MICHIGAN STATE UNIVERSITY**
**OFFICE of INTELLECTUAL PROPERTY**

## CONFIDENTIAL DISCLOSURE AGREEMENT

1. The undersigned parties (herein "Party" or "Parties" as appropriate under the context) agree to the following conditions for the mutual disclosure and exchange of valuable confidential or proprietary materials and information (herein "Confidential Information") relating to DESIGNING A SENIOR FRIENDLY OTC/PHARMACEUTICAL SOLID ORAL MEDICATION/VITAMIN SUPPLEMENTAL ORGANIZER/DISPENSER PACKAGE.
The Confidential Information may include but is not limited to products, processes, techniques, know-how, trade secrets, scientific knowledge, materials, sequences, inventions, machines, data, formulas, samples, models, systems, networks, business plans, customer requirements, software, designs, drawings, schematics, sketches, photographs, digital outputs, specifications, documentation, reports, and/or studies of the originating Party.

2. In consideration for such disclosure, each receiving Party, agrees neither to use the Confidential Information for any purpose other than evaluation nor to provide the Confidential Information to any third party other than a signatory to this Agreement for a period of five (5) years from the date of receipt of the Confidential Information. Nothing herein shall grant or imply a license or right to use any Confidential Information, or any patents, copyrights, trademarks, and trade secrets of the disclosing Party, except to the extent necessary for the evaluation contemplated herein.

3. All Confidential Information provided in a tangible form will be marked as "Confidential." A Party disclosing Confidential Information in verbal or other non-tangible form shall provide the other Parties written notice within thirty (30) days after each such communication identifying the confidential aspects of the disclosure.

4. Each receiving Party agrees to limit access to the other Parties' Confidential Information only to its employees, students, research assistants, postdoctoral fellows, agents, vendors and consultants for whom such access is necessary, and only to the extent that such individuals have an obligation of confidentiality to said receiving Party. The Parties shall exercise reasonable care to prevent disclosure of the Confidential Information to any third party that is not bound by this Agreement.

5. Each receiving Party agrees to make its evaluation as promptly as possible and, upon request by the providing Party at any time, agrees to return any or all samples and

Confidential Information together with any and all copies thereof, with the exception of one copy of Confidential Information which may be held for archival purposes only.

6. The secrecy and non-disclosure obligations of this Agreement do not apply to information that:

a) at the time of the disclosure was generally available to the public or thereafter has become generally available to the public through no breach of the Agreement by the receiving Party.

b) the receiving Party can show by written records was in its possession prior to the time of disclosure and was not acquired, directly or indirectly, from the disclosing Party.

c) the receiving Party can show by written records was discovered or developed independently, without use or knowledge of the Confidential Information.

d) the receiving Party can show by written records was obtained from a third party that reasonably believed it was under no obligation of confidentiality or secrecy to the originating Party.

e) is required to be disclosed by law, legal process, government agency, or court order.

7. Modifications, extensions, or amendments to this Agreement shall be done in writing and executed by all Parties to this Agreement. The Parties agree that any photocopied or electronically produced copy of this fully executed original Agreement shall have the same legal force and effect as a copy of the Agreement that has the original signatures.

8. This Agreement shall be executed by all Parties through duly authorized representative and shall be effective as of the date of last signing.

| | |
|---|---|
| MICHIGAN STATE UNIVERSITY | Party: _____ |
| By: Loraine J. Hudson | By: _____ |
| Typed Name: Loraine J. Hudson | Typed Name: _____ |
| Title: Director, Office of Intellectual Property | Title: _____ |
| Address: 246 Administration Building | Address _____ |
| East Lansing, MI 48824-1046 | _____ |
| Date: 11/21/03 | Date: _____ |

## Appendix 6: Questionnaire

Questionnaire

**Determining the Ease of Use of a Newly Developed Child-Resistant OTC/Pharmaceutical Solid Oral Medication/Vitamin Supplemental Organizer/Dispenser Package**

**A. General Information** *(Please check all that apply)*

1. What is your age?
   - ☐ 21 – 45
   - ☐ 60 – 77
   - ☐ 46 – 60
   - ☐ 77+

2. What is your sex?
   - ☐ Male
   - ☐ Female

**B. Health and Solid Oral Daily Consumption**

3. Physical condition: *(Please check all that apply)*
   - ☐ Normal
   - ☐ Secondary →
     - ☐ Arthritis →
       - ☐ Osteo Arthritis
       - ☐ Rheumatoid Arthritis
       - ☐ Other _____
     - ☐ Stroke →
       - ☐ Minor
       - ☐ Major → paralysis ☐ Yes ☐ No
     - ☐ Other: _____

4. Solid oral Vitamin/Supplement
   Do you take medication/vitamin supplements on a daily basis and how many?
   - ☐ Yes → Solid Oral ☐ Yes →
     - ☐ Medication #____
     - ☐ Vitamin Supplement #____
     - ☐ Both #____
   - Liquid ☐ Yes
   - ☐ No

**C. Packaging**

5. In most cases, what types of containers do your OTC/pharmaceutical/vitamin supplemental solid orals come in? *(Please check all that apply)*
   - ☐ Paperboard carton with blister sheets
   - ☐ Bottle with child resistant closure
   - ☐ Bottle without child resistant closure
   - ☐ Other: _____

6. Of the above child resistant containers that you use please rate the containers for ease of use *(Please check one)*
   - ☐ Very easy
   - ☐ About right
   - ☐ Somewhat difficult
   - ☐ Very difficult

(go to next page)

1

7. Do you use pill organizers/dispensers?
   ☐ Yes
   ☐ No

8. What kind of pill organizer/dispenser do you, or would you prefer to use?

   ☐ Daily – child resistant
   ☐ Daily – not child resistant
   ☐ Multi dose per day – child resistant
   ☐ Multi dose per day – not child resistant
   ☐ None

**D. Newly Designed Package Questions**

Please indicate how much you agree or disagree with the following statements concerning the newly designed package?

| Statements | Strongly agree | agree | Neither Agree or Disagree | Disagree | Strongly Disagree |
|---|---|---|---|---|---|
| **9.** The package method of use was easy to learn | | | | | |
| **10.** The feel of the handle is comfortable | | | | | |
| **11.** The distance of the two buttons are at an adequate distance apart | | | | | |
| **12.** The distance of the buttons is comfortable for individuals with decreased physical hand dexterity, such as gripping or pinch strength | | | | | |
| **13.** I would feel comfort in knowing that the dispenser I use is child-resistant | | | | | |
| **14.** This package will aid in medical compliance for both individuals with or without physical hand dexterity | | | | | |
| **15.** If manufactured, I have a desire to own and use this package | | | | | |

You have completed this questionnaire.
Please return it to Amy S. Houghtaling.
Remember to get your compensatory award.

☺ **Thank You** ☺

## Appendix 7: Questionnaire Data

***Section 1: Secondary Test Subject Information***

*Secondary Test Subject Physical Condition*

Of the secondary test subjects 69% male and 81% female test subjects had arthritis, 11% female test subjects had strokes, and 31% male and 8% of female had other kinds of physical aliments. (Figure 79)

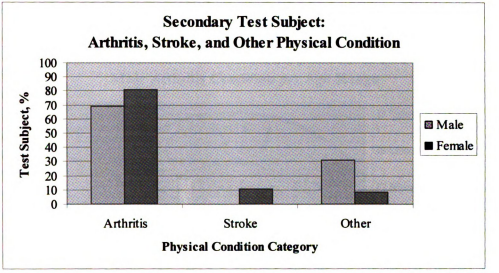



Figure 79 – Secondary Test Subject: Arthritis, Stroke, and Other Physical Condition

*Secondary Male Test Subject Physical Condition*

Of the secondary male test subjects, 33% of age range 46 – 60, 33% of age range 60 – 77, and 33% of age range 77+, had unspecified arthritis. Of the secondary male test subjects, 14% of age range 21 – 45, 43% of age range 46 – 60, 29% of age range 60 – 77, and 14% of age range 77+ had rheumatoid arthritis. None of the secondary male test subjects tested had osteoarthritis. (Figure 80)

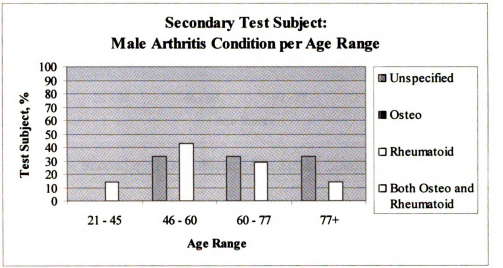



Figure 80 – Secondary Test Subject: Male Arthritis Condition per Age Range

None of the secondary male test subjects had any type of stroke condition.

(Figure 81)

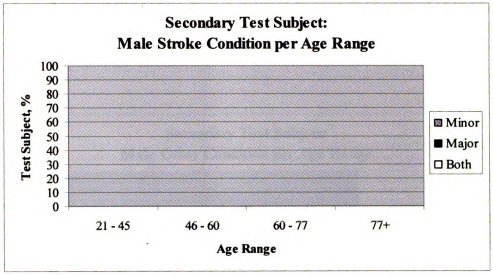



Figure 81 – Secondary Test Subject: Male Stroke Condition per Age Range

Of the secondary male test subjects with other physical conditions, 50% of age range 21 – 45, and 50 % of age range 46 – 60, had a disabled hand or arm. Other secondary male test subject physical conditions, such as conditions like Ankylosing Spondylitis, accounted for 67% of age range 46 – 60 and 33% of age range 60 – 77. (Figure 82)

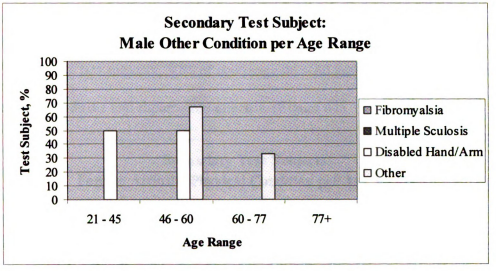



Figure 82 – Secondary Test Subject: Male Other Condition per Age Range

Of the secondary male test subjects having multiple physical conditions, 100% of age range 60 – 77 had a combination of rheumatoid arthritis and other. (Figure 83)

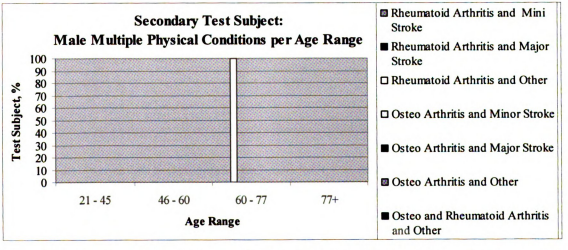



Figure 83 – Secondary Test Subject: Male Multiple Physical Conditions per Age Range

*Secondary Female Test Subject Physical Condition*

Of the secondary female test subjects, 25% of age range 21 – 45, 25% of age range 46 – 60, 25% of age range 60 – 77, and 25% of age range 77+, had unspecified arthritis. Of the secondary females, 8% of age range 21 – 45, 31% of age range 46 – 60, 38% of age range 60 – 77, and 23% of age range 77+ had osteoarthritis. Of the secondary female test subjects, 17% of age range 21 – 45, 42% of age range 46 – 60, 33% of age range 60 – 77, and 8% of age range 77+ had rheumatoid arthritis. Of the secondary female test subjects, 50% of age range 46 – 60 and 50% of age range 60 – 77 had both osteoarthritis and rheumatoid arthritis. (Figure 84)

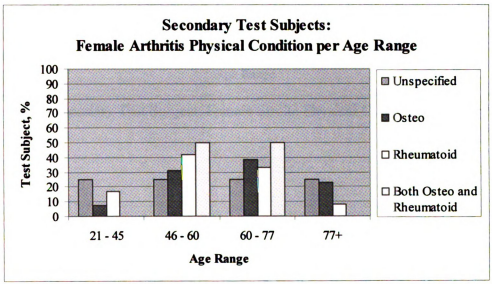



Figure 84 – Secondary Test Subject: Female Arthritis Physical Condition per Age Range

Of the secondary female test subjects, 33% of age range 46 – 60, 33% of age range 60 – 77, and 33% of age range 77+ had minor stroke conditions. Of the secondary female test subjects, 100% of age range 46 – 60 had major stroke conditions. (Figure 85)

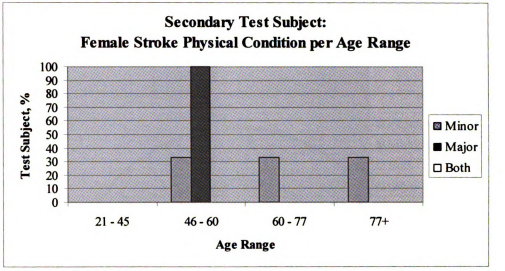



Figure 85 – Secondary Test Subject: Female Stroke Physical Condition per Age Range

Of the secondary female test subjects with other physical conditions, 100% of age range 46 – 60 had fibromyalsia, 100% of age range 46 – 60 had multiple sclerosis, 30% of age range 46 – 60, 30% of age range 60 – 77, and 40% of age range 77+ had physical ailments, such as congenital skeletal deformities. (Figure 86)

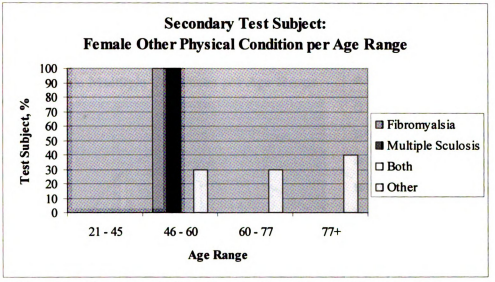



Figure 86 – Secondary Test Subject: Female Other Physical Condition per Age Range

Of the secondary female test subjects that had multiple physical conditions, 100% of age range 46 – 60 had both rheumatoid arthritis and major strokes, 50% of age range 46 – 60 and 50% of age range 60 – 77 had both rheumatoid arthritis and other, 29% of age range 46 – 60 and 29% of age range 60 – 77 had osteoarthritis and other, and 100% of age range 46 – 60 had minor strokes and other. (Figure 87)

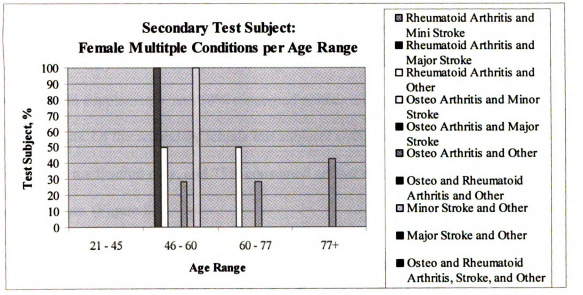



Figure 87 – Secondary Test Subject: Female Multiple Conditions per Age Range

***Section 2: Test Subject Solid Oral Medication/Vitamin Supplement and Quantity Use***

*Normal and Secondary Solid Oral Medication/Vitamin Supplement and Quantity Use*

Of the normal male test subjects within age range 21 – 45, 4% consumed medication only, 39% consumed vitamin supplements only, and 57% neither medication nor vitamin supplements only. Of the normal female test subject age range 21 – 45, 36% consumed vitamin supplements only, 14% consumed both medication and vitamin supplements, and 50% consumed neither medication nor vitamin supplements. Of the secondary male test subject age range 21 – 45, 50% consumed both medication and vitamin supplements, and 50% consumed neither medication nor vitamin supplements. Of the secondary female test subjects within age range 21 – 45, 25% consumed medication only, and 75% consumed neither medication nor vitamin supplements. (Figure 88)

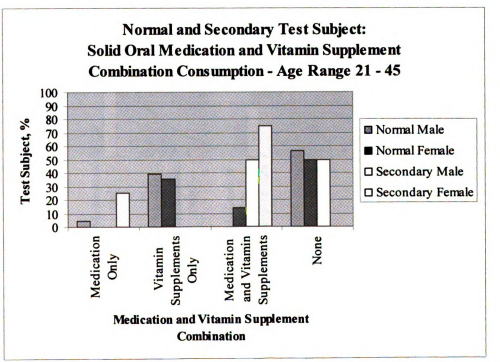



Figure 88 – Normal and Secondary Test Subject: Solid Oral Medication and Vitamin Supplement Combination Consumption - Age Range 21 – 45

Of the normal male test subjects within age range 46 – 60, 50% consumed both medication and vitamin supplements, and 50% consumed neither medication nor vitamin supplements. Of the normal females within age 46 – 60, 25% consumed only medication, 25% consumed both medication and vitamin supplements, and 25% consumed neither medication nor vitamin supplements. Of the secondary male test subjects within age range 46 – 60, 60% consumed medication only, and 40% consumed both medication and vitamin supplements. Of the secondary female test subjects within age range 46 – 60, 33% consumed only medication, 7% consumed vitamin supplements only, 47% consumed both medication and vitamin supplements, and 13% consumed neither medication nor vitamin supplements. (Figure 89)

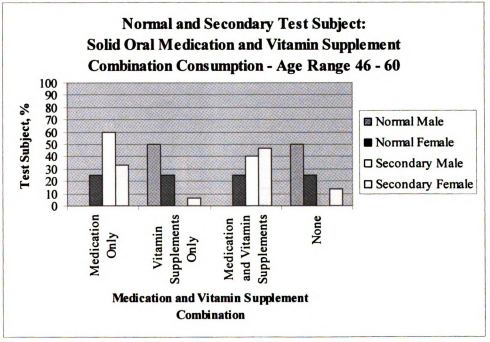



Figure 89 – Normal and Secondary Test Subject: Solid Oral Medication and Vitamin Supplement Combination Consumption - Age Range 46 – 60

Of the normal male test subjects within age range 60 – 77, 100% consumed both medication and vitamin supplements. Of the normal females within age range 60 – 77, 67% consumed vitamin supplements only, and 33% consumed both medication and vitamin supplements. Of the secondary male test subjects within age range 60 – 77, 50% consumed medication only, 25% consumed vitamin and supplements only, and 25% consumed both medication and vitamin supplements. Of the secondary female test subjects within age range 60 – 77, 27% consumed vitamin supplements only, 64% consumed both medication and vitamin supplements, and 9% consumed neither medication nor vitamin supplements. (Figure 90)

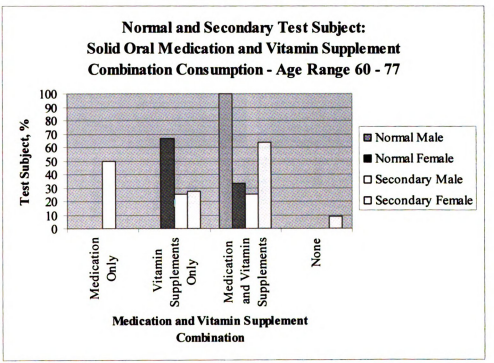



Figure 90 – Normal and Secondary Test Subject: Solid Oral Medication and Vitamin Supplement Combination Consumption - Age Range 60 – 77

Of the normal male test subjects within age range 77+, 50% consumed vitamin supplements only, and 50% consumed both medication and vitamin supplements. Of the normal females within age range 77+, 100% consumed both medication and vitamin supplements. Of the secondary male test subjects within age range 77+, 100% consumed both vitamin and supplements only. Of the secondary female test subjects within age range 77+, 14% consumed medications only, and 86% consumed both medication and vitamin supplements. (Figure 91)

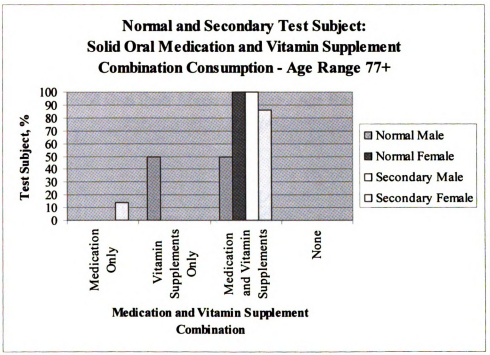



Figure 91 – Normal and Secondary Test Subject: Solid Oral Medication and Vitamin Supplement Combination Consumption - Age Range 77+

*Normal Test Subject Medication Consumption Quantities per Age Range*

Of the normal male test subjects within age range 21 – 45, 96% did not consume medication, and 4% consumed 4 medication doses, on a daily basis. Of the normal females within age range 21 – 45, 86% did not consume medication, and 14% consumed 1 medication dose, on a daily basis. Of the secondary male test subjects within age range 21 – 45, 50% did not consume medication, and 50% consumed 2 medication doses on a daily basis. Of the secondary female test subjects within age range 21 – 45, 50% consumed 7 medications doses, and 50% consumed 10 or more medication doses, on a daily basis. (Figure 92)

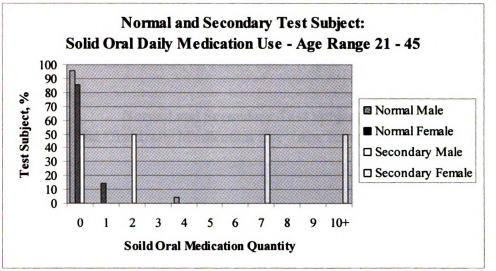



Figure 92 – Normal and Secondary Test Subject: Solid Oral Daily Medication Use - Age Range 21 – 45

Of the normal male test subjects within age range 46 – 60, 100% did not consume any medications. Of the normal females within age range 46 – 60, 50% did not consume any medications, 25% consumed 1 medication dose, and 25% consumed 4 does of medication, on a daily basis. Of the secondary male test subjects within age range 46 – 60, 20% consumed 1 medication dose, 20% consumed 2 medication doses, 20% consumed 4 medication doses, 20% consumed 8 medication doses, and 20% consumed 9 medication doses, on a daily basis. Of the secondary female test subjects within age range 46 – 60, 20% did not consume any medications, 7% consumed 1 medication dose, 13% consumed 3 medication doses, 20% consumed 4 medication doses, 7% consumed 5 medication doses, 7% consumed 9 medication doses, and 27% consumed 10 or more medications, on a daily basis. (Figure 93)

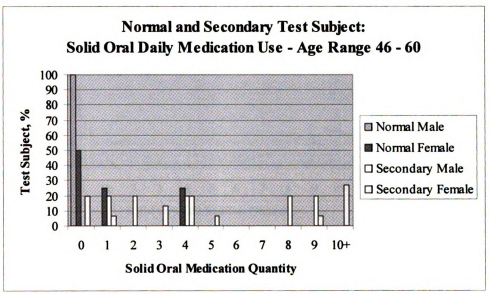



Figure 93 – Normal and Secondary Test Subject: Solid Oral Daily Medication Use - Age Range 46 – 60

Of the normal male test subjects within age range 60 – 77, 100% consumed 10 or more medications on a daily basis. Of the normal females within age range 60 – 77, 67% did not consume any medications, and 33% consumed 9 medication doses, on a daily basis. Of the secondary male test subjects within age range 60 – 77, 25% did not consume any medications, 25% consumed 7 medication doses, and 50% consumed 10 or more medication doses, on a daily basis. Of the secondary female test subjects within age range 60 – 77, 36% did not consume any medications, 9% consumed 2 medication doses, 18% consumed 4 medication doses, 9% consumed 5 medication doses, 9% consumed 9 medication doses, and 18% consumed 10 or more medications, on a daily basis. (Figure 94)

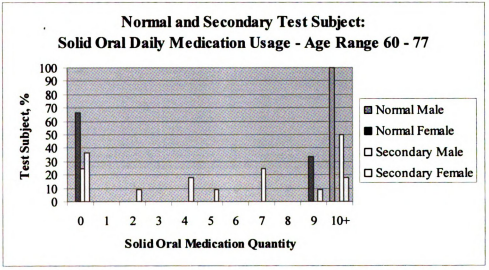



Figure 94 – Normal and Secondary Test Subject: Solid Oral Daily Medication Use - Age Range 60 – 77

Of the normal male test subjects within age range 77+, 50% did not consume any medications and 50% consumed 2 medication doses, on a daily basis. Of the normal females within age range 77+, 100% consumed 6 medication doses, on a daily basis. Of the secondary male test subjects within age range 77+, 50% consumed 3 medication doses and 50% consumed 10 or more medication doses, on a daily basis. Of the secondary female test subjects within age range 77+, 14% consumed 1 medication dose, 14% consumed 4 medication doses, 14% consumed 6 medication doses, 14% consumed 9 medication doses, and 29% consumed 10 or more medications, on a daily basis. (Figure 95)

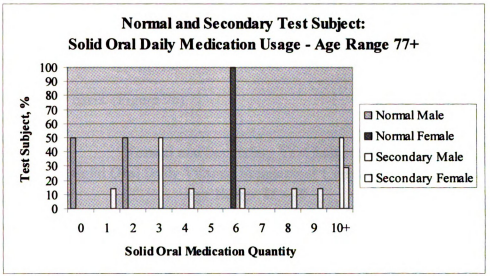



Figure 95 – Normal and Secondary Test Subject: Solid Oral Daily Medication Use - Age Range 77+

*Vitamin Supplement Usage Quantities per Age Range*

Of the normal male test subjects within age range 21 – 45, 61% did not consume any vitamin supplements, 30% consumed 1 vitamin supplement dose, 4% consumed 3 vitamin supplement doses, and 4% consumed 5 vitamin supplement doses, on a daily basis. Of the normal females within age range 21 – 45, 50% did not consume any vitamin supplements, 21% consumed 1 vitamin supplement dose, 7% consumed 2 vitamin supplement doses, 14% consumed 3 vitamin supplement doses, and 7% consumed 7 vitamin supplement doses, on a daily basis. Of the secondary male test subjects within age range 21 – 45, 50% did not consume any vitamin supplements and 50% consumed 3 vitamin supplement doses, on a daily basis. Of the secondary female test subjects within age range 21 – 45, 25% did not consume any vitamin supplements, 50% consumed 1vitamin supplement dose, and 25% consumed 7 vitamin supplement doses, on a daily basis. (Figure 96)

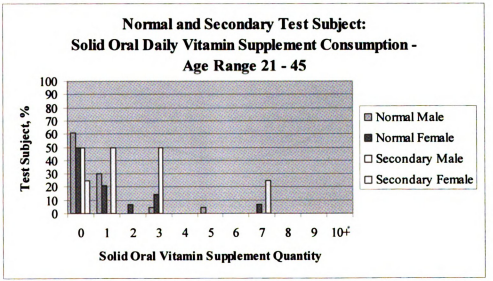



Figure 96 – Normal and Secondary Test Subject: Solid Oral Daily Vitamin Supplemental Consumption - Age Range 21 – 45

Of the normal male test subjects within age range 46 – 60, 50% did not consume any vitamin supplements and 50% consumed 5 vitamin supplement doses, on a daily basis. Of the normal females within age range 46 – 60, 50% did not consume any vitamin supplements, 21% consumed 1 vitamin supplement dose, and 25% consumed 3 vitamin supplement doses, on a daily basis. Of the secondary male test subjects within age range 46 – 60, 60% did not consume any vitamin supplements, 20% consumed 1 vitamin supplement dose, and 20% consumed 3 vitamin supplement doses, on a daily basis. Of the secondary female test subjects within age range 46 – 60, 47% did not consume any vitamin supplements, 20% consumed 1vitmain supplement dose, 7% consumed 2 vitamin supplement doses, 13% consumed 3 vitamin supplement doses, 7% consumed 5 vitamin supplement doses, and 7% consumed 6 vitamin supplement doses, on a daily basis. (Figure 97)

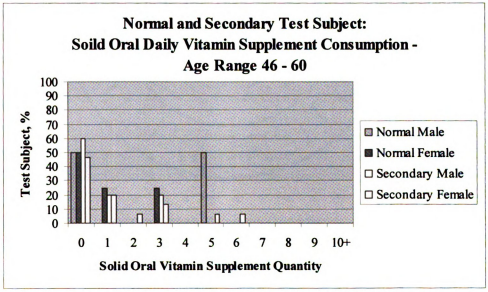



Figure 97 – Normal and Secondary Test Subject: Solid Oral Daily Vitamin Supplemental Consumption - Age Range 46 – 60

Of the normal male test subjects within age range 60 – 77, 100% consumed 3 vitamin supplement doses, on a daily basis. Of the normal females within age range 60 – 77, 33% consumed 1 vitamin supplement dose, 33% consumed 4 vitamin supplement doses, and 33% consumed 6 vitamin supplement doses, on a daily basis. Of the secondary male test subjects within age range 60 – 77, 50% did not consume any vitamin supplements, 25% consumed 4 vitamin supplement doses, and 25% consumed 3 vitamin supplement doses, on a daily basis. Of the secondary female test subjects within age range 60 – 77, 9% did not consume any vitamin supplements, 45% consumed 1 vitamin supplement dose, 9% consumed 2 vitamin supplement doses, 9% consumed 3 vitamin supplement doses, 18% consumed 4 vitamin supplement doses, and 9% consumed 8 medication doses, on a daily basis. (Figure 98)

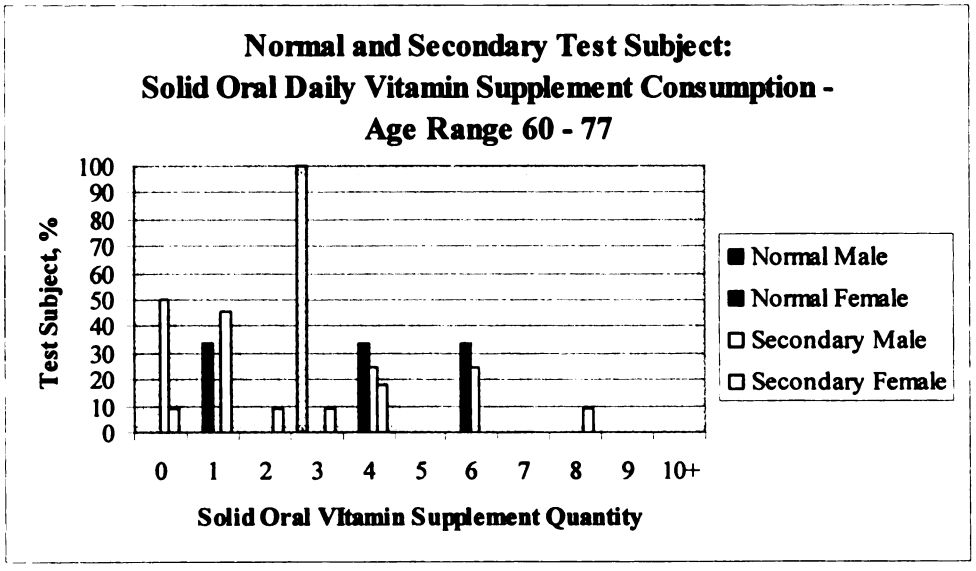



Figure 98 – Normal and Secondary Test Subject: Solid Oral Daily Vitamin Supplemental Consumption - Age Range 60 – 77

Of the normal male test subjects within age range 77+, 50% consumed 1 vitamin supplement dose and 50% consumed 2 vitamin supplement doses, on a daily basis. Of the normal females within age range 77+, 100% consumed 5 vitamin supplement doses, on a daily basis. Of the secondary male test subjects within age range 77+, 50% consumed 1 vitamin supplement dose and 50% consumed 4 vitamin supplement doses, on a daily basis. Of the secondary female test subjects within age range 77+, 14% did not consume any vitamin supplements, 57% consumed 1medication dose, and 29% consumed 2 vitamin supplements, on a daily basis. (Figure 99)

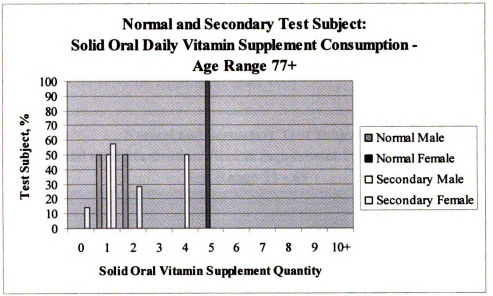



Figure 99 – Normal and Secondary Test Subject: Solid Oral Daily Vitamin Supplemental Consumption - Age Range 77+

***Section 3: Normal and Secondary Test Subject Medication/Vitamin Supplement Packaging Use***

Of the normal male test subjects within age range 21 – 45, 4% use paperboard cartons with blister sheets, 65% use bottles with child-resistant closures, and 9% use bottles without child-resistant closures. Of the normal females within age range 21 – 45, 14% use paperboard cartons with blister sheets, 36% use bottles with child-resistant closures, and 29% use bottles without child-resistant closures. Of the secondary male test subjects within age range 21 – 45, 50% use bottles with child-resistant closures, and 50% use bottles without child-resistant closures. Of the secondary female test subjects within age range 21 – 45, 25% use bottles with child-resistant closures, and 75% use bottles without child-resistant closures. (Figure 100)

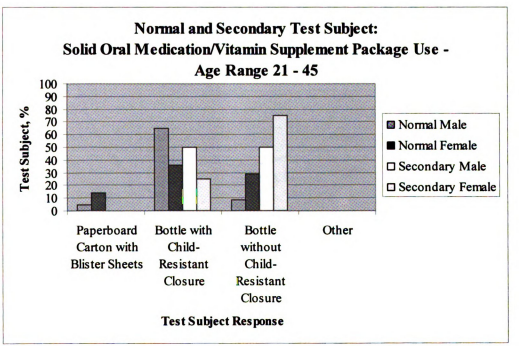



Figure 100 – Normal and Secondary Test Subject: Solid Oral Daily Medication/Vitamin Supplement Package Use - Age Range 21 – 45

Of the normal male test subjects within age range 46 – 60, 50% use bottles with child-resistant closures, and 50% use other kinds of medication/vitamin supplement packaging. Of the normal females within age range 46 – 60, 25% use paperboard cartons with blister sheets, 50% use bottles with child-resistant closures, and 25% use bottles without child-resistant closures. Of the secondary male test subjects within age range 46 – 60, 40% use bottles with child-resistant closures, 40% use bottles without child-resistant closures, and 20% use other kinds of medication/vitamin supplement packaging. Of the secondary female test subjects within age range 46 – 60, 7% use paperboard cartons with blister sheets, 40% use bottles with child-resistant closures, 27% use bottles without child-resistant closures, and 7% use other kinds of medication/vitamin supplement packaging. (Figure 101)

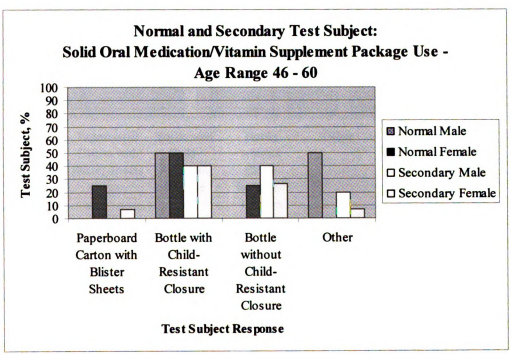



Figure 101 – Normal and Secondary Test Subject: Solid Oral Daily Medication/Vitamin Supplement Package Use - Age Range 46 – 60

Of the normal male test subjects within age range 60 – 77, 100% use bottles with child-resistant closures. Of the normal females within age range 60 – 77, 67% use bottles without child-resistant closures. Of the secondary male test subjects within age range 60 – 77, 50% use bottles with child-resistant closures and 25% use other kinds of medication/vitamin supplement packaging. Of the secondary female test subjects within age range 60 – 77, 9% use paperboard cartons with blister sheets, 45% use bottles with child-resistant closures, and 27% use bottles without child-resistant closures. (Figure 102)

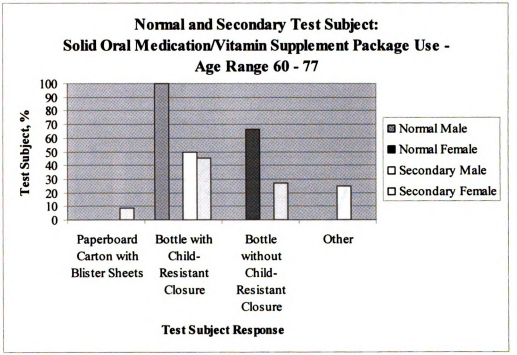



Figure 102 – Normal and Secondary Test Subject: Solid Oral Daily Medication/Vitamin Supplement Package Use - Age Range 60 – 77

Of the normal male test subjects within age range 77+, 100% use bottles without child-resistant closures. Of the normal females within age range 77+, 100% use bottles with child-resistant closures. Of the secondary male test subjects within age range 77+, 50% use paperboard cartons with blister sheets, and 50% use bottles with child-resistant closures. Of the secondary female test subjects within age range 77+, 14% use paperboard cartons with blister sheets, 29% use bottles with child-resistant closures, 29% use bottles without child-resistant closures, and 29% use bottles without child-resistant closures. (Figure 103)

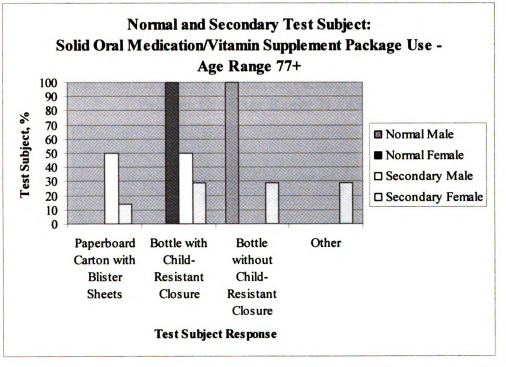



Figure 103 – Normal and Secondary Test Subject: Solid Oral Daily Medication/Vitamin Supplement Package Use - Age Range 77+

Of the normal male test subjects within age range 21 – 45, 9% use both paperboard cartons with blister sheets and bottles with child-resistant closures, 9% use paperboard cartons with blister sheets and bottles without child-resistant closures, 4% use bottles with and without child-resistant closures. Of the normal females within age range 21 – 45, 21% use paperboard cartons with blister sheets and bottles without child-resistant closures, 21% use paperboard cartons with blister sheets and bottles without child-resistant closures and 7% use bottles with and without child-resistant closures. Of the secondary female test subjects within age range 21 – 45, 50% use bottles without child-resistant closures. (Figure 104)

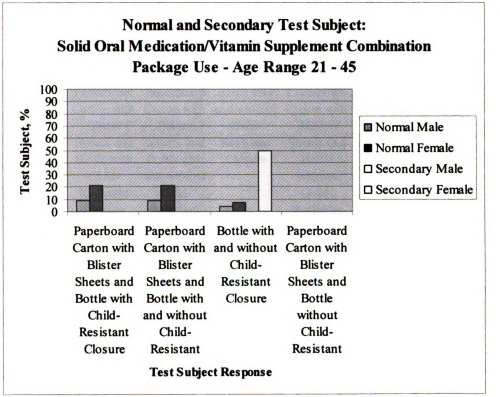



Figure 104 – Normal and Secondary Test Subject: Solid Oral Daily Medication/Vitamin Supplement Combination Package Use - Age Range 21 – 45

Of the normal females within age range 46 – 60, 25% use paperboard cartons with blister sheets and bottles with child-resistant closures and 25% use bottles with and without child-resistant closures. Of the secondary female test subjects within age range 46 – 60, 13% use paperboard cartons with blister sheets and bottles with child-resistant closures and 7% use bottles with and without child-resistant closures. (Figure 105)

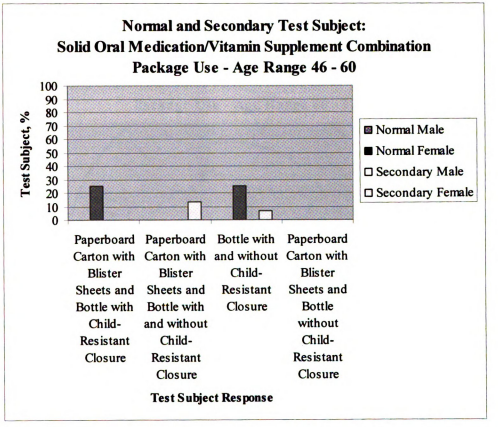



Figure 105 – Normal and Secondary Test Subject: Solid Oral Daily Medication/Vitamin Supplement Combination Package Use - Age Range 46 – 60

Of the normal males within age range 60 – 77, 100% use paperboard cartons with blister sheets and bottles without child-resistant closures. Of the normal females within age range 60 – 77, 33% use paperboard cartons with blister sheets and bottles with child-resistant closures. Of the secondary female test subjects within age range 60 – 77, 9% use paperboard cartons with blister sheets and bottles with child-resistant closures, and 9% use bottles with and without child-resistant closures. (Figure 106)

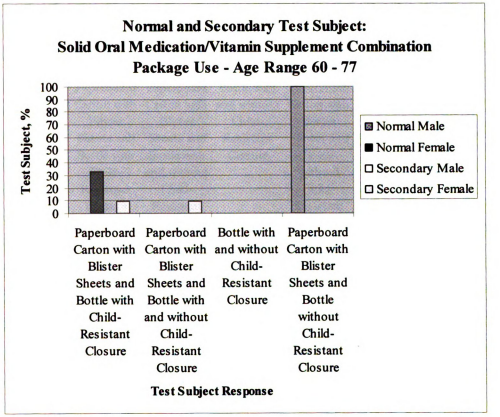



Figure 106 – Normal and Secondary Test Subject: Solid Oral Daily Medication/Vitamin Supplement Combination Package Use - Age Range 60 – 77

None of the normal males within age range 77+ used combinations of packaging for their medications/vitamin supplements. (Figure 107)

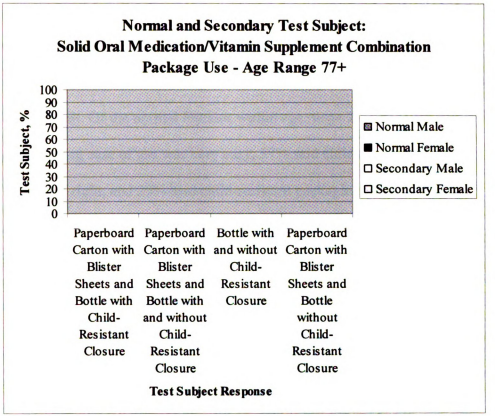



Figure 107 – Normal and Secondary Test Subject: Solid Oral Daily Medication/Vitamin Supplement Combination Package Use - Age Range 77+

***Section 4: Normal and Secondary Test Subject Child-Resistant Medication/Vitamin Supplement Packaging Ease of Use***

Of the normal male test subjects within age range 21 – 45, 22% said child-resistant packaging ease of use was very easy, 52% said child-resistant packaging ease of use was about right, and 26% thought child-resistant packaging ease of use was somewhat difficult. Of the normal females within age range 21 – 45, 14% said child-resistant packaging ease of use was very easy, 57% said child-resistant packaging ease of use was about right, and 29% said child-resistant packaging ease of use was somewhat difficult. Of the secondary male test subjects within age range 21 – 45, 50% said child-resistant packaging ease of use was very easy and 50% said child-resistant packaging ease of use was somewhat difficult. Of the secondary female test subjects within age range 21 – 45, 25% said child-resistant packaging ease of use was very easy, and 75% said child-resistant packaging ease of use was somewhat difficult. (Figure 108)

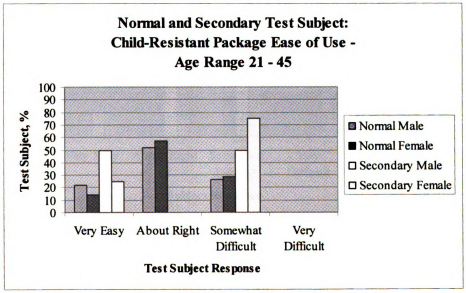



Figure 108 – Normal and Secondary Test Subject: Child-Resistant Package Ease of Use - Age Range 21 – 45

Of the normal male test subjects within age range 46 – 60, 50% said child-resistant packaging ease of use was very easy, and 50% said child-resistant packaging ease of use was somewhat difficult. Of the normal females within age range 46 – 50, 25% said child-resistant packaging ease of use was about right, and 75% said child-resistant packaging ease of use was somewhat difficult. Of the secondary male test subjects within age range 46 – 60, 20% said child-resistant packaging ease of use was very easy, 40% said child-resistant packaging ease of use was about right, and 40% said child- resistant packaging ease of use was somewhat difficult. Of the secondary female test subjects within age range 21 – 45, 13% said child-resistant packaging ease of use was very easy, 13% said child-resistant packaging ease of use was about right, 40% said child-resistant packaging ease of use was somewhat difficult, and 33% said child-resistant packaging ease of use was very difficult. (Figure 109)

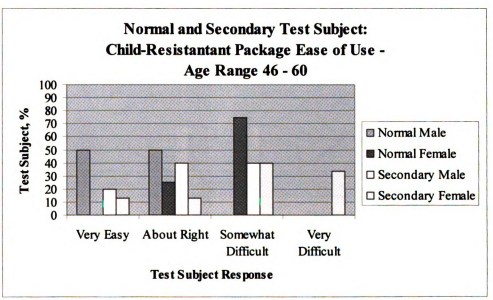



Figure 109 – Normal and Secondary Test Subject: Child-Resistant Package Ease of Use - Age Range 46 – 60

Of the normal male test subjects within age range 60 – 77, 100% said child-resistant packaging ease of use was very easy. Of the normal females within age range 60 – 77, 33% said child-resistant packaging ease of use was about right, and 67% said child-resistant packaging ease of use was somewhat difficult. Of the secondary male test subjects within age range 60 – 77, 50% said child-resistant packaging ease of use was about right, and 50% said child-resistant packaging ease of use was somewhat difficult. Of the secondary female test subjects within age range 60 – 77, 9% said child-resistant packaging ease of use was very easy, 18% said child-resistant packaging ease of use was about right, 36% said child-resistant packaging ease of use was somewhat difficult, and 29% said child-resistant packaging ease of use was very difficult. (Figure 110)

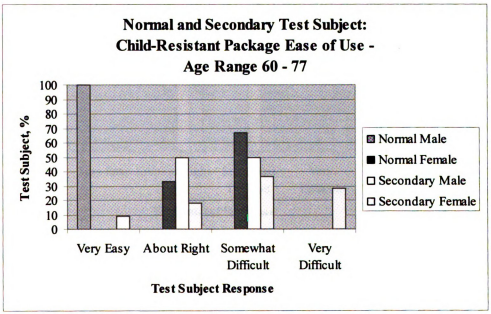



Figure 110 – Normal and Secondary Test Subject: Child-Resistant Package Ease of Use - Age Range 60 – 77

Of the normal male test subjects within age range 77+, 100% said child-resistant packaging ease of use was somewhat difficult. Of the normal females within age range 77+, 100% said child-resistant packaging ease of use was about right. Of the secondary male test subjects within age range 77+, 50% said child-resistant packaging ease of use was about right, and 50% said child-resistant packaging ease of use was somewhat difficult. Of the secondary female test subjects within age range 77+, 43% said child-resistant packaging ease of use was about right, 29% said child-resistant packaging ease of use was somewhat difficult, and 29% said child-resistant packaging ease of use was very difficult. (Figure 111)

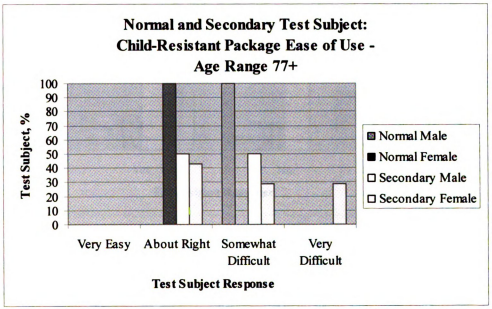



Figure 111 – Normal and Secondary Test Subject: Child-Resistant Package Ease of Use - Age Range 77+

***Section 5: Normal and Secondary Test Subject Medication/Vitamin Supplement Solid Oral Organizer Use***

Of the test subjects within age range 21 – 45, 13% of normal males, 21% of normal females, 50% of secondary males, and 25% of secondary females, use pill organizers. Of the test subjects within age range 21 – 45, 87% of normal males, 79% of normal females, 50% of secondary males, and 75% of secondary females, do not use pill organizers. (See Figure 112)

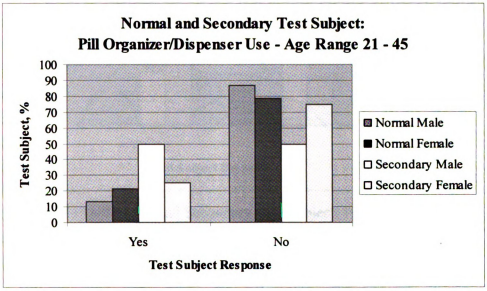



Figure 112 – Normal and Secondary Test Subject: Pill Organizer Use - Age Range 21 – 45

Of the test subjects within age range 46 – 60, 25% of normal females, 40% of secondary males, and 67% of secondary females, use pill organizers. Of the test subjects within age range 21 – 45, 100% of normal males, 75% of normal females, 60% of secondary males, and 33% of secondary females, do not use pill organizers. (Figure 113)

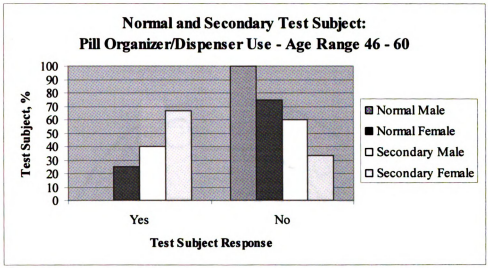



Figure 113 – Normal and Secondary Test Subject: Pill Organizer Use - Age Range 46 – 60

Of the test subjects within age range 60 – 77, 100% of normal males, 67% of normal females, 75% of secondary males, and 55% of secondary females use pill organizers. Of the test subjects within age range 60 – 77, 33% of normal females, 25% of secondary males, and 45% of secondary females, do not use pill organizers. (Figure 114)

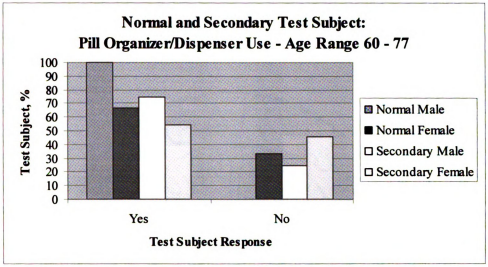



Figure 114 – Normal and Secondary Test Subject: Pill Organizer Use - Age Range 60 – 77

Of the test subjects within age range 77+, 50% of normal males, 50% of secondary males, and 43% of secondary females, use pill organizers. Of the test subjects within age range 77+, 50% of normal males, 100% of normal females, 50% of secondary males, and 57% of secondary females, do not use pill organizers. (Figure 115)

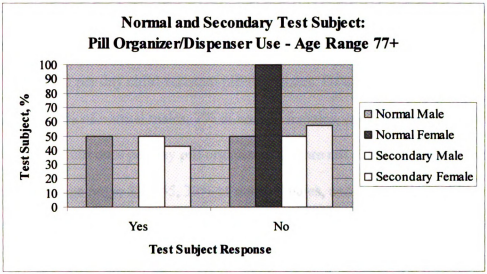



Figure 115 – Normal and Secondary Test Subject: Pill Organizer Use - Age Range 77+

***Section 6: Normal and Secondary Test Subject Medication/Vitamin Supplement Solid Oral Organizer Preference***

Of the test subjects within age range 21 – 45, 30% of normal males, 43% of normal females, and 50% of secondary males prefer daily child-resistant pill organizers. Of the test subjects within age range 21 – 45, 7% of normal females and 50% of secondary males prefer daily pill organizers that are not child-resistant. Of the test subjects within age range 21 – 45, 26% of normal males, and 21% of normal females prefer multi-dose per day child-resistant pill organizers. Of the test subjects within age range 21 – 45, 4% of normal males, 7% of normal females, and 100% of secondary females prefer multi dose per day pill organizers that are not child-resistant. Of the test subjects within age range 21 – 45, 39% of normal males, and 21% of normal females prefer to not use any kind of pill organizer. (Figure 116)

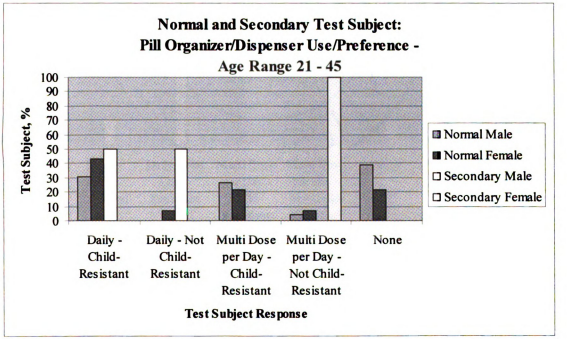



Figure 116 – Normal and Secondary Test Subject: Pill Organizer/Dispenser Use/Preference - Age Range 21 – 45

Of the test subjects within age range 46 – 60, 25% of normal females, 20% of secondary males, and 13% of secondary females prefer daily child-resistant pill organizers. Of the test subjects within age range 46 – 60, 60% of secondary males, and 20% of secondary females prefer daily pill organizers that are not child-resistant. Of the test subjects within age range 46 – 60, 50% of normal males, 50% of normal females, and 7% of secondary females prefer multi-dose per day child-resistant pill organizers. Of the test subjects within age range 46 – 60, 53% of secondary females prefer multi dose per day pill organizers that are not child-resistant. Of the test subjects within age range 46 – 60, 50% of normal males, 25% of normal females, 20% of secondary males, and 7% secondary females prefer to not use any kind of pill organizer. (See Figure 117)

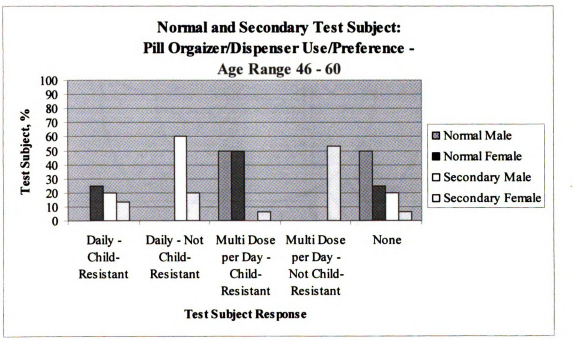



Figure 117 – Normal and Secondary Test Subject: Pill Organizer/Dispenser Use/Preference - Age Range 46 – 60

Of the test subjects within age range 60 – 77, 25% of secondary males and 9% of secondary females prefer daily child-resistant pill organizers. Of the test subjects within age range 60 – 77, 25% of secondary males and 18% of secondary females prefer daily pill organizers that are not child-resistant. Of the test subjects within age range 60 – 77, 100% of normal males prefer multi-dose per day child-resistant pill organizers. Of the test subjects within age range 60 – 77, 100% of normal females, 25% of secondary males, and 45% of secondary females prefer multi dose per day pill organizers that are not child-resistant. Of the test subjects within age range 60 – 77, 50% of normal males, 25% of secondary males and 27% of secondary females prefer not to use any kind of pill organizer. (Figure 118)

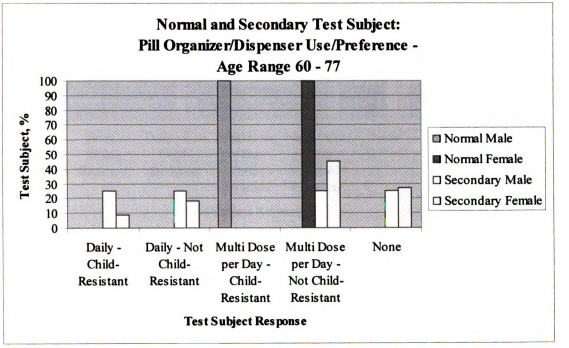



Figure 118 – Normal and Secondary Test Subject: Pill Organizer/Dispenser Use/Preference - Age Range 60 – 77

Of the test subjects within age range 77+, 50% of secondary males and 14% of secondary females prefer daily pill organizers that are not child-resistant. Of the test subjects within age range 77+, 50% of normal males and 57% of secondary females preferred multi dose per day pill organizers that are not child-resistant. Of the test subjects within age range 77+, 50% of normal males, 100% of normal females, 50% of secondary males, and 29% of secondary females prefer to not use any kind of pill organizer. (Figure 119)

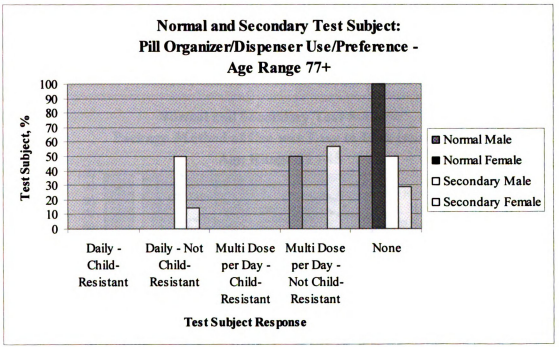



Figure 119 – Normal and Secondary Test Subject: Pill Organizer/Dispenser Use/Preference - Age Range 77+

***Section 7: Normal and Secondary Test Subject New Package Questions***

*Package Method of Use was Easy to Understand per Age Range*

Of the test subjects within age range 21 – 45, 57% of normal males, 50% of normal females, 100% of secondary males, and 75% of secondary females strongly agreed that the package method of use was easy to understand. Of the test subjects within age range 21 – 45, 43% of normal males, 50% of normal females, and 25% of secondary females agreed that the package method of use was easy to understand. Of the test subjects within age range 21 – 45, 57% of normal males, 50% of normal females, 100% of secondary males, and 75% of secondary females strongly agreed that the package method of use was easy to understand. (Figure 120)

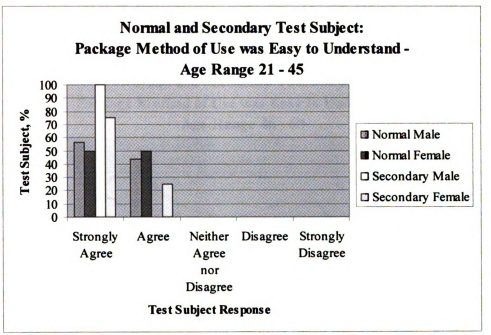



Figure 120 – Normal and Secondary Test Subject: Package Method of Use was Easy to Understand - Age Range 21 – 45

Of the test subjects within age range 46 – 60, 100% of normal males, 100% of normal females, 60% of secondary males, and 53% of secondary females strongly agreed that the package method of use was easy to understand. Of the test subjects within age range 46 – 60, 20% of secondary males and 20% of secondary females agreed that the package method of use was easy to understand. Of the test subjects within age range 46 – 60, 20% of secondary males and 13% of secondary females neither agreed nor disagreed that the package method of use was easy to understand. Of the test subjects within age range 46 – 60, 7% of secondary females disagreed that the package method of use was easy to understand. Of the test subjects within age range 46 – 60, 7% of secondary females strongly disagreed that the package method of use was easy to understand. (Figure 121)

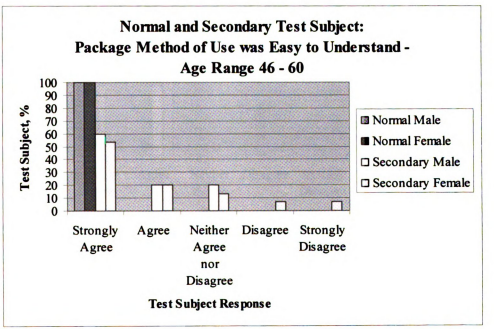



Figure 121 – Normal and Secondary Test Subject: Package Method of Use was Easy to Understand - Age Range 46 – 60

Of the test subjects within age range 60 – 77, 50% of secondary males and 18% of secondary females strongly agreed that the package method of use was easy to understand. Of the test subjects within age range 60 – 77, 100% of normal males, 67% of normal females, 50% of secondary males, and 73% of secondary females agreed that the package method of use was easy to understand. Of the test subjects within age range 60 – 77, 9% of secondary females neither agreed nor disagreed that the package method of use was easy to understand. Of the test subjects within age range 60 – 77, 33% of normal females disagreed that the package method of use was easy to understand. (Figure 122)

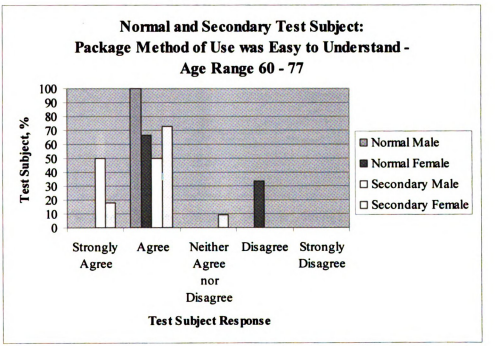



Figure 122 – Normal and Secondary Test Subject: Package Method of Use was Easy to Understand - Age Range 60 – 77

Of the test subjects within age range 77+, 50% of secondary males and 14% of secondary females strongly agreed that the package method of use was easy to understand. Of the test subjects within age range 77+, 50% of secondary males and 71% of secondary females agreed that the package method of use was easy to understand. Of the test subjects within age range 77+, 50% of normal males, 100% of normal females, and 14% of secondary females neither agreed nor disagreed that the package method of use was easy to understand. Of the test subjects within age range 77+, 50% of normal males disagreed that the package method of use was easy to understand. (Figure 123)

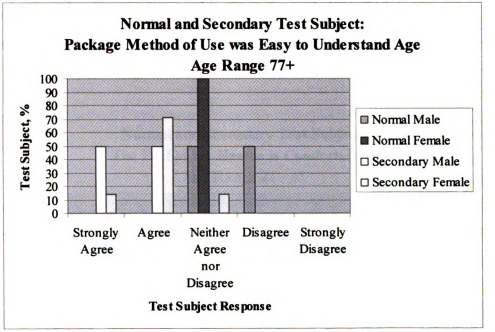



Figure 123 – Normal and Secondary Test Subject: Package Method of Use was Easy to Understand - Age Range 77+

*The Feel of the Handle is Comfortable per Age Range*

Of the test subjects within age range 21 – 45, 9% of normal males, 100% of secondary males, and 25% of secondary females strongly agreed that the package handle was comfortable. Of the test subjects within age range 21 – 45, 43% of normal males, 64% of normal females, and 25% of secondary females agreed that the package handle was comfortable. Of the test subjects within age range 21 – 45, 9% of normal males, 7% normal females, and 25% of secondary females neither agreed nor disagreed that the package handle was comfortable. Of the test subjects within age range 21 – 45, 39% of normal males, 14% of normal females, and 25% of secondary females disagreed that the package handle was comfortable. Of the test subjects within age range 21 – 45, 14% of normal females strongly disagreed that the package handle was comfortable. (Figure 124)

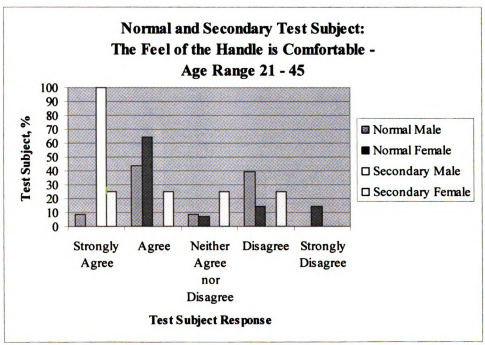



Figure 124 – Normal and Secondary Test Subject: The Feel of the Handle is Comfortable - Age Range 21 – 45

Of the test subjects within age range 46 – 60, 50% of normal males, 25% of normal females, 20% of secondary males, and 33% of secondary females strongly agreed that the package handle was comfortable. Of the test subjects within age range 46 – 60, 50% of normal males, 75% of normal females, 60% of secondary males, and 13% of secondary females agreed that the package handle was comfortable. Of the test subjects within age range 46 – 60, 13% of secondary females neither agreed nor disagreed that the package handle was comfortable. Of the test subjects within age range 46 – 60, 20% of males and 20% of secondary females disagreed that the package handle was comfortable. Of the test subjects within age range 46 – 60, 20% of secondary females strongly disagreed that the package handle was comfortable. (Figure 125)

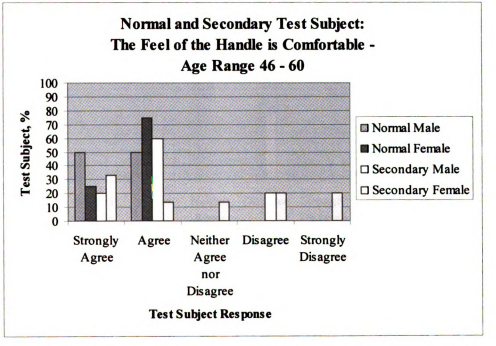



Figure 125 – Normal and Secondary Test Subject: The Feel of the Handle is Comfortable - Age Range 46 – 60

Of the test subjects within age range 60 – 77, 18% of secondary females strongly agreed that the package handle was comfortable. Of the test subjects within age range 60 – 77, 33% of normal females, 50% of secondary males, and 36% of secondary females agreed that the package handle was comfortable. Of the test subjects within age range 60 – 77, 100% of normal males neither agreed nor disagreed that the package handle was comfortable. Of the test subjects within age range 60 – 77, 67% of normal females, 50% of secondary males, and 27% of secondary females, disagreed that the package handle was comfortable. Of the test subjects within age range 60 – 77, 18% of secondary female test subjects strongly disagreed that the package handle was comfortable. (Figure 126)

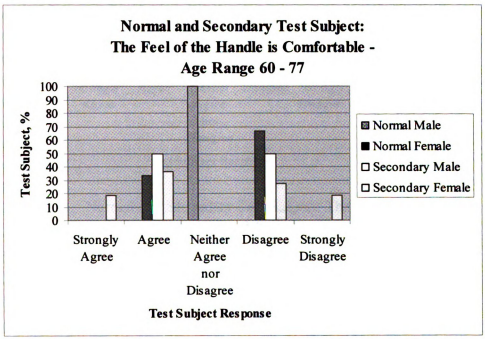



Figure 126 – Normal and Secondary Test Subject: The Feel of the Handle is Comfortable - Age Range 60 – 77

Of the test subjects within age range 77+, 9% of normal males and 50% of secondary males strongly agreed that the package handle was comfortable. Of the test subjects within age range 77+, 100% of normal males, 100% of normal females, 50% of secondary males, and 57% of secondary females agreed that the package handle was comfortable. Of the test subjects within age range 77+, 43% of secondary females neither agreed nor disagreed that the package handle was comfortable. (Figure 127)

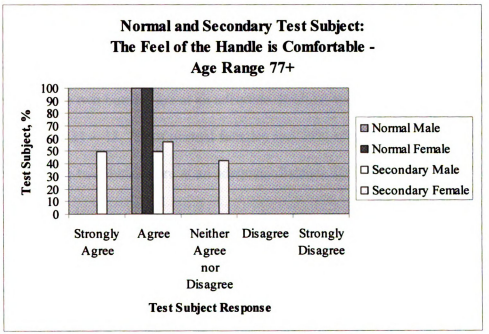



Figure 127 – Normal and Secondary Test Subject: The Feel of the Handle is Comfortable - Age Range 77+

*The Two Buttons are at an Adequate Distance Apart per Age Range*

Of the test subjects within age range 21 – 45, 4% of normal males and 7% of normal females, 100% of secondary males, and 25% secondary females strongly agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 21 – 45, 70% of normal males, 43% of normal females, and 25% of secondary females agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 21 – 45, 9% of normal males neither agreed nor disagreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 21 – 45, 17% of normal males, 43% of normal females, and 25% of secondary females disagreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 21 – 45, 7% of normal females and 25% of secondary females strongly disagreed that the two buttons are at an adequate distance apart. (Figure 128)

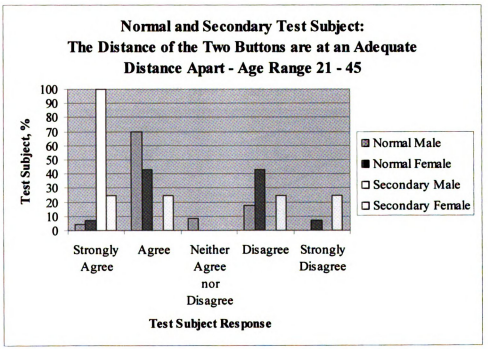



Figure 128 – Normal and Secondary Test Subject: The Distance of the Two Buttons is Adequate - Age Range 21 – 45

Of the test subjects within age range 46 – 60, 50% of normal males, 25% of normal females, 20% of secondary males, and 40% secondary females strongly agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 46 – 60, 50% of normal males, 75% of normal females, 40% of secondary females, and 7% of secondary females agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 46 – 60, 7% of secondary females neither agreed nor disagreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 46 – 60, 20% of secondary males, and 7% of secondary females disagreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 46 – 60, 20% of secondary males and 40% of secondary females strongly disagreed that the two buttons are at an adequate distance apart. (Figure 129)

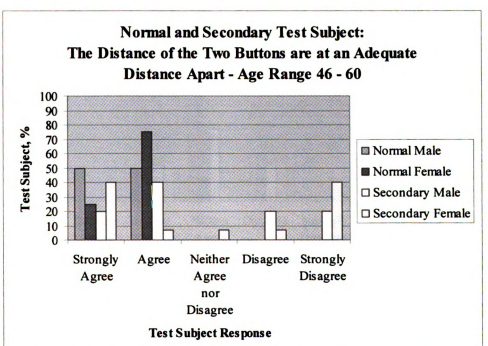



Figure 129 – Normal and Secondary Test Subject: The Distance of the Two Buttons is Adequate - Age Range 46 – 60

Of the test subjects within age range 60 – 77, 9% of secondary females strongly agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 60 – 77, 33% of normal males, 25% of normal females, and 27% of secondary females agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 60 – 77, 100% of normal males, 33% of normal females, 50% secondary males, and 9% secondary females neither agreed nor disagreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 60 – 77, 33% of normal females, and 27% of secondary females disagreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 60 – 77, 27% of secondary females strongly disagreed that the two buttons are at an adequate distance apart. (Figure 130)

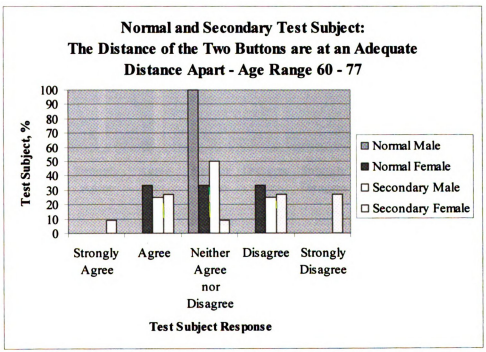



Figure 130 – Normal and Secondary Test Subject: The Distance of the Two Buttons is Adequate - Age Range 60 – 77

Of the test subjects within age range 77+, 50% of secondary males and 14% secondary females strongly agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 77+, 50% of normal males, 100% of normal females, 50% of secondary males, and 29% of secondary females agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 77+, 14% of secondary females neither agreed nor disagreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 77+, 50% of normal males and 43% of secondary females disagreed that the two buttons are at an adequate distance apart. (Figure 131)

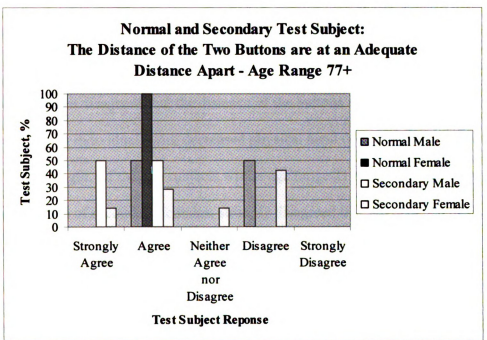



Figure 131 – Normal and Secondary Test Subject: The Distance of the Two Buttons is Adequate - Age Range 77+

*The Distance of the Buttons are at Comfortable Distance Apart for Individuals with Decreased Physical Hand Dexterity, Such as Gripping or Pinching Strength, per Age Range*

Of the test subjects within age range 21 – 45, 7% of normal females and 100% of secondary males strongly agreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 21 – 45, 39% of normal males and 36% of normal females agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 21 – 45, 26% of normal males, 21% of normal females, and 25% secondary females neither agreed nor disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 21 – 45, 35% of normal males, 29% of normal females and 50% of secondary females disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 21 – 45, 7% of normal females and 25% of secondary females, strongly disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. (Figure 132)

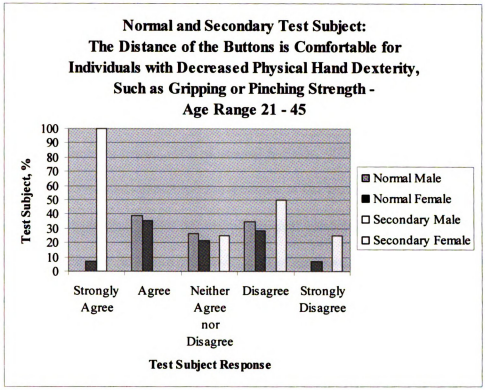



Figure 132 – Normal and Secondary Test Subject: The Distance of the Buttons is Comfortable for Individuals with Decreased Physical Hand Dexterity, Such as Gripping and Pinching Strength - Age Range 21 – 45

Of the test subjects within age range 46 – 60, 25% of normal females, 20% of secondary males, and 27% secondary females strongly agreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 46 – 60, 100% of normal males, 50% of normal females, 40% of secondary males, and 47% of secondary females agreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 46 – 60, 25% of normal females and 20% secondary females neither agreed nor disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 46 – 60, 7% of secondary females disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 46 – 60, 40% of secondary males and 40% of secondary females strongly disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. (Figure 133)

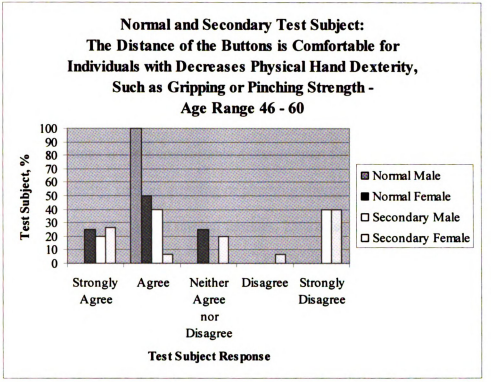



Figure 133 – Normal and Secondary Test Subject: The Distance of the Buttons is Comfortable for Individuals with Decreased Physical Hand Dexterity, Such as Gripping and Pinching Strength - Age Range 46 – 60

Of the test subjects within age range 60 – 77, 33% of normal females and 27% of secondary females agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 60 – 77, 100% of normal males, 33% normal females, 75% secondary males, and 9% secondary females neither agreed nor disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 60 – 77, 33% of normal females, 25% of secondary male and 45% of secondary females disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 60 – 77, 18% of secondary females strongly disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. (Figure 134)

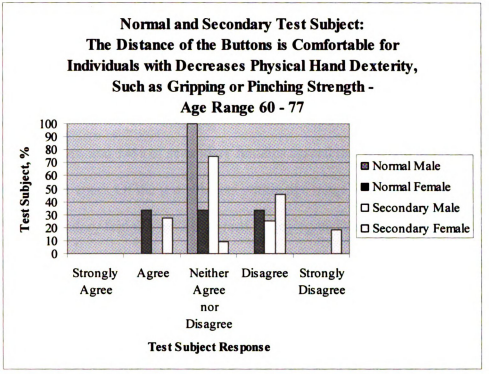



Figure 134 – Normal and Secondary Test Subject: The Distance of the Buttons is Comfortable for Individuals with Decreased Physical Hand Dexterity, Such as Gripping and Pinching Strength - Age Range 60 – 77

Of the test subjects within age range 77+, 14% of secondary females strongly agreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 77+, 50% of normal males, 100% of normal females, 50% of secondary males, and 14% of secondary females agreed that the two buttons are at an adequate distance apart. Of the test subjects within age range 77+, 50% of normal males and 29% of secondary females neither agreed nor disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 77+, 50% of secondary males and 29% of secondary females disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. Of the test subjects within age range 77+, 14% of secondary females strongly disagreed that the distance of the buttons are at a comfortable distance apart for individuals with decreased physical hand dexterity, such as gripping or pinching strength. (Figure 135)

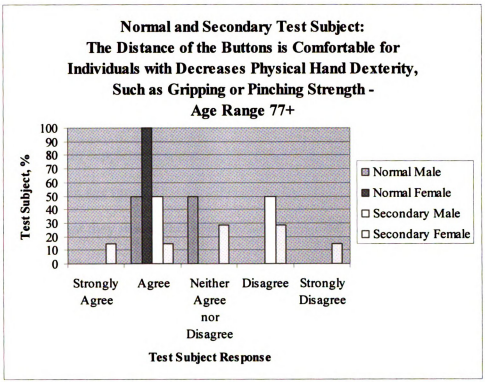



Figure 135 – Normal and Secondary Test Subject: The Distance of the Buttons is Comfortable for Individuals with Decreased Physical Hand Dexterity, Such as Gripping and Pinching Strength - Age Range 77+

*I Would Feel Comfort in Knowing that the Medication/Vitamin Supplement Organizer/Dispenser I Use is Child-Resistant*

Of the test subjects within age range 21 – 45, 61% of normal males, 100% of normal females, 57% of secondary males, 100% of secondary males, and 25% of secondary females strongly agreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 21 – 45, 26% of normal males and 36% of normal females agreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 21 – 45, 9% of normal males and 50% of secondary females neither agreed nor disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 21 – 45, 4% of normal males and 7% of normal females disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 21 – 45, 25% of secondary females strongly disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. (Figure 136)

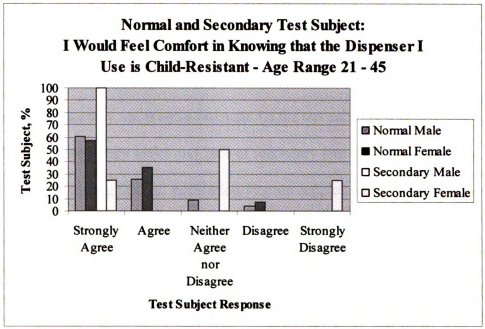



Figure 136 – Normal and Secondary Test Subject: I Would Feel Comfort in Knowing that the Dispenser I Use is Child-Resistant - Age Range 21 – 45

Of the test subjects within age range 46 – 60, 50% of normal males, 75% of normal females, 40% of secondary males, and 53% secondary females strongly agreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 46 – 60, 20% of secondary males and 20% of secondary females agreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 46 – 60, 50% of normal males, 25% of normal females, and 13% of secondary females neither agreed nor disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 46 – 60, 20% of secondary males and 7% of secondary females disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 46 – 60, 20% of secondary males and 7% of secondary females strongly disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. (Figure 137)

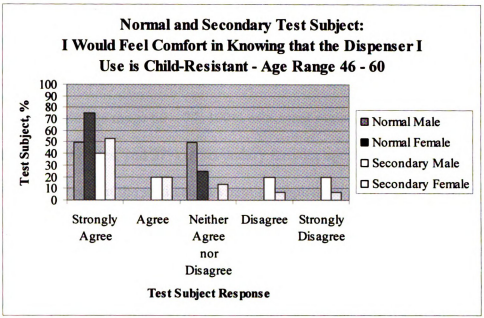



Figure 137 – Normal and Secondary Test Subject: I Would Feel Comfort in Knowing that the Dispenser I Use is Child-Resistant - Age Range 46 – 60

Of the test subjects within age range 60 – 77, 25% of secondary males and 18% secondary females strongly agreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 60 – 77, 100% of normal males, 33% of normal females, 25% of secondary males, and 27% of secondary females agreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 60 – 77, 67% of normal females, 50% of secondary males, and 27% secondary females neither agreed nor disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 60 – 77, 18% of secondary females disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 60 – 77, 9% of secondary females strongly disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. (Figure 138)

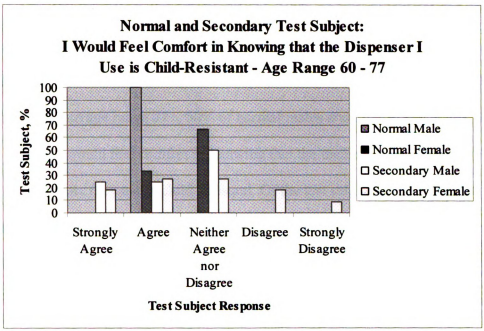



Figure 138 – Normal and Secondary Test Subject: I Would Feel Comfort in Knowing that the Dispenser I Use is Child-Resistant - Age Range 60 – 77

Of the test subjects within age range 77+, 100% of normal females and 14% of secondary females strongly agreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 77+, 50% of normal males and 29% of secondary females agreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 77+, 50% of normal males, 50% secondary males, and 43% secondary females neither agreed nor disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. Of the test subjects within age range 77+, 50% secondary males and 14% of secondary females disagreed that they would feel comfort in knowing that the medication/vitamin supplement organizer/dispenser they use is child-resistant. (Figure 139)

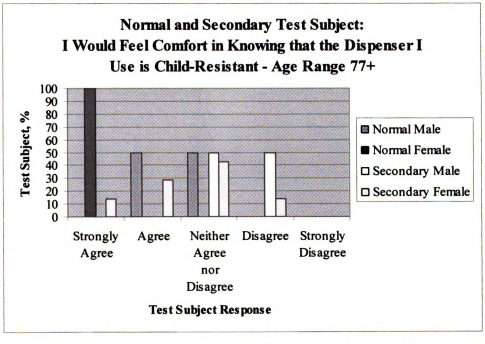



Figure 139 – Normal and Secondary Test Subject: I Would Feel Comfort in Knowing that the Dispenser I Use is Child-Resistant - Age Range 77+

*This Package Will Aid in Medication Compliance for Both Individuals with or without Physical Hand Dexterity*

Of the test subjects within age range 21 – 45, 22% of normal males, 43% of normal females, 100% of secondary males, and 75% secondary females strongly agreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 21 – 45, 57% of normal males and 43% of normal females agreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 21 – 45, 17% of normal males, 14% normal females, and 25% secondary females neither agreed nor disagreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 21 – 45, 4% of normal males disagreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. (Figure 140)

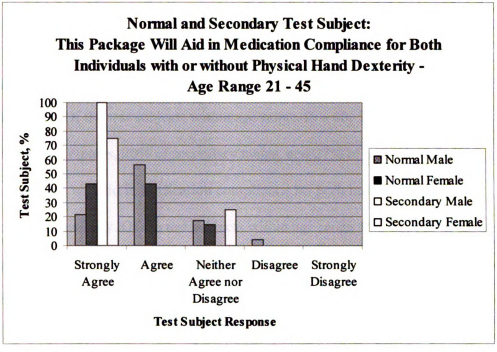



Figure 140 – Normal and Secondary Test Subject: This Package will Aid in Medication Compliance for Both Individuals with or Without Decreased Physical Hand Dexterity - Age Range 21 – 45

Of the test subjects within age range 46 – 60, 4% of normal males, 7% of normal females, 100% of secondary males, and 25% secondary females strongly agreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 46 – 60, 50% of normal males, 50% of normal females, 20% of secondary males, and 27% of secondary females agreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 46 – 60, 7% of secondary females neither agreed nor disagreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 46 – 60, 20% of secondary males and 7% of secondary females disagreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 46 – 60, 20% of secondary males and 27% of secondary females strongly disagreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. (Figure 141)

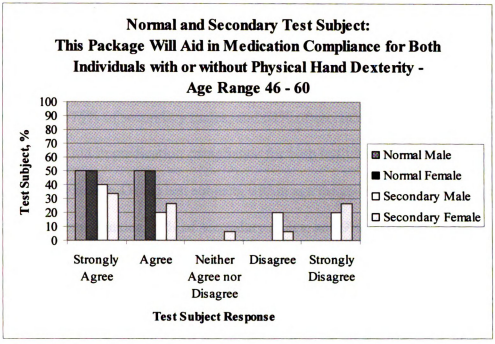



Figure 141 – Normal and Secondary Test Subject: This Package will Aid in Medication Compliance for Both Individuals with or Without Decreased Physical Hand Dexterity - Age Range 46 – 60

Of the test subjects within age range 60 – 77, 18% secondary females strongly agreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 60 – 77, 67% of normal females, 75% of secondary males, and 64% of secondary females agreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 60 – 77, 100% of normal males, 33% normal females, 25% of secondary males, and 9% secondary females neither agreed nor disagreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 60 – 77, 9% of secondary females disagreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. (Figure 142)

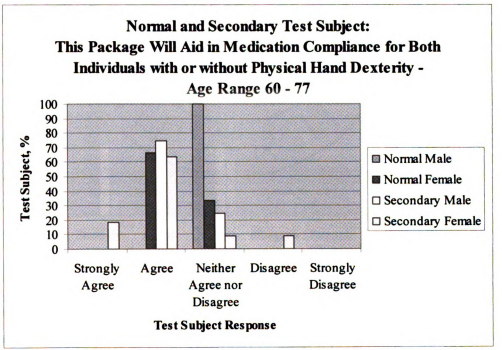



Figure 142 – Normal and Secondary Test Subject: This Package will Aid in Medication Compliance for Both Individuals with or Without Decreased Physical Hand Dexterity - Age Range 60 – 77

Of the test subjects within age range 77+, 100% of normal females, 50% of secondary males, and 14% of secondary females strongly agreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 77+, 100% of normal males and 29% of secondary females agreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 77+, 50% of secondary males and 43% secondary females neither agreed nor disagreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. Of the test subjects within age range 77+, 14% secondary females disagreed that the package will aid in medication compliance for both individuals with or without physical hand dexterity. (Figure 143)

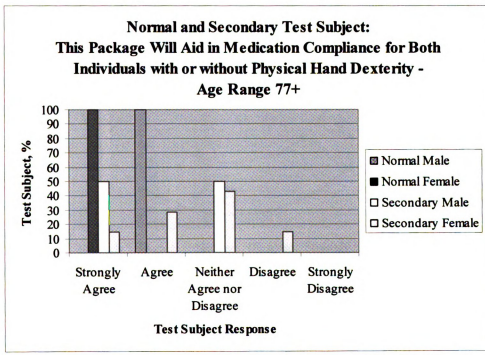



Figure 143 – Normal and Secondary Test Subject: This Package will Aid in Medication Compliance for Both Individuals with or Without Decreased Physical Hand Dexterity - Age Range 77+

*If Manufactured, I have a Desire to Own and Use this Package*

Of the test subjects within age range 21 – 45, 22% of normal males, 7% of normal females, 100% of secondary males, and 25% secondary females strongly agreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 21 – 45, 43% of normal males, 57% of normal females, and 50% of secondary females agreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 21 – 45, 26% of normal males, 21% normal females, and 25% of secondary females neither agreed nor disagreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 21 – 45, 9% of normal males and 14% of normal females disagreed that, if manufactured, they have a desire to own and use the newly designed package. (Figure 144)

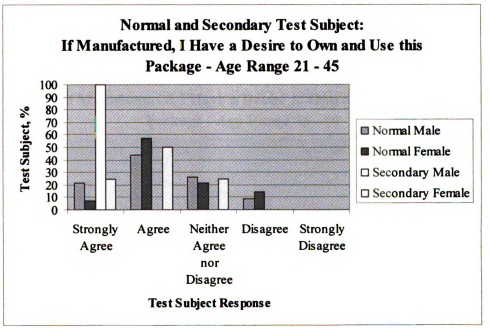



Figure 144 – Normal and Secondary Test Subject: If Manufactured, I Have a Desire to Own and Use This Package - Age Range 21 – 45

Of the test subjects within age range 46 – 60, 50% of normal males, 50% of normal females, 40% of secondary males, and 40% secondary females strongly agreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 46 – 60, 50% of normal males, 50% of normal females, 20% of secondary males, and 20% of secondary females agreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 46 – 60, 20% of secondary males neither agreed nor disagreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 46 – 60, 20% of secondary males and 7% of secondary females disagreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 46 – 60, 33% of secondary females strongly disagreed that, if manufactured, they have a desire to own and use the newly designed package. (Figure 145)

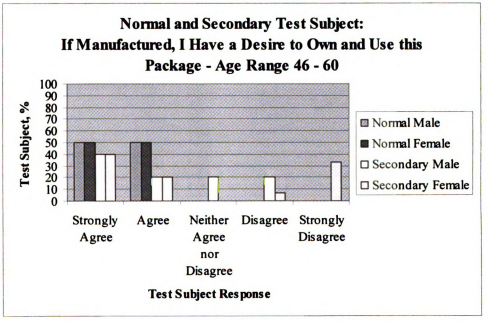



Figure 145 – Normal and Secondary Test Subject: If Manufactured, I Have a Desire to Own and Use This Package - Age Range 46 – 60

Of the test subjects within age range 60 – 77, 25% of secondary males strongly agreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 60 – 77, 25% secondary males and 36% secondary females agreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 60 – 77, 100% of normal, 67% of normal females, 25% of secondary males, and 27% of secondary females neither agreed nor disagreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 60 – 77, 33% of normal females, 25% secondary males, and 18% of secondary females disagreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 60 – 77, 18% of secondary females strongly disagreed that, if manufactured, they have a desire to own and use the newly designed package. (Figure 146)

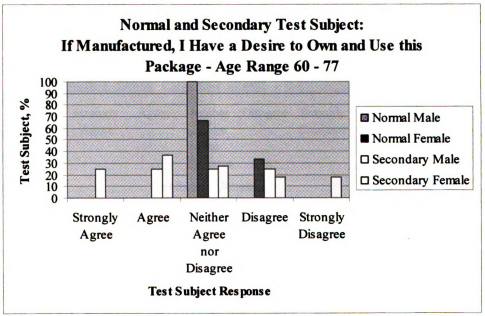



Figure 146 – Normal and Secondary Test Subject: If Manufactured, I Have a Desire to Own and Use This Package - Age Range 60 – 77

Of the test subjects within age range 77+, 100% of normal females and 14% of secondary females strongly agreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 77+, 50% of secondary males and 14% of secondary females agreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 77+, 29% of secondary females neither agreed nor disagreed that, if manufactured, they have a desire to own and use the newly designed package. Of the test subjects within age range 77+, 100% of normal males, 50% of secondary males, and 43% of secondary females disagreed that, if manufactured, they have a desire to own and use the newly designed package. (Figure 147)

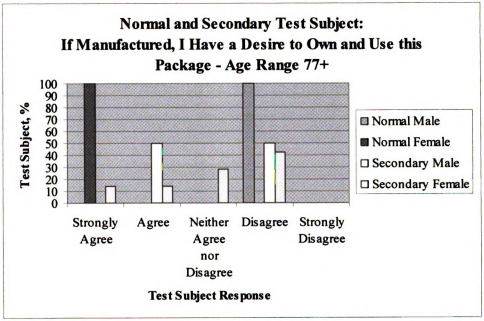



Figure 147 – Normal and Secondary Test Subject: If Manufactured, I Have a Desire to Own and Use This Package - Age Range 77+

# Bibliography

## Bibliography


Arias, Elizabeth and Smith, Betty L., Deaths: Preliminary Data for 2001, *National Vital Statistics Reports*, Vol. 51, No. 5, pg. 3, March 2003.

Better Packages, Inc., How Important is Easy Opening, http://betterpackages.com/cgi-bin/news.pl?display=10, February 10, 2004.

Bix, Laura, *Toward a Performance Standard for Typeface Legibility: The Lockhart Legibility Instrument,* Doctoral Dissertation, Michigan State University, 2001.

Bush, President George W., "National Poison Prevention Week," *Federal Register*, Proclamation 7653, Vol. 68, No. 52, March 14, 2003.

Burgess, John H., *Designing for Humans: The Human Factor in Engineering*, Petrocelli Books, Princeton, New Jersey, Pp. xvii, 3-17, 81, 1986.

Dhlillon, Balbir S., *Human Reliability with Human Factors*, Pergamon Books Inc., Oxford, England, 1986.

Federal Interagency Forum on Aging-Related Statistics, Older Americans 2000: Key Indicators of Well-Being, Federal Interagency Forum on Aging-Related Statistics, Washington, DC: U.S. Government Printing Office, August 2000.

Fisk, Arthur D., Rogers, Wendy A., Handbook of Human Factors and the Older Adult, Academic Press, Inc., Sand Diego, California, Pp. 269, 291, 305, 309, 1997.

Fuller, Ken, McNeal Health Care, Conversation. November 28, 2002.

Gleason, Kent, Personal Communication, August, 2003.

Hambrick, Zachary D., PSY 401-Memory and Skill Lecture Notes, Michigan State University, East Lansing, MI, November 4, 2003.

The Ibberson Center, "Packaging Needs Analysis," http://www.shef.ac.uk/~ibberson/NA1.html, December 15, 2000.

King, A.C. Rejeski, W.J. Buchner, D. M., *Physical Activity Interventions Targeting Older Adults: A Critical Review and Recommendations*, American Journal of Preventative Medicine, Vol. 15 (4): 316-331, 1998.

Lockhart, Hugh, Medical Packaging – Readings, Michigan State University, East Lansing, MI, 2002.

McMath, Robert M., Forbes, Thom, "What Were They Thinking? Marketing Lessons You Can Learn from Products that Flopped," Three Rivers Press, New York, New York, Pp. 36-37, 1998.

Mediamark Research. Healthcare report, Vol. 20, Spring: 139, 141, 1997.

Minino, Arialdi, M., M.P.H., Smith, Betty L., B.S. Ed., Division of Vital Statistics Deaths: Preliminary Data for 2000, National Center for Health Statistics, *National Vital Statistics Reports,* vol. 49, no. 12, Oct. 9, 2001.

Neath, Ian and Suprenant, Aimée M., Human Memory, 2nd ed., Wadsworth, Thomson Learning, Inc., Canada, Pp. 151, 166, 168, 471, 474, 2003.

Park, Denise C. and Schwarz, Norbert, Cognitive Aging: A Primer, Psychology Press, George H. Buchanan Co., Philadelphia, PA, Pp. 8, 9, 77, 221, 2000.

Pebley, A.R. and Rudkin, L., Grandparents Caring for Grandchildren: What Do We Know?, *Journal of Family Issues*, 20(2):218-242, 1999.

Rose, Betty, et al, The Principles of Universal Design, The Center for Universal Design, NC State University, Version 2.0, 1997.

Rousseau, Gabriel; Lamson, Nina and Rodgers, Wendy, "Designing Warnings to Compensate For Age Related Changes in Perceptual and Cognitive Abilities," Psychology and Marketing, Vol. 15 (7): 643-662, 1998.

Salvendy, Gavriel, Handbook of Human Factors and Ergonomics, 2nd ed., J. Wiley, New York, NY, Pp. 53, 65, 263, 1134-1135, 2016-2018, 1997.

Saxon, Sue V. and Etten, Mary Jean., *Physical Change and Ageing*, 2nd ed., The Tiresias Press, Inc., New York, NY, Pp. 73-76, 79, 82-83, 1987.

Smith, D., "Compliance Packaging: A Patient Education Tool," *American Pharmacy*, Vol. NS29 (2), p. 127, February 1989.

Spirduso, Waneen W., *Physical Dimensions of Aging*, Human Kinetics, Champaign, IL, Pp. 5-6, 24, 71, 77, 80, 124, 251, 1995.

Tilley, Alvin R., *The Measure of Man and Woman*: Human Factors in Design, Henry Tilley Associates, Whitney Library of Design, New York, NY, Pp. 9-11, 26, 43, 74, 1993.

Tillman, Peggy and Tillman Barry, *Human Factors Essentials*, McGraw-Hill, Inc., New York, NY, 1991.

Trochim, William M.K., Likert Scaling, http://trochim.human.cornell.edu/kb/scallik.htm, 2002.

U.S. Census Bureau, 12th Anniversary of Americans with Disabilities Act, *Facts for Features*, http://www.census.gov/PressRelease/www/2002/cb02ff11.html, July 12, 2002.

U. S. Consumer Product Safety Commission, "National Poison Prevention Week Warns New Parents to Lock Up Medicines and Household Chemicals," Office of Information and Public Affairs, Release #03-092, March 10, 2003.

U. S. Consumer Product Safety Commission, 16 CFR 1700, 2003.

U.S. Department of Commerce, "Disabilities Affect One-Fifth of all Americans: Proportion Could Increase in Coming Decades," *Census Brief*, http://www.census.gov/prod/3/97pubs/cenbr975.pdf, December, 1997.

United States Pharmacopeia, <671> Containers – Permeation.

Visual Expert, "Warnings and Warning Labels," http://www.visualexert.com/Resources/warnings.html, November, 2002.

Wong, Sau Mei B. and Norman D., Evaluation of a Novel Medication Aid, The Calander BlisterPak, and its Effect on Drug Comliance in a Geriatric Outpatient Clinic, Journal of the American Gerontology Society, Vol. 35: 21-26, 1987.

Zuger, Abigail, "The 'Other' Drug Problem: Forgetting to Take Them," *The New York Times*, Late Edition - Final, Section F, p. 1, Column 2, June 2, 1998.