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ABSTRACT

TOWARD A PERFORMANCE STANDARD FOR TYPEFACE LEGIBILITY: THE LOCKHART LEGIBILITY INSTRUMENT

By

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On March 17, 1999 the Food and Drug Administration (FDA) issued a regulation mandating the design and font size of over-the-counter (OTC) drug labels. The FDA used a prescriptive approach in an attempt to ensure label legibility. Research presented here proposes that this not the best way to ensure the legibility of labels. A performance standard, one that incorporated the Lockhart Legibility Instrument (LLI) for instance, would be a better approach.

This research tests two hypotheses using the LLI: (1) noncompliant labels can be created that have equal or greater legibility than labels that comply with FDA's regulation; and (2) labels that contain a familiar drug message will be easier for subjects to read than those that are not familiar (a nonsense message).

Hypothesis 1, noncompliant labels can be created that have equal or greater legibility than compliant labels, was found to be true at a statistical level of α=0.01. This result is especially pertinent because one of the two compliant designs tested did not just meet FDA's 6 point minimum, it exceeded it. Noncompliant messages created using a typeface that was 5.5 points were found to be more legible than the compliant designs, which were created using a typeface that was 9.0 points in size. This difference was highly significant, $p= 5.0*10^{-7}$, vividly illustrating the flaws of the prescriptive approach.

Hypothesis 2, labels that contain a familiar drug message will be easier for subjects to read than those that are not familiar, was not found to be true at a statistical level of α=0.05. There are two possibilities with regard to this result. The first is that subjects arrive at the same measurement on the instrument, regardless of their level of familiarity with message; a desirable outcome for the LLI.

The second possibility is that subjects were no more familiar with this common drug message (a decongestant) than the message that was created using random words. This conclusion would support the idea that, despite potential dangers of OTC misuse, consumers are not highly involved with OTC products (Reisenwitz and Wimbish, 1997; Sansgiry and Cady, 1995; Robinson and Stewart, 1981); uninvolved consumers are less likely to seek information, use complex rules when evaluating alternatives, and devote focal attention and controlled comprehension to the product (Rifon, 2000). In other words, the finding supports the idea that consumers are not reading OTC labels.

This is consistent with the findings of a survey conducted by Dr. Janet Engle, Professor of Pharmacy at the University of Illinois, Chicago. At a news conference in December 1998 she indicated, "47% failed to always read the product label before starting a pain medication, and one-third were unaware that over-the-counter (OTC) drugs carry risk" (Norton, 1999). Given the significant ramifications of improper OTC use, and the difficulty in changing consumer/product involvement, this second possibility is a frightening, but real, risk.

Dedication

This dissertation is dedicated to my wingman. In the words of Bob Dylan, you give me "shelter from the storm." I love you.

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I would like to take this opportunity to officially thank my major professor for his dedication to both my research and professional development (past and future). Dr. Lockhart serves as an example both professionally and personally. He treats students with respect and dignity. He is my role model for both the academic community and the general community; the world is a better place as a result of his presence.

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Dr. Diana Twede has been another tremendous mentor to me while I have attended MSU. Her financial assistance and interest in me personally made me feel comfortable from the beginning of my graduate career (long, long ago). She is not only a mentor, but a friend.

Dr. Nora Rifon has opened my eyes to research beyond the narrow scope of legibility. She has helped me to see the cognitive and psychological aspects of labeling, and has brought me to a place where I can see multiple avenues for future research. Her enthusiasm and different viewpoints have opened doors that I never even realized were there. A scholar approaches topics in ways that leap beyond incremental improvements into innovation, and then conveys that information to others in ways that energize them to act. She has done this for me.

The final two members of my committee, Dr. Michael Fanizza and Dr. Joe Kuszai, have also been tremendous assets to my work. Like Dr. Rifon, they bring a completely different perspective to the problem, enriching the solution. Their impressive knowledge of the design of typeface, message layout and legibility are the backbone of this entire document (from the formulation of the hypothesis, to the design of the labels, to the results that we obtained). Thank you.

"A teacher affects eternity; [s]he can never tell where his [her] influence stops."

Henry Books Adams

I would also like to thank a newly found resource, the Statistical Consulting Center of the CANR Biometry Group. Specifically, I would like to thank my consultant, Fernando Cardoso. Fernando worked exhaustively with me to ensure that my statistics were solid, despite my fear and lack of ability with regard to statistical methods. Fernando was patient, kind and went well beyond the call of duty.

Finally, but not least, I would like to acknowledge the MSU Writing Center at Bessey Hall. My writing team, Rosamari Feliu-Baez, Catherine Fleck and Michelle Ryan reviewed my writing every other Monday without fail (unless I failed to write). It is because of these tremendous people that I have gotten this far this fast. Thank you for your advice, your grammatical expertise and, most of all, your friendship.

"No matter what accomplishment you make, somebody helps you."

Althea Gibson Darben

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Introduction

A major function of packaging is communication. Graphics, labels, inserts, tags, time and temperature indicators (TTIs) and barcodes are just a few of the tools used to communicate information about a packaged product. These tools serve a variety of purposes, from motivating sales to keeping consumers safe. For products like over-the-counter (OTC) drugs, the information on the package, usually in the form of a printed label, is essential for the safe and effective use of the product and is frequently the only form of information used by the consumer (Tennesen, 1999; Sansgiry and Cady, 1996A; Wogalter et al., 1996A; Braus, 1993; Discenza and Ferguson, 1992; Lumpkin et al., 1990). If an OTC label fails to communicate vital information about the drug, consequences can range in severity from the inefficacy of the product to the death of the user.

Exacerbating the potential for label failure is the aging of the population. "Chronic diseases and disorder in old age are multiple and synergistic. They bring on functional decline and require multiple medication - a recipe for noncompliance" (Fulmer et al., 2000-2001). The elderly represent a "worst case" scenario with regard to OTC products, and as the population ages, the potential for drug related complications increases. It is predicted that 20% of the US population will be age 65 or older by 2030, and that by 2050 people over 85 will constitute 5% of the population (Federal Interagency Forum on Aging, 2000). Policy makers, researchers and manufacturers, aware of the increasing potential for medication-related complications and the financial clout of the up-and-coming baby boomers, have begun to investigate ways that label

information can be made accessible to elderly consumers. This effort will not only benefit the elderly, but the general population as well.

When a label is effective, consumers successfully accomplish four steps of consumer/label interaction (Rousseau et al, 1998). Labels must be (1) noticed, (2) encoded [read], (3) comprehended and, finally, consumers must (4) comply with the information given. Failures at any of these steps diminish the label's ability to fulfill the communication function. The consumer reading the label, the label itself and the environment in which the interaction takes place determine the success or failure of each of these steps.

The Food and Drug Administration (FDA) has concentrated much of its effort on regulating labels so that consumers can successfully accomplish step two of Rousseau's model (1998). They recognized that consumers had difficulty reading OTC drug labels in 1990, when The Pharmacist Planning Service of Sausalito, CA. and several citizens' groups petitioned them in an attempt to get standards set for the size and style of text used on OTC labels (Sansgiry et al., 1997; Wechsler, 1991). "That same year the California legislature enacted a bill (A.B. 2713) requiring manufacturers to assess and improve label readability" (Sansgiry et al., 1997).

The Nonprescription Drug Manufacturers Association (NDMA) responded swiftly to the legislative and regulatory action. In 1991 they convened a task force that produced "The NDMA Label Readability Guidelines". It contained a set of recommendations that drug manufacturers could voluntarily adopt to improve the legibility of their products' labels.

One study of OTC drug labels on the market in 1996 indicated that manufacturers were not adopting the voluntary guideline, and that there was still reason to be concerned about encoding. "Study results indicate that not all of the recommendations stated in the NDMA Label Readability Guidelines have been adopted by manufacturers." Perhaps more alarming than the high rate of noncompliance with the voluntary standard was the finding that "font size of warnings did not increase with an increase of package size, but remained constant at a level that might be difficult for certain patients to read" (Sansgiry et al., 1997).

FDA conducted research studies, sought comment, reviewed existing knowledge and, ultimately, imposed a new regulation for OTC label design. In the Federal Register published March 17, 1999, the FDA published a final rule entitled "Over-the-Counter Human Drugs; Labeling Requirements" (see Appendix 1 for regulation details). This rule established,

> "a standardized format and standardized content requirements for the labeling of OTC drug products. This final rule is intended to assist consumers in reading and understanding OTC drug product labeling so that consumers may use these products safely and effectively. This final rule will require all OTC drug products to carry the new, easy-to-read format and the revised content requirements ..." (Food and Drug Administration, 1999)

The standardized, prescriptive approach directed by FDA is problematic. Previous research cautions against the use of standardized warnings because of a phenomenon referred to as "habituation".

> "Over time and repeated exposure, a warning will attract less attention...There are many ways to retard habituation, however. One way is to alter the characteristics of an existing warning from time to time so that it looks different"(Wogalter and Laughery, 1996B)

Altering the appearance of OTC warnings is not possible under the current rule; label format is explicitly prescribed by the regulation.

Prescribing the details of OTC label design may not be the most effective alternative for ensuring accessibility to the information they provide. FDA's approach does not directly address consumers' abilities to read information, but assumes a legible solution has been found and sweepingly applies that solution to all labels (Bix and Lockhart, 2000). This approach oversimplifies the complex interactions that can occur when all the elements of design come together to convey a message.

The research presented in this document challenges the idea that a prescriptive approach to regulation addresses the true issue of importance: the consumer's ability to visually read the label. The Lockhart Legibility Instrument (LLI), an instrument developed at the MSU School of Packaging, provides a direct measure of a subject's ability to read text. The numerous elements of letter, word and message design, and the complicated interactions that can occur between these elements are evaluated for legibility with a single test. A performance standard for legibility, utilizing an instrument like the LLI, would better serve consumers by ensuring that they could effectively read essential information provided on drug labels, helping to ensure their safe and effective use.

The fundamental hypothesis of this research is that by manipulating the many components of letter, word and message design, a noncompliant label can be created that is at least as legible as one that complies with the 1999 regulation, as measured with the LLI. The ability of people to effectively read OTC label information should be the focus of FDA's regulation, not compliance with a prescribed standard.

Literature Review

Why Examine OTC drug labels?

Although creating labels that can be successfully read by consumers will benefit all products, effective OTC label design is paramount for a variety of reasons.

When prescription drugs are sold to consumers, it is typical that two sources will act as "learned intermediaries" to inform them of possible adverse consequences, or risks, associated with product use (Alsobrook, 1992). The physician who prescribes the drug has the opportunity to provide consumers with information, as does the pharmacist who sells the drug.

> "...consumers generally cannot hold manufacturers of prescription drugs liable provided the manufacturer has adequately warned the prescribing physician of pertinent side effects and manufactured the drug properly" (Alsobrook, 1992).

Guidance provided by the physician and the pharmacist augments the printed label information that appears on prescription drug packaging, and "buffers" prescription drug manufacturers from liability (Alsobrook, 1992).

This is not the case with OTC drug products. Although consumers can seek information from other sources, in the majority of cases, the label is the sole provider (Wogalter et al., 1996A). In fact, the number of consumers that actually seek advice from a health-care professional while selecting OTC medications is very low (Tennesen, 1999; Sansgiry and Cady, 1996; Braus, 1993; Lumpkin et al., 1990). The courts have taken notice of the importance of the need for sufficient OTC labeling, and it is reflected in the jurisprudence. "Although many theories are available to an injured consumer of an

OTC, proof of inadequate warning is most effective in obtaining relief according to the restatement and jurisprudence" (Alsobrook, 1992).

The potential for manufacturer liability is increasing as the use of OTC medication continues to rise.

> "Switching drugs from prescription to over-the-counter (OTC) status is proceeding at an ever-increasing pace. In the 10 years from 1984 to 1994, 9 drugs were switched from prescription to OTC status - an average of about 1 a year. But in 1995 alone, 7 agents were moved to OTC status, and last year (1996), 13 drugs were switched to OTC" (Marwick, 1997).

It is no wonder that the popularity of OTC drugs is increasing: self-medicating offers an average savings of $84 per illness (Tarlach, 1998) when compared with the average cost of a trip to the doctor and the purchase of a prescription medication. "Although 60% of the drugs purchased by consumers in the United States are OTC, they account for less than 2 % of the US health care dollar" (Marwick, 1997; People's Medical Society, 1997). In addition to saving money, self-medicating is convenient. Over-the-Counter (OTC) drugs can be purchased at almost any grocery store, making them attractive to consumers who are increasingly pushed for time.

Although self-medication offers freedom, flexibility and cost savings to consumers, it has risks.

> "Researchers and the trade press have reported cases of inappropriate consumer use of nonprescription medicines (OTCs), primarily involving misinterpretation and misuse. Some consumers are unable to interpret label information correctly and others delay medical treatment for a more serious underlying disease, overdose, or use nonprescription drugs chronically...Non prescription drugs also are known to interfere with laboratory test values, cause adverse interactions with prescription drugs, and sometimes even render prescription drugs ineffective" (Gore et al., 1994).

Further increasing consumer risk is the fact that stronger and stronger drugs are being switched from prescription status to OTC. The Consumer Healthcare Products Association, a trade group that represents nonprescription drug makers, indicates, "more than 600 OTC drugs contain ingredients and dosages that 20 years ago were available only by prescription" (Nordenberg, 1999).

"While information alone will not ensure a secure patient, the corollary is more difficult to refute.... It is essential that individuals understand the nature of OTC medications, the consequences and benefits of compliance" (Lumpkin et al., 1990). This is especially true for the elderly population, who are at increased risk for adverse reactions from OTC drugs for various reasons.

Why has the Aging of the Population Brought Attention to Label Design?

Financial Benefit

Designing more accessible OTC labels as the population ages is not just "the right thing to do"; it makes good business sense. Recent American Association of Retired Persons (AARP) research indicates that 8 in 10 baby boomers expect to work at least part time during their retirement (Hignite, 2000). Couple this with the recently passed "Senior Citizen's Freedom to Work Act of 2000" and the result is a substantial segment of the population with increasing financial clout.

Not only do older adults work longer and keep more of the money they earn, they spend more on drugs then other segments of the population. "People 65 and older are more likely to require multiple medications, both prescription and OTC. Consumers over age 50 used an estimated $41 billion in prescription drugs last year (1998)...twice the per-capita consumption of the rest of the population" (Woolley, 1999), and elderly consumers spend even more on OTC drugs. A study conducted at the University of

Missouri Columbia's School of Nursing (Conn, 1992) indicated "elderly subjects reported using almost twice as many OTC as prescription medications."

Manufacturers are beginning to take notice of this financially attractive population by creating products and packages that target their needs and desires. John Bitner (2000), Packaging Manager for Pharmacia Corporation, explains, "Older Americans are becoming less tolerant of inconvenience and having their needs generally ignored... in not too many years, this population segment will have the leverage to demand performance."

Drug Mismanagement in the Elderly Population

Even more compelling than the financial benefits, are the safety issues. The most readily available, economically attractive source of information about a product is on its label. Accessible information is important for all products, but can be of life and death importance for products like OTC drugs. A number of factors place the elderly population at particular risk for misuse.

> "People over age 65 are especially vulnerable to medication-related problems because of the number of medications that they take and the biological changes of aging and disease. Older people are the greatest consumers of prescription and OTC medications, and they are more likely to be taking multiple medications at the same time...Changes in physiology place older people at greater risk of adverse reactions... Visual or cognitive impairment can combine with psychological, social and care giving needs to interfere with the proper use of medications" (Beers, 2000-2001).

The statistics of misuse confirm the risk to the elderly population. "Older people are the group most likely to take medicine improperly, according to a study reported in the New England Journal of Medicine" (Braus, 1993). "Americans aged 60 and older account for 40% of adverse drug reaction cases" (Braus, 1993) and ".....51% of deaths from drug reactions" (Holt and Hall, 1990).

Older adults are less able to effectively navigate the four steps of consumer/label interaction (notice, encode, comprehend and comply) (Rousseau, 1998) than their younger counterparts because of changes in their perceptual and cognitive abilities. Combine this with changes in the psychological, physiological and social states of the elderly and you begin to see why they account for large percentages of drug related hospitalizations and deaths.

Changes in Vision

To effectively notice and encode (read) printed label information, consumers must physically perceive the text using their vision. As people age, ocular declines interfere with their ability to successfully complete the first two steps of Rosseau's (1998) model, putting them at increased risk for improper use. Age-related changes in the pupil, cornea, lens, vitreous humor and retina (see Figure 1) combine with an increased propensity for ocular disease to diminish visual function and fuel the need for additional light.

The sclera and the cornea form the outermost portion of the eye (see Figure 1). The sclera is a fibrous coating that protects and shapes the eye, providing an anchor for muscles. The cornea bulges from the sclera and is transparent, allowing light to enter the eye (Marieb, 1992). As light enters the eye, it is refracted by the cornea, which provides approximately 75% of the eye's focusing power (Kelly, 1993). It then passes through the aqueous humor to the lens, where it is refocused and passed through the vitreous humor, a clear fluid, to the retina (Marieb, 1992).

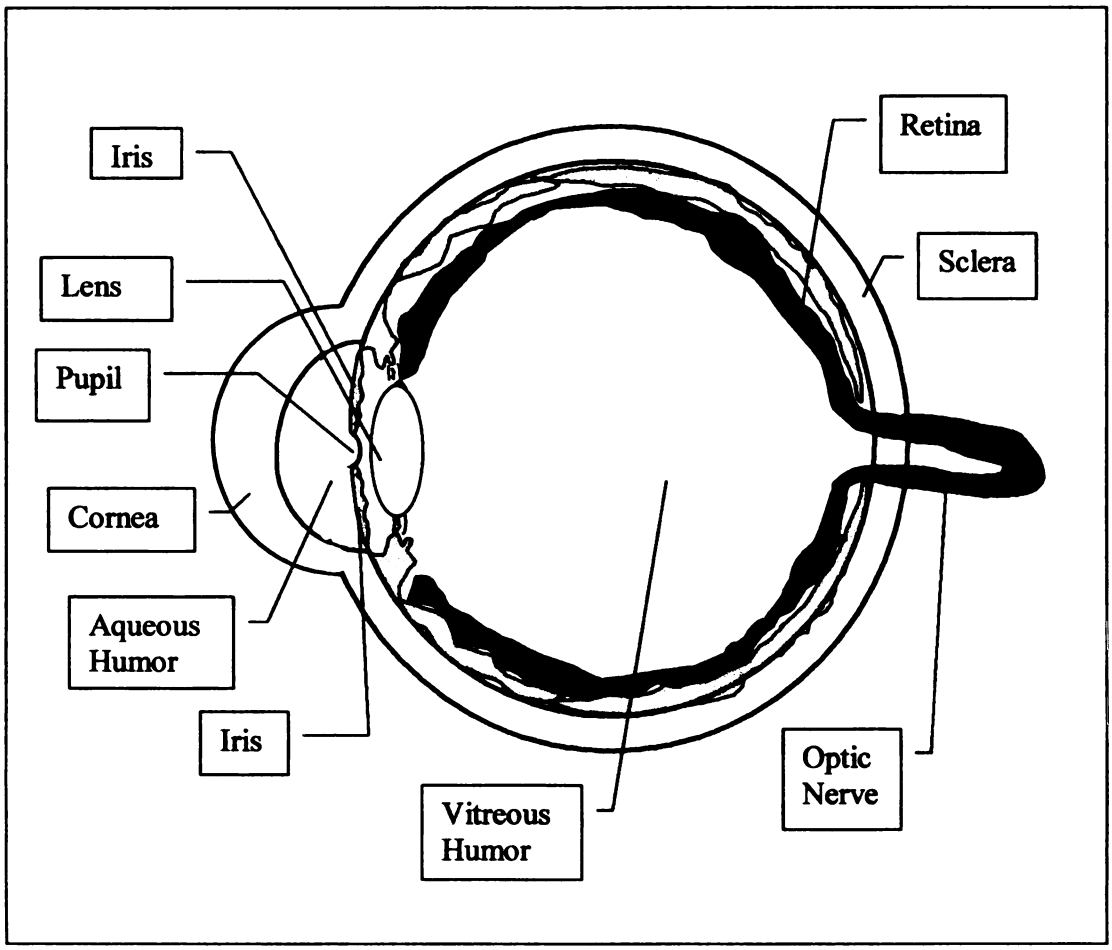


FIGURE 1- THE STRUCTURE OF THE EYE

One of the cornea's most significant age-related changes is a "flattening" that results in astigmatism. Degenerative changes also occur in the sclera, which result in a loss of clarity that affects the quality of vision of older adults. These changes result in a loss of accommodation, the ability to focus at a variety of distances, in aging adults.

Aging also affects the retina, the vitreous humor and the lens of the eye. As aging takes place, the retina, the vitreous humor and the lens yellow and thicken. These changes reduce the short-wave lengths of light (the blue color) entering the eye and scatter the light that does enter. The resultant effect is that colors such as violet, blue and

green are filtered out, reducing the contrast sensitivity of the eye and causing glare which interferes with the visual image.

Visual quality of older adults is also affected by changes in the pupil. "The iris is unable to dilate as much as in youth under all light conditions, but this is especially evident and troublesome under dark-adapted conditions" (Kelly, 1993). As a result of the iris's inability to dilate, the size of the pupil decreases with age. This creates a kind of chain reaction. The iris is unable to dilate, keeping the pupil small and, ultimately, decreasing the amount of light reaching the retina, which, as a result of age-related thickening, is not as sensitive as in younger subjects.

Not only do older adults have to contend with changes that result in diminished visual function, they are also more likely to develop certain ocular pathologies. Cataracts, glaucoma, senile macular degeneration (SMD), diabetic retinopathy, and presbyopia, a decrease in the ability to focus, are diseases that are more prevalent in the elderly (Kelly, 1993; Holt et al., 1990).

Cognitive Changes

In addition to perceptual losses, aging consumers frequently experience several cognitive changes that can affect their ability to successfully use labels. Unlike perceptual changes, cognitive changes generally impact the consumer's ability to comprehend and comply with label information, the final two steps of Rousseau's (1998) consumer/label interaction. Cognitive changes include decreases in working memory, language comprehension, prospective memory, and the comprehension of symbols.

Reductions in Working Memory

One age related phenomenon that affects the ability of consumers to comprehend and comply with label information is a reduction of working memory. Working memory

refers to a person's capacity to store and process information (Rousseau et al., 1998; Morrow and Leirer, 1999). "Memory load" is the amount of information that individuals have to process. Higher "memory loads" exacerbate problems associated with decreases in working memory. Older adults experience a reduction in working memory, yet have higher memory loads related to medication instructions due to their propensity to use multiple medications (Morrow and Leirer, 1999; Woolley, 1999; Sansgiry and Cady, 1996).

Additionally, "older adults may have trouble understanding instructions that require inferring or reorganizing information, which impose heavy demands on working memory" (Morrow and Leirer, 1999). Despite this knowledge, many warning labels still use instruction statements that require consumers to make inferences and reorganize the information presented. One example is a label that requires consumers to integrate time ("take twice daily") and dosage information ("take two pills") (Morrow and Leirer, 1999). Clear dosage charts complete with prescribed amount and explicit time of day reduce the requirement for working memory.

Explicit directions that do not require inferences will do no good if consumers do not remember to read them. "Older adults benefit from environments or contexts that provide meaningful cues for remembering information" (Rousseau et al., 1998). One way to apply this to OTC drug labels is to place the label information on the primary package, the package that contains the product, rather than on the secondary package, which is typically an outer wrap or folding carton. When packages are designed in this fashion, the relevant information is part of the immediate environment, available to the older consumer as they are using the product.

Difficulties with Language Comprehension

Reduction of working memory also creates problems with language comprehension. In 1978 Kintsch and van Dijk proposed one of the most prominent language comprehension models for text processing:

> "According to their [Kintsch and van Dijk] model, text is read and brought into memory as propositions, which are information packets containing a predicate and an argument (e.g., a verb and a noun). The maintenance of these propositions in working memory depends upon their relevance to the text. Important (high involvement) information is maintained and propositions of less importance (low involvement) fade from memory" (Rousseau et al., 1998).

Light (1990) proposed that several age-related effects impact the Kintsch and van Dijk model. Light suggested that the decreased working memory capacity of older adults resulted in faster decay of propositions from memory. He also hypothesized that older adults have more difficulty associating propositions that occur farther apart, and that older adults have a harder time "keeping extraneous, irrelevant information out of the working memory, further reducing its capacity" (Light, 1990). The implications of decreased language comprehension for the labels of OTC drug products are fairly clear. Label information should be simple, direct and explicit.

Decreasing Prospective Memory

Another problem faced by elderly consumers is a decrease in "prospective memory." According to cognitive psychologists, "prospective memory" entails "remembering to perform an action in the future" (Rousseau et al, 1998). Prospective memory is related to the task prescribed by the label. Rousseau indicates that elderly consumers have less difficulty remembering event-based tasks. "Take two pills after breakfast" is an example of an event-based task. Elderly consumers have been shown to

have a harder time complying with time-based tasks, such as "take two pills every eight hours" due to losses in prospective memory (Rousseau et al., 1998).

The introduction of environmental cues alleviates the age-related decline in prospective memory. "Interactive warnings" are a relatively new type of design that is meant to take advantage of environmental cues, increasing label effectiveness.

> "This format (interactive warnings) requires the product user to physically manipulate the warning when using the product, and researchers have found that these types of warnings increase the likelihood of the user noticing and complying with the information... the interactive labels serve as an event-based cue to recall the appropriate safety procedures" (Rousseau et al., 1998).

One field where interactive labels have proven successful is in the furniture industry. Directions for assembly are placed in such a way that the consumer must physically destroy the label to accomplish the directed task.

Few studies have applied the use of interactive labels to packaging. Wogalter et al. (1996A) investigated the effect of an additional label on understanding of elderly consumers by adding a printed "easy open fin" to the caps of OTC drug bottles that contained motion sickness tablets. "The information on the cap label (the fin) was extracted from the main label text and was chosen, based on consultation with a pharmacist, to reflect the most important cautions and directions for proper, safe use of the product." Consistent with Rousseau's findings, Wogalter's research team found that this simple change in package design and label format improved knowledge acquisition. Interactive warnings and their application to OTC drug packages is a rich area for future research.

Problems with Symbol Comprehension

A final type of cognitive deterioration that occurs during the course of aging is a decrease in symbol comprehension.

> "Age-related changes in text comprehension would seem to indicate that symbols would have particular utility for improving older adults' understanding of warning information. However, symbols may not always facilitate comprehension for everyone, and this is particularly the case for older adults. In addition, some working memory limitations that are known to affect language comprehension may also affect symbol comprehension"(Rousseau et al., 1998)

A study conducted by Morrell et al. (1990) examined the effect of age on the ability to comprehend text-only labels and labels that contained a combination of text and symbols. While younger adults benefited from the combined format, older adults performed best when text-only formats were supplied. Researchers did not suggest a reason for this effect.

Sansgiry and Cady (1996) also evaluated the effect of age and pictorial information (symbols) on the comprehension of OTC drug product labels. A study they conducted in 1996 was divided into two parts.

In the first part subjects were asked to interpret eight pictures (symbols), six of which were taken from actual OTC labels. Subjects were allowed as much time as they needed to view labels and make interpretations. Numbers of responses and percentage of correct responses were tabulated. Results of the 1996 study supported Rousseau's position that the comprehension of symbols decreases with increasing age. "Older adults had greater difficulty in interpreting correct responses" (Sansgiry and Cady, 1996); the elderly group's score was below that of the young adults for all eight pictures. At least 80% of the younger group paired symbol with affliction correctly for five pictures. By

contrast, the older group had 80% of its participants make the correct pairing for only 2 of the eight pictures.

The second part of the experiment dealt with the effect of pictorial information on subject understanding. Four OTC products intended for medicating headaches, sinus conditions, menstrual pain and sleeplessness were investigated using four treatments. The first treatment was a picture only label. The second treatment was a text only presentation. The third and fourth treatments were a combination of text and pictorial information; one depicted an incongruent picture/text combination and the other displayed a congruent message. It was hypothesized,

> "Congruent picture-verbal label design (picture matched with written information) will enhance understanding of information in both younger and older adults, compared to verbal only, picture only, and incongruent picture-verbal (picture and written information does not match and the written information represents a distracter) label designs" (Sangsgiry and Cady, 1996).

Sansgiry and Cady found the congruent picture/text combination to be the most easily interpreted, followed by text-only designs. However, when the results of these two designs were compared, the difference was found to be insignificant. This result is consistent with those of the study conducted by Morrell et al. (1990). "Addition of a picture complementing written information did not enhance understanding significantly" (Sansgiry and Cady 1996). When the results were compared between age groups, significant differences occurred in all but one label design at $p<0.001$. Older adults had lower understanding scores for all label designs when compared with the younger group, suggesting that symbol comprehension does decrease with age.

Pharmacokinetic and Pharmodynamic Changes

Not only do perceptual and cognitive changes make consumers less likely to effectively use drug labels, physiological changes negatively impact how the body processes the drug, and what the drug does to the body. All of these changes combine to put elderly consumers at even more risk from the ill effects of mismedication.

Pharmacokinetics refers to how the body processes medication. According to Beers (2000-2001) there are three components of pharmacokinetics. The first component is absorption, how the body gets the drug. The second component is distribution, "where and how the medication goes once it is in the body" (Beers, 2000-2001). The last component, elimination, refers to the system's ability to clear the drug.

Although aging significantly impacts how the body processes medications, the first component, absorption, is affected very little by age. Distribution, the second component of pharmacokinetics, is substantially impacted as people age.

> "Most medications are distributed to either body fat or body water. With aging, there is an increase in the percentage of body fat. The typical older person has about 25 to 30 percent more fat than the typical younger person; the percentage is higher for older women. With the increase in percentage of body fat, there is a corresponding decrease in the percentage of the body consisting of water. In older people, blood levels of water-soluble medications will be higher than would be expected in younger people because there is less body water to distribute into. Fat-soluble medications stay in the body much longer because there is more fat in which to be stored" (Beers, 2000-2001).

The final component, elimination, is even more dramatically impacted by age. Drugs are eliminated from the body either through the kidneys or metabolized in the liver. "There is about a 50 percent decline in the renal (kidney) clearance of medications by the time people reach age 75 to 80". Drugs that are metabolized by the liver are also affected. Beers (2000-2001) indicates that hepatic (liver)

blood flow in a person between the ages of 75-80 is about half that of younger adults, which substantially impacts drug clearance. Additionally, the P450 system, the major enzymatic system by which the liver metabolizes medication, is rapidly saturated in old age.

Pharmacodynamics, the way that drugs affect the body, also changes with age, further compounding the problems that the elderly have with drug products. "As we get older we are more sensitive, rather than less sensitive to most drugs" (Beers, 2000-2001). Age-related changes in pharmacodynamics result in increased potential for toxicity. This is particularly true of drugs that act on the central nervous system; as a result, the "list of medications that cause confusion or changes to the central nervous system in older people is very long" (Beers, 2000-2001).

Social Changes

The elderly not only have to contend with perceptual, cognitive and physiological changes that put them at increased risk for mismedication, but many of them live in social conditions that exacerbate the risk further. The number of elderly people that live alone is on the rise. In 1989 the U.S. Senate Special Committee on Aging estimated that 47% of people 85 and older lived independently. According to the U.S. Senate Special Committee on Aging, they are one of the most vulnerable groups in America. 60% of the elderly living alone are reported to have chronic problems with vision or hearing (U.S. Senate Special Committee on Aging, 1991). As a result, a significant portion of older adults have no one to assist them with their medical regimen, are suffering from afflictions that require polypharmacy, and do not have sufficient vision to read printed information.

Design and Legibility

The aging of the population, combined with the risks of self-medicating, its increasing prevalence, and the trend to switch drugs from prescription to OTC status have all contributed to the need for printed OTC labels that are easily read and understood. Recognizing these trends, FDA published a regulation entitled "Over-the-Counter Human Drugs; Labeling Requirements" (1999). The regulation is an attempt to ensure that OTC labels are sufficiently legible. It dictates, among other things, a minimum font size, sufficient contrast, minimum leading, a maximum number of letters per inch, and strongly recommends that manufacturers use a specific style of type.

FDA's approach looks at the elements of design as distinct entities that can be isolated and manipulated one at a time to improve label legibility. Reality does not match the simplicity of this approach. Legibility is the overall goal in a complex system of interrelated elements (letter weight, letter compression, counter form shape, stress, type style, type size, message layout, leading, kerning, ink, substrate, and printing process) that come together to create a message. Researchers who recognize the complexity of the elements of typography understand that changes in design do not occur in a vacuum. In changing one element, it is likely that numerous others, all of which impact legibility, will be affected (e.g. increasing stroke weight will decrease counter form size).

Letter Design and Legibility

When creating messages, designers must be careful to not affect basic letters, thus weakening communication (Craig, 1980). The challenge is to make the most effective use of the enormous flexibility that is inherent in typographic design (Bigelow and Day, 1983) by creating designs that are both interesting and practical. Effective designers develop a high level of awareness of font in order to construct messages that not only

attract readers (notice), but allow them to easily read (encode) and understand (comprehend) the message they have created. This awareness begins with a basic understanding of the "anatomy" of letters.

Textual messages are usually constructed of words that are made of upper and lower case letters that are set in a single font. "A font consists of all the characters (upper and lowercase, figures, fractions, reference marks, etc.) of one size of one particular typeface" (Craig, 1980). Typeface (see Figure 2) is defined as the full range (size) of type of the same design (Department of Mathematics, University of Utah, 2001). In other words, a typeface consists of all characters, in all sizes, of a particular design. "Typefaces are usually available in 6- to 72-point [one point is equal to 1/72"], with a complete font in each size" (International Paper, 1997). A family of type encompasses all related typefaces (see Figure 2).

FIGURE 2- FONT, TYPEFACE AND FAMILY

There are several common elements of letters that can be examined. These include x-height, ascenders and descenders, counters (also called counter forms) serifs (or lack of serifs, referred to as sans serif), and stroke weight (thick and thin). The terms x-height, ascender and descender refer only to lower-case letters, while counters, serifs, and stroke weight apply to both upper and lower case letters.

X-height refers to the height of the body of a lowercase letter. It is called the x-height because it is equal to the height of the lowercase x (see Figures 3 and 4).

> "Although the x-height is not a unit of measurement, it is significant because it is the x-height - not the point size - that conveys the visual impression of the size of the letter. Typefaces of the same point size may appear larger or smaller because of variations in the x-height" (see Appendix 2 and Figure 3) (Craig, 1980).

49 Point Garamond	49 Point Baskerville	49 Point Modern 20	49 Point Century	49 Point Helvetica Light

FIGURE 3- COMPARING THE X-HEIGHTS OF VARIOUS FONTS

Despite the fact that it is the x-height that conveys the visual impression of letter size, not the point size, the FDA regulation mandates a minimum type size of 6 points, and makes no direct reference to x-height. FDA does, however, strongly recommend the use of a sans serif font. These fonts are characterized by larger x-heights, indirectly addressing the issue. FDA suggests that adhering to their standard will produce legible results, "the agency [FDA] believes it has selected type sizes [6 point minimum] and styles [sans serif] that are consistent with the need for readable OTC drug product

labeling by a majority of OTC drug consumers" (FDA, 1999). Despite the urging of FDA, companies may dismiss the recommended typefaces in favor of others; it is not mandated that they comply. Even if manufacturers strictly adhere to the recommendation and use sans serif type styles, the x-heights from family to family vary dramatically (see Figure 4). The result is that 6 point fonts with varying x-heights (see Figures 3 and 4), and presumably varying legibility, are allowed by the regulation.

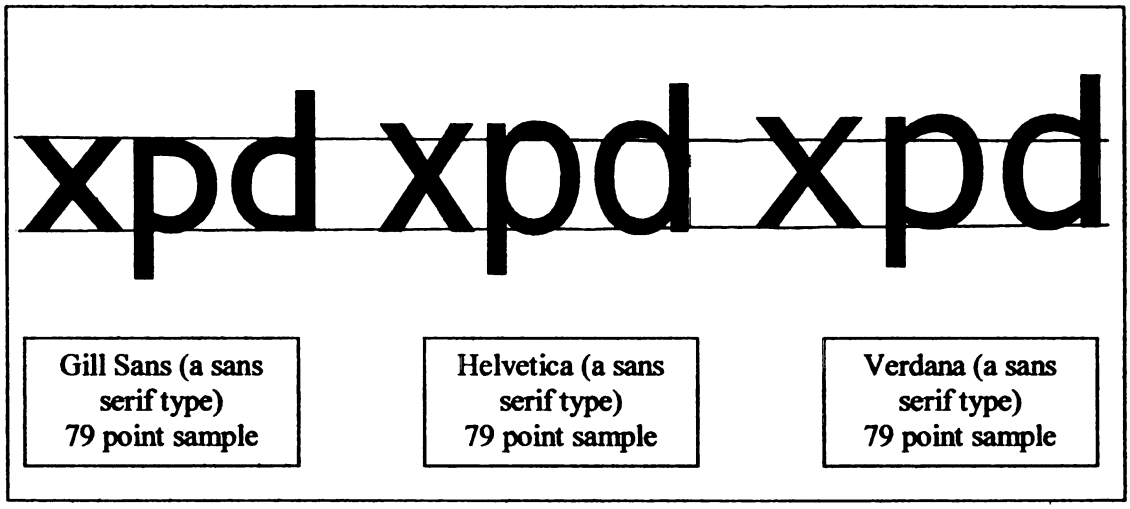


FIGURE 4- COMPARING THE X HEIGHTS OF VARIOUS SANS SERIF FONTS

Type size is, perhaps, the letter characteristic that is most frequently manipulated to improve legibility; a common perception is that increasing type size will automatically improve message legibility. To some extent, this is true. However, to say that type size determines legibility is an oversimplification. The design elements of letters, and the way they are presented, can have a greater impact on legibility than size of the type.

A study conducted at the New England College of Optometry (Watanabe, 1994) found elements other than type size had a more significant impact on legibility. "Type

size alone may not be responsible for poor readability. Other factors that may be contributing to this difficulty include letter and line spacing, letter contrast, print and background color, and type style" (Watanabe, 1994). The study concluded, "horizontal letter compression had a greater effect on readability than vertical letter height."

An experiment conducted at the Michigan State University School of Packaging in July 1997 (Lockhart and Bix, 1997) also suggests that more factors influence legibility than font size. A message in 4.5 point type with black on white contrast was more easily read than the same message printed in 6 point type with yellow on red contrast. These results indicate that color contrast can have a greater impact on legibility than type size.

Regulating the 6 point minimum is also problematic because measuring type size is not straightforward. The size of a given font is based on the now-antiquated system of setting metal type. Metal type setting was the system used when letterpress, a type of relief printing, was the only way to print text. In letterpress printing, each letter is raised from the surface of a metal block (see Figure 5). The block is referred to as the body; the printing surface (the letter) is referred to as "the face" (Craig, 1980). Type size is based on the size of the block from which the letter is carved and is not directly related to the height of the letter.

The difficulty occurs because different typefaces utilize different areas of the block, and even though type is now created using computer programs, type size is still based on the letterpress system. As a result, a type size of 6 points does not equal a 6 point letter height. Typefaces, like Verdana (see Figure 4 and 6 and Appendix 2), that utilize a large percentage of the block are close to 6 points tall. Typefaces that do not use as much of the block are much shorter, but they are still referred to as 6 point type.

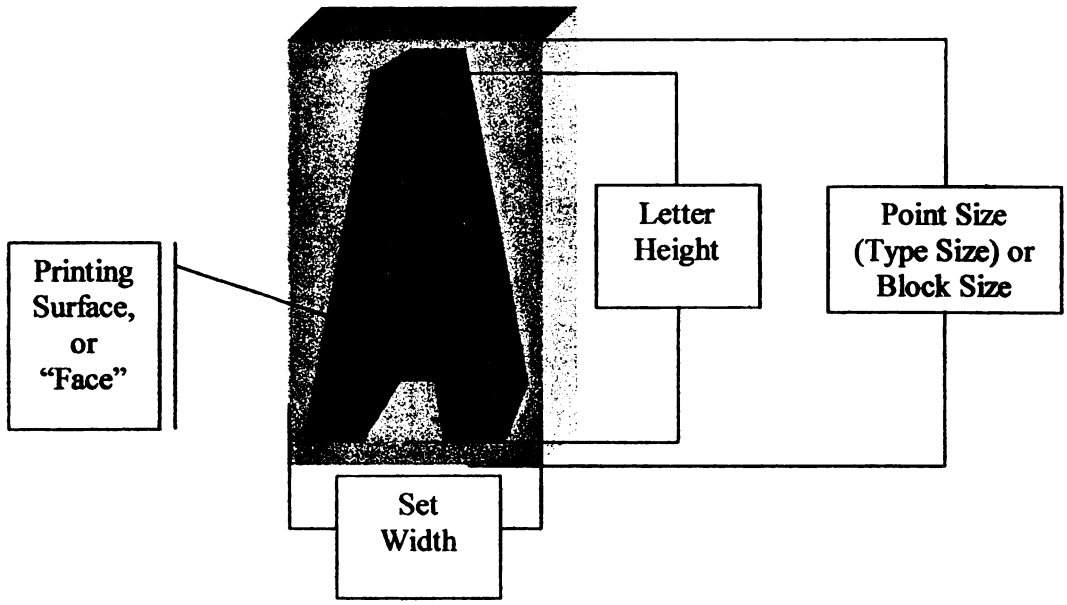
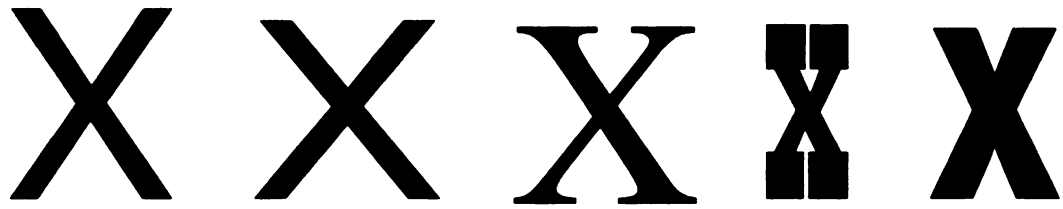


FIGURE 5- DIAGRAM OF A BLOCK OF TYPE

As a result, "the face of any letter is not the full point size.... Corresponding letters in the same size type may vary in height" (see Figure 6 for a limited sample and Appendix 2 for a more extensive example) (International Paper, 1997). "No type face fills the amount of space allowed in its measure, e.g. a type face in 10 point may print a letter only 6 points high; another type face in 10 point will print a letter 8 points high" (Ralph, 1982).



100 point Verdana Capital X	100 point Helvetica Light Capital X	100 point Times Capital X	100 point Play Bill Capital X	100 point Tw Cen MT Condensed Capital X

FIGURE 6-VARYING FONTS OF THE SAME TYPE SIZE ARE NOT EQUAL IN HEIGHT

Occasionally, individuals will measure type size from the bottom of the descender to the top of the ascender or cap-line (see Figure 7). Ascenders refer to any portion of the letter extending above the x-height; a lower-case "h" contains an ascender (see Figure 7). Letters with descenders contain portions that fall below the x-height. A lower-case "p" contains a descender (see Figure 7). Ascenders and descenders are only found in lower case letters. International Paper's Pocket Pal: A Graphic Arts Production Handbook advises against measuring type in this fashion. "Type size cannot be measured from the top of an ascending letter to the bottom of a descending letter. The face of any letter is not the full point size" (International Paper, 1997).

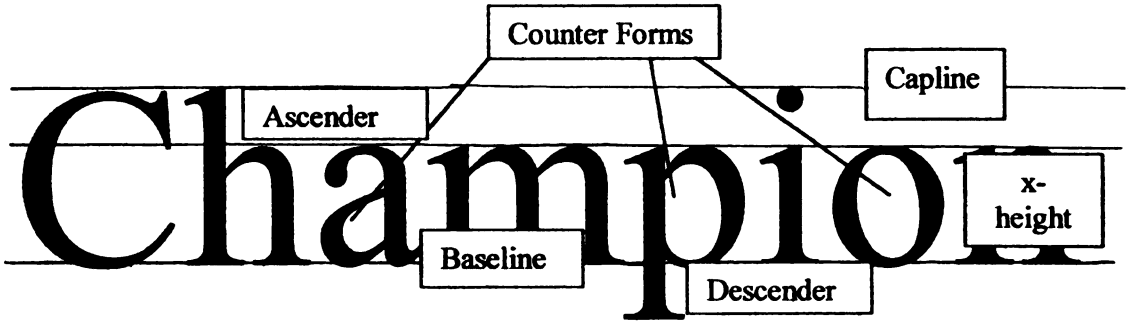


FIGURE 7- ASCENDERS, DESCENDERS AND X-HEIGHT

Even if FDA does find a way to accurately determine the point size of letters on OTC labels, scientists and manufacturers continue to debate what constitutes the minimum legible type size. Many authors indicate that for type to be legible it should be well above the 6-point size decreed by FDA. Hauptman (1979) recommends a minimum of 7 points, while Jewler (1981) suggests sizes no smaller than 10 points. If visually limited persons are considered (as previously noted, 60% of the elderly living alone are reported to have chronic problems with vision [U.S. Senate Special Committee on Aging, 1991]), it is suggested that a minimum of 12 points be used (Ralph, 1982).

Others argue that smaller type sizes can be used to create sufficiently legible messages (CHPA, 1999; NDMA, 1991). They indicate that 6 points is too large for small medication bottles, and not feasible from a production standpoint (CHPA, 1999; NDMA, 1991). In a statement to FDA, R. William Soller of the Consumer Healthcare Products Association (CHPA), argues against the 6 point minimum,

> ".....[there is a] notable lack of convincing objective support that 6-point type adds an advantage in legibility over smaller types sizes down to and including 5.0 point type... These are important observations, and it is important to find ways to address them. They are important because they suggest a ripple in what has been up to the Final Rule a fairly reasonable and productive partnership on labeling" (CHPA, 1999).

This is where the prescriptive approach that is being used by FDA fails. Specifying a minimum type size does not ensure legible labels. Wide variance in the heights of different type styles is likely to yield designs with varying degrees of legibility. Even if with the use of a 6-point minimum guaranteed legibility, it is difficult to determine the type size from the height of printed letters. This reality makes regulating the current mandate a formidable task. These issues provide further evidence that a performance standard for the legibility of OTC products is in the best interest of the public and the FDA.

Other design elements that impact legibility include counters (counter forms), the presence or absence of serifs, and variations in thickness. These elements all apply to both upper and lower case letters. Although most readers do not have a conscious awareness of the negative spaces within letters, also called counter forms or counters (see Figures 7 and 8), the design of these spaces significantly impacts letter identification. Both the negative and positive spaces of each letter work in concert to allow viewers to identify letters at a glance.

Helvetica Light "g"	Century "e"	Modern 20 "x"	Baskerville "p"	Garamond "a"

FIGURE 8–COUNTER FORMS OF VARIOUS TYPE FACES
(Negative spaces are in black while strokes are in white)

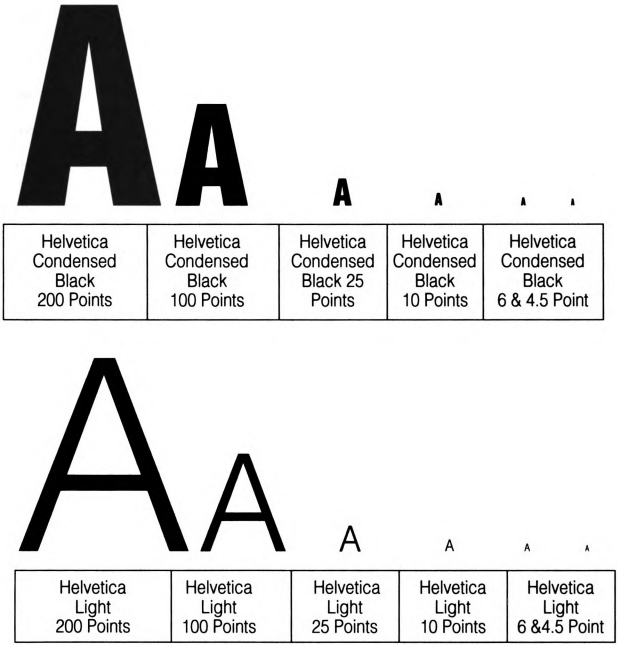


FIGURE 9 –SMALL COUNTERFORMS VS LARGE COUNTERFORMS

A comparison of the two typefaces in Figure 9 reveals that a typeface with large counters, like Helvetica Light, is easier to read at smaller sizes when compared with a typeface that

contains smaller counters, like Helvetica Condensed Black. This is because the counters of the letter are not "swallowed up" as letter size decreases; readers are able to use both positive and negative spaces to identify the letter.

Letters are produced in a wide variety of stroke weights (see Figure 10). Possible weights, arranged from lightest to heaviest, are: hairline, extralight, **light**, book, **regular**, medium, demibold, semibold, **bold**, extrabold, heavy, **black**, ultra and poster (weights that appear in bolded type are pictured below) (Department of Mathematics, University of Utah, 2001). Letters with thinner strokes are characterized by more open counter forms than their thicker counter parts (see Figure 9), allowing readers to use the positive and negative spaces for easy letter identification at small type sizes (Craig, 1980).

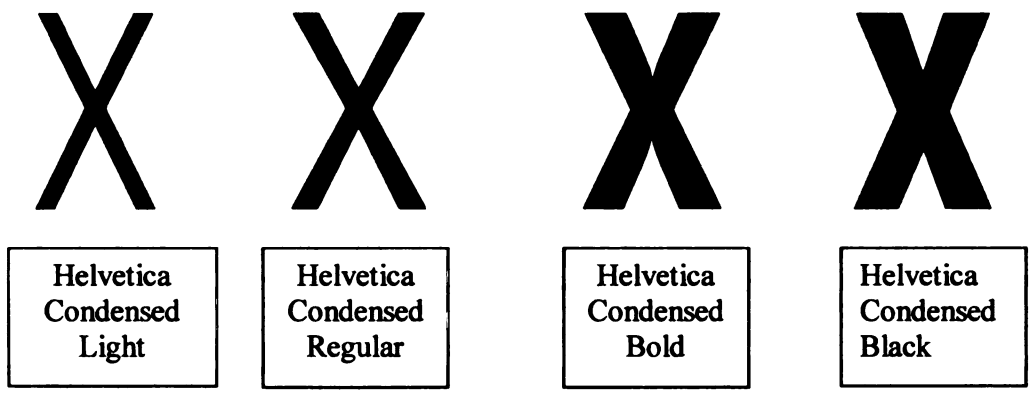


FIGURE 10- LETTERS WITH VARYING WEIGHTS (Within letter thickness is uniform.This sample includes only four possible stroke weights.)

Stroke thickness is not always uniform (as pictured in Figure 10); thickness can vary within a single letter (see Figure 11). A prominent characteristic of the Old Style faces, those designed between 1450 and 1693, is little contrast in weight between the thick and thin strokes of the character (Craig, 1980). Transitional faces, developed by

designers between 1693 and 1784, had "a tendency toward refinement and greater contrast between the thicks and thins" (Craig, 1980). Typefaces designed between 1784 and 1815, the Modern era, show an even greater contrast in thick and thin. The Slab Serif, or Egyptian, (1815-1930) era of typography marked a return to less contrast. This trend was continued in the Contemporary era (1816-present); contemporary designs are characterized by uniformity in thickness (see Figure 11). They have no contrast in thick and thin.

100 point Garamond, an "Old Style" Typeface 1617	100 point Baskerville, a "Transitional" Typeface 1757	100 point Modern No. 20, a "Modern" Typeface 1788	100 point Century Schoolbook, a refined version of an Egyptian, or slab serif typeface 1894	100 point Helvetica Light, a "Contemporary" typeface 1957

FIGURE 11- AN EVOLUTION OF CONTRAST IN LETTER WEIGHT
(Thick and thin)

Another design element utilized to classify typefaces is the use (see Figure 12), or exclusion (see Figure 14) of serifs. Serif fonts have terminal strokes that are short cross lines at the end of the main stroke (International Paper, 1997). "Serifs originated with the Roman masons who terminated each stroke in a slab of stone with a serif to correct the uneven appearance made by their tools" (Craig, 1980).

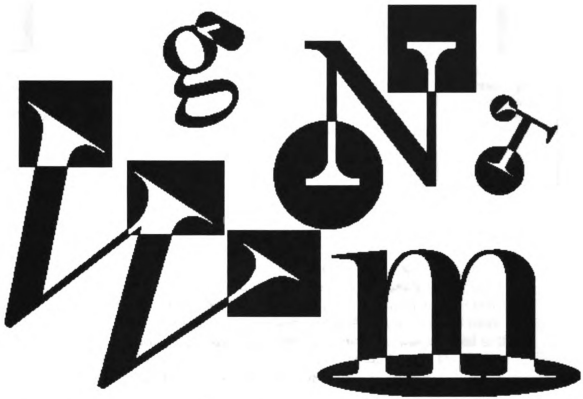
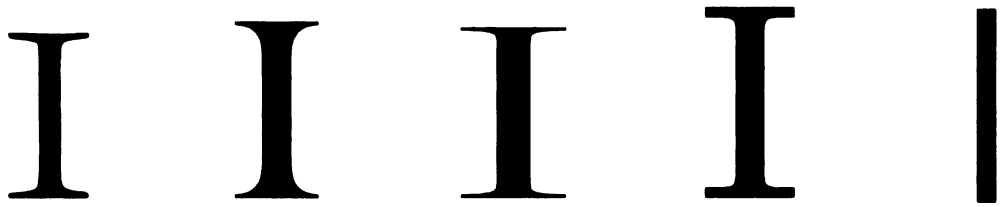


FIGURE 12- THE SERIFS OF A VARIETY OF TYPEFACES -Serifs are in white. "T" appears in Garamond. "m" appears in Modern No. 20. "N" appears in Century. "W" appears in Baskerville, and "g" appears in Times New Roman.

Serifs vary in their weight and design. The appearance of serifs, like the contrast of thick and thin, can be used to identify periods of type design.



Garamond, an "Old Style" Typeface 1617	Baskerville, a "Transitional" Typeface 1757	Modern No. 20, a "Modern" Typeface 1788 (Bodoni)	Century Schoolbook, a refined version of An "Egyptian", or slab serif typeface 1894	Helvetica Light, a "Contemporary" typeface 1957

FIGURE 13- THE EVOLUTION OF SERIF STYLE

> "Over the centuries type became more and more refined; that is, the contrast between the thick and thin strokes became greater (see Figure 13) and the serifs became finer (see Figure 10). This refinement was possible because of the development of smoother papers, better inks, and more advanced printing methods. The ultimate refinement was attained in the late 1700's (the Modern era) when Bodoni reduced the thin strokes and serifs to fine hairline strokes" (Craig, 1980).

Literature reviewing how serifs impact legibility is divided. Many works indicate that serifs positively contribute to message legibility, while others indicate that sans-serif fonts are more easily read.

Researchers who believe serifs contribute positively to legibility (Rehe, 1990; Craig, 1980; McLean, 1980; Vanderplas and Vanderplas, 1980; Wright et. al, 1977; Perles, 1977; Tinker, 1963; Burt, 1959) generally provide two reasons for the improvement of legibility when using serif types: (1) "They (serifs) contribute effectively to the horizontal movement of the reading eye and thus help in combining separate letters

into word-wholes"(Perles, 1977) (2) Letters with serifs are more easily differentiated by readers than letters without serifs (sans serif: see Figure 14).

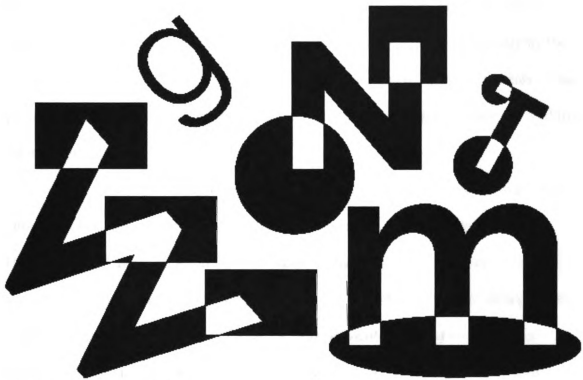


FIGURE 14- SANS SERIF IN A VARIETY OF TYPEFACES (Fonts that do not have the short terminal strokes required to hide imperfections caused by the early printing processes).

Researchers who support the legibility of sans serif types (Food and Drug Administration, 1999 and 1997; Bix, 1998; Pietrowski, 1993; NDMA, 1991) generally provide the following explanations for improved legibility in the absence of serifs. "Sans serif type is free of visual distractions" (Garcia, 1981) which improves legibility. Additionally, the x-heights of sans serif fonts are frequently greater than the x-heights of serif fonts of equal point size (see Figure 3 and Figure 11); this increase allows for more

open counter forms, filling more of the space provided by the type size measure, improving legibility.

Message Design and Legibility

The preceding discussion involves the elements that come together to create letters. However, messages are not merely letters. Letters must be integrated into words to be used to convey meanings through messages. Legibility is affected not only by the design of the letters, but also by the way that they are presented. Several elements of the presentation, or layout of the letters and words, can impact the reader's ability to read the information.

"Letter spacing is the amount of space used between letters, negative or positive, either for readability, aesthetics or to fill a certain area" (International Paper, 1997). Historically, in letterpress printing, which used "...metal type, letter spacing is [was] accomplished mechanically by inserting pieces of metal between the type" (Craig, 1980). Currently, letter spacing is accomplished by using computer programs to adjust the distance between letters. Because designers no longer have the physical limitations imposed by a metal block, negative spacing between letters is now possible. "Negative letter spacing involves the removal of space between letters individually (kerning) or between all letters equally (white space reduction or tracking)" (International Paper, 1997). Letter combinations that typically allow kerning (negative spacing between pairs of individual letters) include: we, We, yo, Yo, wa, Wa, Ta, To, ye, Ye, wo, Wo, va, Va, WA, VA (International Paper, 1997). The first letter in each of these two letter combinations provides a negative space that allows for the "overlap" of the two letters in the form of kerning (see Figure 15).

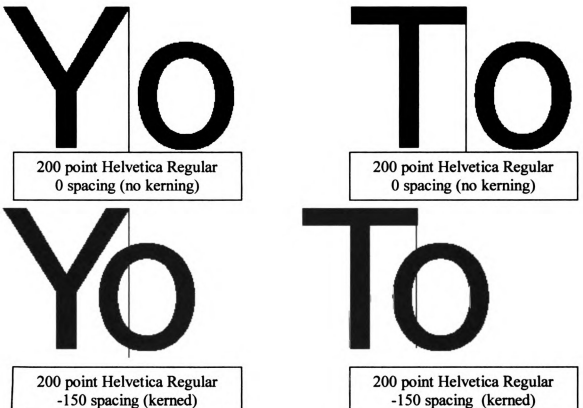


FIGURE 15- KERNING (NEGATIVE LETTER SPACING BETWEEN SPECIFIC LETTER PAIRS)

Although FDA's current regulation does not directly address the use of kerning, they are aware that manufacturers try to exploit label space by using negative letter spacing and typefaces with minimal widths. The width of a typeface is dependent on the compression or expansion of the font. Arranged from narrowest to widest, the various widths for type include: ultra compressed, extra condensed, compressed, **narrow**, **condensed**, **regular**, expanded and wide (widths that appear in bolded type are pictured in Figure 16) (Department of Mathematics, University of Utah, 2001).

FDA indirectly regulates typeface width and negative spacing by mandating "type styles which ensure letter compression of no more than 39 characters per inch" (FDA,

1999). This decision was largely based on research conducted at the New England College of Optometry (Watanabe, 1994). Watanabe's research indicates that the elderly population had a "great degree of sensitivity to small changes in horizontal letter compression". His work suggests that compression has a greater impact on legibility than letter height. The FDA followed his recommendation that "39 characters per inch is sufficient to allow good readability" (Watanabe, 1994).

Helvetica- Narrow (190 points)

Helvetica- Condensed (190 points)

Helvetica- Regular (190 points)

FIGURE 16- A COMPARISON OF TYPEFACES WITH DIFFERENT SET WIDTHS

Leading, the amount of space between lines of type, is also directed by the 1999 regulation. Leading is measured from baseline to baseline (see Figure 7) and is expressed in points or fractions of a point. "The amount of space or leading used in printing is usually 0 to 2 points depending on the typeface used" (Ralph, 1982). 50-point type with no lead is written as 50/50; the type size is 50 and the distance between baselines (see Figure 7) is 50. 50-point type with 10 points of leading is written 50/60 (see Figure 17). The type size is 50 and the distance between base lines is 60.

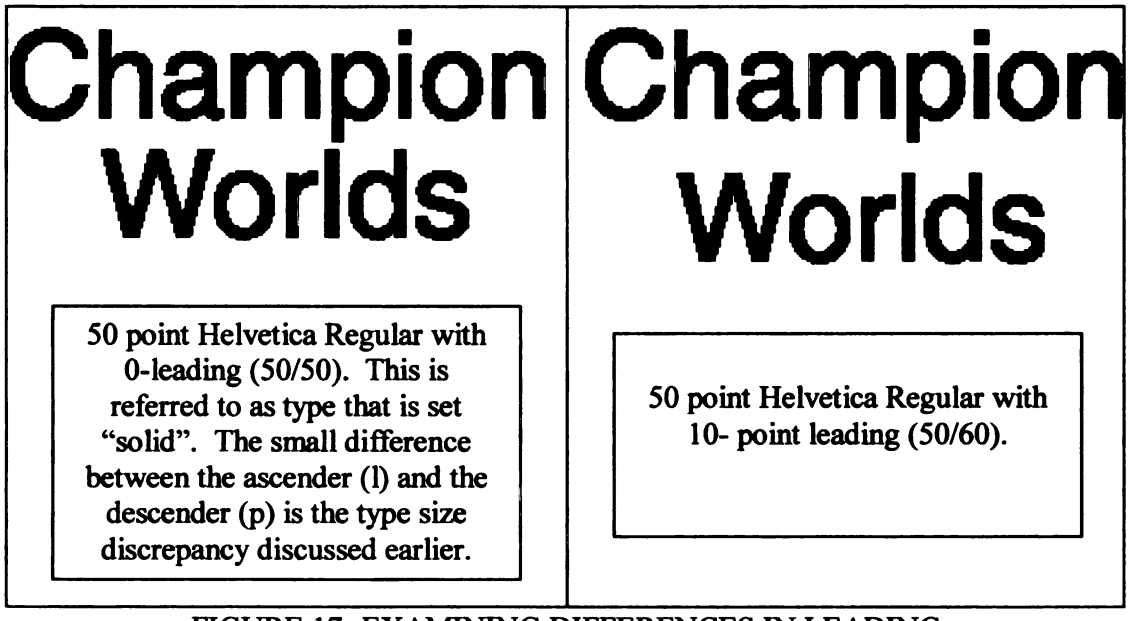


FIGURE 17- EXAMINING DIFFERENCES IN LEADING

Leading is known to contribute significantly to legibility, although "there is no set rule to follow (with regard to appropriate lead)" (International Paper, 1997).

> "Too much leading can sometimes be as bad as not enough. Typefaces with long ascenders and descenders require more leading. Also, the wider the measure of text composition, the more leading is required for good readability" (International Paper, 1997).

Ascenders and descenders are not the only aspect of typeface that dictate differences in leading, "serif type calls for less leading than sans serif type because the serifs reinforce

the horizontal eye flow. Bolder typefaces require more leading than lighter faces" (Rehe, 1990). Typographical researchers Becker et al. (1970), agree that optimal leading is dependent on a variety of design factors, "different typefaces need different amounts of leading."

FDA does provide a "set-rule" for the designers to follow on OTC labels, regardless of typeface or message presentation. The FDA regulation specifies a minimum of 0.5 point leading "to ensure readability" (FDA, 1999). The minimum 0.5 point requirement is less than the 1-point minimum that was specified in the proposed rule (FDA, 1997). This change was made in response to comments that indicated that if graphical features (i.e., type size, leading, kerning, and highlighting) were required (many comments indicated that they should not be), that minimum type size and leading should be reduced to maximize label space.

Research indicates that 0.5 point leading may be problematic. It is likely that the manufacturers of OTC drugs will use the minimum as a "standard" element of design because it will result in smaller labels. However, using the minimum as a standard will not necessarily produce the most legible labels. As mentioned previously, optimal line spacing is dependent on typeface and layout. Even if the impact of typeface and layout is ignored, Ralph's (1982) findings suggest that FDA is not using sufficient leading for elderly consumers. His "Publishing Guidelines for Geriatric Visual Concerns" indicates "no less than two points of leading should be used with smaller than 11 point type" (Ralph, 1982).

Another factor to consider when discussing legibility is color contrast, the color of the text and the background on which it is printed. FDA's regulation does address the

issue of color contrast. "The type must be all black or one dark color, printed on white or other light, neutral color, contrasting background" (FDA, 1999).

FDA's contrast mandate is consistent with the vast majority of research findings. A study conducted at Michigan State University (Lockhart and Bix, 1996) examined the legibility of 6 color combinations: black type on a white background, blue type on a yellow background, white type on a blue background, blue type on a white background, yellow type on a red background and black type on a red background. Black type on a white background proved the easiest combination to read for all age groups tested (six age groups ranged in age from 19 to 81; see Appendix 3 for a more complete review of data). Research conducted by Sorg (1985) concurs that black on white is the easiest combination to read. The work of the Institute of Grocery Distribution (IGD) (1994), Arnold (1972), and Summer (1932) further supports the FDA's use of a light colored background paired with a dark type; Arnold and Summer found dark ink printed on yellow paper to be highly legible, while the IGD supports "dark print on a light background." Bradley et al. (1994) concur that black text on a white or yellow background provides good legibility; they also suggest that these combinations avoid difficulties associated with red/green color blindness so that messages are accessible to a large percentage of the population.

Substrate (paper) color not only is a factor in color contrast, it also affects the color of the text and graphics printed on the package surface. International Paper (1997) advises, "Type is more easily read against a soft (yellowish) white, while process colors reproduce most accurately on neutral white paper." As a result, the optimal printing substrate for a textually oriented design may be quite different than one that is graphically

loaded; in the case of pharmaceutical messages, this would suggest a soft (yellowish) white is optimal.

Substrate smoothness, or surface consistency, also affects message legibility. Smoothness can be the result of calendering, a processing technique where paper is run between a stack of rollers. Papers are frequently classified as "uncalendered, machine calendered, and supercalendered" (International Paper, 1997), depending on the process used during their manufacture. Papers produced using these processes vary greatly in surface consistencies.

Surface treatments, called coatings, also have a significant impact on smoothness. Coated papers were developed in response to the demand for high quality reproduction of photographs.

> "[They] reproduce much finer halftone screens with sharper definition, improved density and greater color fidelity than can be reproduced on uncoated papers. Coated paper finishes range from dull to very glossy, have a greater affinity for printing inks, greater smoothness, higher opacity and better ink hold out than uncoated papers" (International Paper, 1997).

In a recent interview, Tom Michalsen of Web Marking Systems emphasized the importance of using smooth substrates for drug packaging. Michalsen believes that his pharmaceutical customers are his most demanding customers due to the paramount importance of legibility for drug labels, and the small fonts that are common in the drug industry. Because of these stringent requirements, Michalsen indicates extremely smooth substrate surfaces are required for improved ink release for pharmaceutical applications (Mateo, 2000). Ink release refers to the transfer of the inked image area of the plate onto the substrate during the printing process. Smoother surfaces result in a more complete transfer of the ink.

Substrate-ink affinity, like smoothness, substantially impacts ink release, which impacts legibility.

> "If a paper (the substrate) absorbs too much ink (as in newsprint) the images appear weak, desaturated and flat (no gloss). If absorbency is low (as in coated paper) the ink sets near the surface and dries with a reasonable gloss. This is *holdout.* If holdout is too high it can cause *set-off* (transfer to the back of adjacent sheet) in the paper pile" (International Paper, 1997).

Either end of the absorbency spectrum can negatively impact the inked image and, therefore, legibility.

Both the substrate and ink have the ability to affect message legibility. The process by which the package is printed can also have a significant impact. Packages are usually printed using one of three techniques: gravure, flexography or lithography. These three processes differ in the type of plate that transfers the ink to the substrate, the way that the ink is transferred, the type of ink used, and the appearance of the printed image. Within each of the three processes, quality can vary greatly, depending on the skill of the press associates, the speed that is required by the production schedule, the maintenance schedule of the press, the quality of incoming materials and even the climate of the production environment. As a result, like the elements of letter and message design, the manufacturing process is a series of factors that affect the printed image, and therefore, the legibility. There is no mention of either material quality (substrates and inks) or process requirements in the FDA's prescriptive standard for legibility.

It is tempting to believe that legible labels can be guaranteed by mandating certain elements of design; at a glance, the study of textual elements appears simple. After all, visual recordings have been around for 30,000 years (International Paper, 1997). In truth,

even if we exclude the variability introduced by the user and the reading environment, there are still numerous elements that contribute to design efficacy. In order for designers to create accessible designs, they must develop sensitivity to the multitude of design elements that make up letters, words and messages, the manufacturing methods and materials used to produce the package, and the complex relationships between these elements, all of which contribute to legibility.

It may appear reasonable to conclude that sufficient legibility can be obtained by using a certain size and style of type, with sufficient contrast, a minimum leading and limited compression. FDA has handed down a prescription for OTC labels in exactly this fashion. Reality does not match the simplicity of this approach. Legibility is the overall goal in a complex system of interrelated elements (letter weight, letter compression, counter form shape, stress, type style, type size, message layout, leading, kerning, ink, substrate, and printing process); it is not easily prescribed.

A good performance standard for legibility accounts for all of the elements of design and manufacturing and the interactions of these elements while it is measuring what is truly important, the legibility of the label. It allows designers flexibility in design, provides manufacturers with defensible proof of message accessibility, provides consumers with designs that have been tested to be legible and gets FDA out of the business of "micro managing" label design. A performance standard for legibility would better serve industry, regulators and, most importantly, the consumers of OTC drugs.

Materials and Apparatus

This research was divided into four separate studies. Three studies, termed "preliminary studies", were designed to examine the effect of different procedures and instruments on the reproducibility and repeatability of test data. Results from the preliminary studies aided researchers in determining which procedure to use for the 4th study, referred to as the "primary study".

The primary study compared a set of labels that complied with the FDA regulation to a set that did not. Several of the elements of design previously discussed were manipulated in an attempt to create noncompliant labels that were more easily read than four labels that complied with the FDA regulation. All of the noncompliant label designs contained messages that were created in 5.5 point type, type that did not meet the 6 point minimum set by FDA. This is of interest, because many manufacturers have argued that the 6 point minimum does not ensure, or even appreciably improve, legibility over smaller type (CHPA, 1999; NDMA, 1991).

If successful, this research answers the call from industry issued by R. William Soller. Soller, Senior Vice President and Director of Science & Technology at the Consumer Healthcare Products Association, believes there is a need for an objective method to measure legibility and argues against the 6 point minimum set by FDA.

> ".....[there is a] notable lack of convincing objective support that 6 point type adds an advantage in legibility over smaller types sizes down to and including 5.0 point type... These are important observations, and it is important to find ways to address them" (CHPA, 1999).

Not only does this research provide Dr. Soller with objective evidence, it demonstrates the ability of the Lockhart Legibility Instrument (LLI) to account for the effect of

multiple elements on legibility in a single test, and also provides insight into the complex interactions of the elements of design.

The Lockhart Legibility Instruments (LLIs):

Legibility of printed material can be measured objectively, using instruments and a test protocol being developed at the Michigan State University (MSU) School of Packaging. Instruments referred to as "Lockhart Legibility Instruments" (LLIs) quantify the legibility of textual messages with a single test. Legibility is measured in terms of the degrees of rotation of an analyzing filter. The degrees of rotation is referred to as the "Legibility Index"; the higher the Legibility Index value, the more difficult it is for a subject to read the message being tested.

The LLI has evolved since its creation in the 1960s. Initially, the concept was developed as a way to measure label impact (step one in Rousseau's 1998 model, termed notice); it was primarily used as a marketing device. Dr. Hugh Lockhart, a professor at Michigan State University's School of Packaging, recognized that the instrument was not fulfilling its potential and began using it as a way to measure legibility.

The LLI is essentially a large box with two light sources inside. Printed items to be tested are placed inside the box on an easel (see Figure 18). Two 25-watt incandescent floodlights illuminate the test material. Power to the floodlights, and, ultimately, the light level inside the LLI, is controlled by a rheostat. Once the light level inside the instrument has been adjusted, subjects are asked to look through a viewing screen that is located at the front of the instrument and adjust a handle to their right until the first point that they can easily read the printed message without straining their eyes.

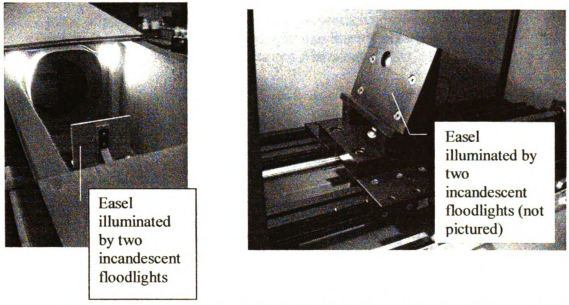


FIGURE 18-LOCKHART LEGIBILITY INSTRUMENT EASELS (Older LLI, built in 1993, is on the left. New model, built in 1999, is pictured on the right.)

The viewing screen that the subject looks through is made of a pair of polarizing filters. Subjects begin by rotating a handle on their right; as they rotate the handle, the first filter inside the viewing screen also rotates. Rotation of the first filter controls the amount of light that reaches the test subject's eyes. Messages that are difficult to read require more light; therefore, difficult messages require the subject to rotate the filter further, resulting in high legibility indexes.

The filters are Polaroid HN22 Linear Polarizing Filters that are 0.030 inches thick. James Pietrowski (1993) indicated that he chose the HN22 filters because they had a uniform level of light transmission through the portion of the spectrum to which the eye responds, 440-750 nm wavelength. The unique properties of Polaroid lend themselves to application within the viewing screen of the LLI.

> "Polaroid represents a class of materials that absorbs light oscillations in one direction but not the component oriented at right angles. These

materials often contain long particles, rods or plates, aligned parallel to each other in a regular arrangement. These aligned particles transmit one plane of polarized light and absorb the perpendicular one..... The Polarizer can transform circularly polarized light into linearly polarized light" [see Figure 19] (Department of Physics and Astronomy, ASU, 1999).

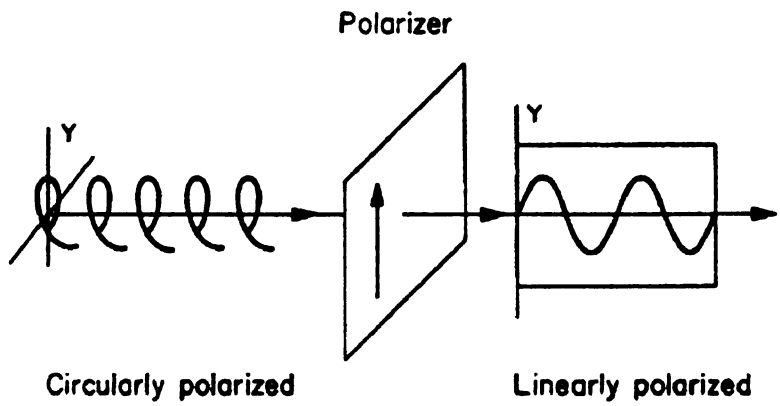


FIGURE 19- CIRCULARLY POLARIZED LIGHT BECOMES LINEARLY POLARIZED AFTER BEING PASSED THROUGH A SINGLE POLARIZING FILTER (Department of Physics and Astronomy, ASU, 1999)

Unlike Figure 19, the LLI uses a pair of filters (see Figures 20 and 21). The filter closest to the subject is referred to as the analyzer. Subjects rotate the analyzer as they adjust a handle to their right. A second filter, placed directly behind the analyzer, is referred to as the polarizer. The polarizer is fixed in place; it does not move as the subject adjusts the handle.

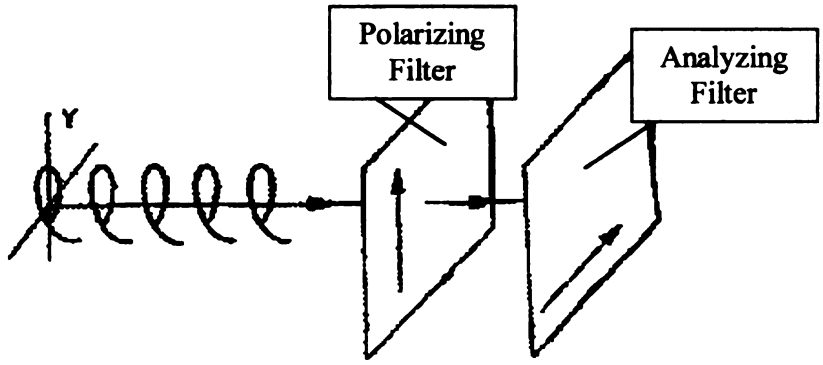


FIGURE 20-POLARIZER AND ANALYZER- AXES CROSSED (0° of rotation)

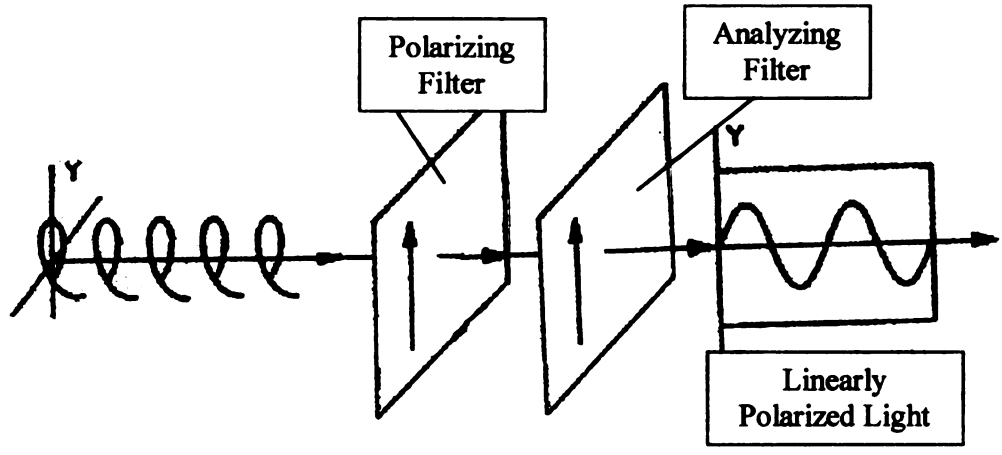


FIGURE 21- POLARIZER AND ANALYZER- AXES PARALLEL (90° of rotation)

Subjects begin at 0° of rotation; the handle to the subject's right is turned clockwise until it comes to a physical stop. At 0° of rotation the axes of the filters are crossed (see Figure 20); when the axes are crossed the analyzer will absorb all the light transmitted by the polarizer. As a result, when testing begins, the viewing screen is black. Subjects are asked to rotate the handle using a counterclockwise motion until the first point that they can easily read the text without straining their eyes. This action

rotates the analyzer (relative to the polarizer) to a maximum of 90°. At 90° the two filters have their orientation axes aligned parallel to each other. The first filter, the polarizer, transmits linearly polarized light (see Figure 19). This linearly polarized light is then transmitted, without absorption, through the second filter, the analyzer (Department of Physics and Astronomy, ASU, 1999). The more difficult the text is for the subject to see, the more light they require. For more light, subjects have to rotate the analyzer further. This results in a higher Legibility Index value for items that are difficult to read.

Two LLIs were used in the research presented here; one was constructed in 1993 and a second was created in 1999. James Pietrowski (1993), a graduate student, developed the older instrument (see Figure 22). Coefficients of variation are large for this instrument, typically ranging from 30-50%. In an attempt to try to reduce the variability of data, Dr. Hugh Lockhart directed the production of a second instrument in 1999 (see Figure 23).

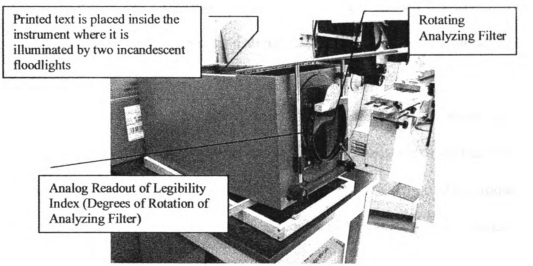


FIGURE 22- THE 1993 LOCKHART LEGIBILITY INSTRUMENT (LLI), BUILT BY JAMES PIETROWSKI
(Preliminary study #3, which investigated the variability of data collected by each of the two LLIs was the only study that used the older instrument)

The 1999 model features several improvements over Pietrowski's model. Many of the improvements were added in an attempt to reduce variability. A light meter is now contained in the easel, allowing researchers more precise control of the intensity of light illuminating the test material. Digital readout of the degrees of filter rotation has replaced an analog system; the digital readout has a sensitivity of 0.1 degrees of rotation, as compared with 1 degree of rotation for the analog. The viewing area has been reduced in size, and a shielded view port has been added in an attempt to block distracting reflections and ambient light. The view port was created using a pair of oxyacetylene welder goggles with the lenses removed.

Another new feature of the 1999 model is the adjustable easel. The new LLI was built so that subjects are able to manipulate the distance that they use to view the test material. The easel inside the new model is mounted to a track (see Figure 18). Subjects can move the easel along the track by adjusting a hand crank at the front of the instrument (see Figure 23). This enables subjects to alter the viewing distance, allowing them to adjust to their "natural" reading distance rather than reading test material from a distance chosen by researchers.

It was hypothesized that the new features of the 1999 instrument, which allow more precise control, would result in smaller coefficients of variation of measurements. Preliminary study 3, one of three studies that examined the variability of data produced by LLIs, tested this hypothesis. The Procedures and Results Chapters of this document detail the experiment and findings, respectively.

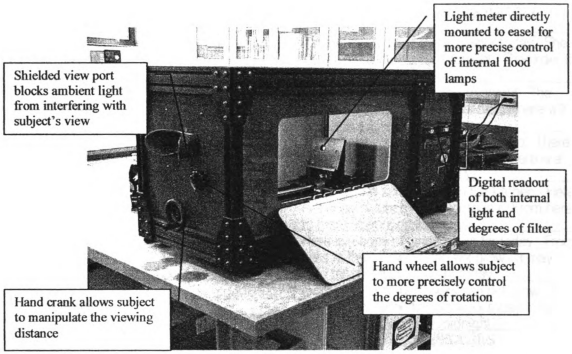


FIGURE 23-THE 1999 LLI, BUILT BY SYCAMORE TECHNICAL SERVICES

Legibility Cards (Preliminary Studies Only):

All three preliminary studies used six cards printed in a single font, 10 point Helvetica Light. Label designs were created using Microsoft Word and were printed using a Hewlett Packard 722 Ink Jet printer. Each card contained a different message (see Table 1). Messages were shown in previous studies to have a statistically marginal (Bix, 1998) or insignificant effect (Lockhart and Bix, 1996) at α=0.05. Cards were labeled one through six so that they could be easily identified (see Table 1).

After messages were printed, they were mounted onto 3" x 4" cards, with a message centered horizontally on each. All messages were printed using a black on white contrast. Black on white was chosen because it provides a high degree of contrast, is generally recognized as highly legible (Lockhart and Bix, 1996; Sorg, 1985; Paterson and Tinker, 1935) and does not pose problems for people with color vision deficiencies.

Font Size	Message #	Font	Message- As it appeared on the card
10 points	1	Helvetica Light	It may help most of them to work today. She works in this club after midnight. The order to gowill be done after two.
10 points	2	Helvetica Light	She works in this club after midnight. The order to go will be done after two. There will be some sugar in the kitchen.
10 points	3	Helvetica Light	The order to go will be done after two. There will be some sugar in the kitchen. Here is a copy of lunch hours for today.
10 points	4	Helvetica Light	There will be some sugar in the kitchen. Here is a copy of lunch hours for today. From here to there flowers cannot grow.
10 points	5	Helvetica Light	Here is a copy of lunch hours for today. From here to there flowers can not grow. It may help most of them to work today.
10 points	6	Helvetica Light	From here to there flowers can not grow. It may help most of them to work today. She works in this club after midnight.

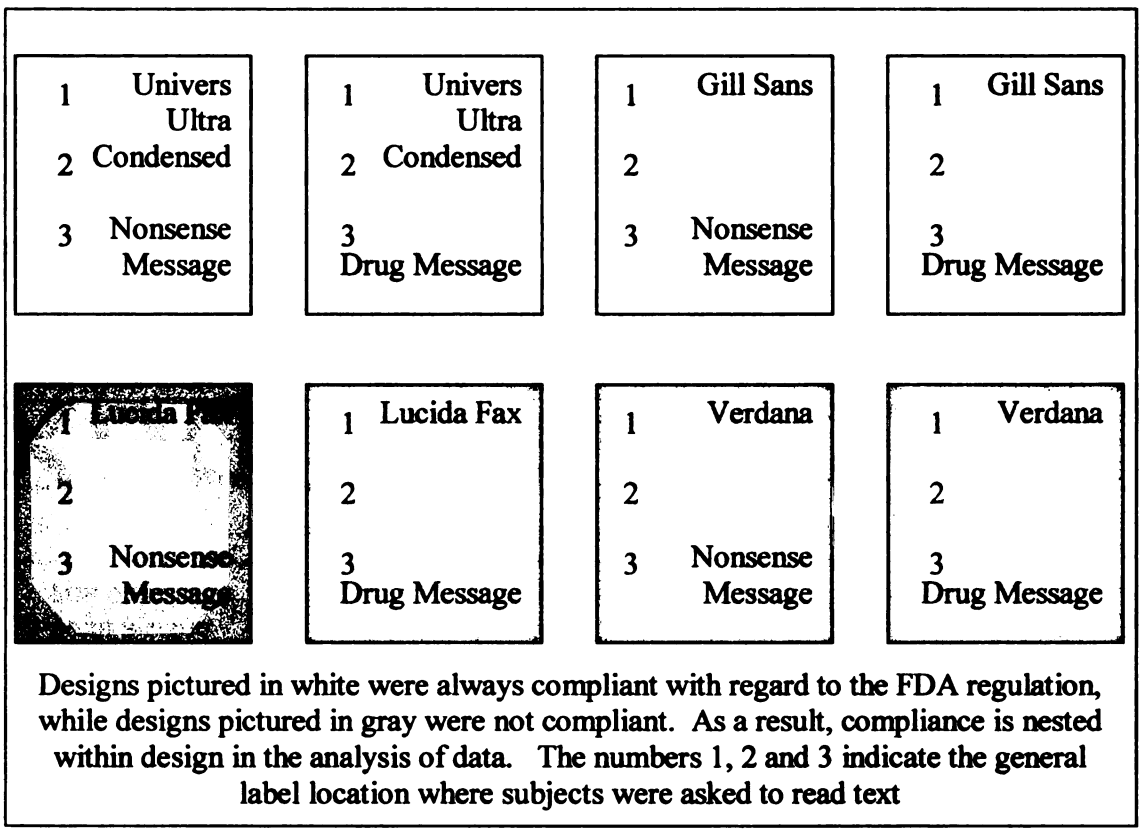
TABLE 1-PRELIMINARY STUDY LABEL MESSAGES

Labels (Primary Study Only):

The primary study used eight labels created using Adobe Illustrator 9.0 (see Appendix 4 for a complete set of labels). Label factors included design, compliance and message. Design contained four levels: Univers Ultra Condensed in 9.0 points, Gill Sans in 6.0 points, Lucida Fax in 5.5 points and Verdana in 5.5 points. Design was nested within compliance; the Univers Ultra Condensed and the Gill Sans labels were always compliant with the FDA regulation, while the Lucida Fax and Verdana designs were always noncompliant (see Figure 24). Compliance indicates that labels complied with the FDA's regulation; noncompliance indicates that labels violated the regulation. The body text of noncompliant labels was only 5.5 points. They did not meet the 6-point minimum prescribed by FDA.

Two levels of message, "drug" and "nonsense", were used to test for an effect of familiarity with message (see Appendix 4 for specific messages). It was hypothesized

that the drug labels would require fewer degrees of rotation than their nonsense counterparts because subjects would be familiar with their contents. The wording for the drug label message was taken from a sample label published in the final rule (FDA, 1999). This message was then converted into the "nonsense" message by replacing each word with a random word of equal length. For example, the word "drug" may have been replaced with the word "golf".



Designs pictured in white were always compliant with regard to the FDA regulation, while designs pictured in gray were not compliant. As a result, compliance is nested within design in the analysis of data. The numbers 1, 2 and 3 indicate the general label location where subjects were asked to read text

FIGURE 24- FACTORS OF LABEL DESIGN

As mentioned previously, several elements of design were manipulated in an attempt to create noncompliant labels that were at least as easily read as labels that complied with the FDA regulation (see Appendices 5 and 6 for designs that were not

used in the study). The major element of design that determined which labels were used in the study was x-height (see Appendix 4 for Primary Study Labels).

Gill Sans was used to create one of the two compliant label designs. Gill Sans is, as FDA recommends, a sans serif typeface. It was chosen because it is firmly within the guidelines set by FDA but has a small x-height for a sans serif font (see Figure 25). By contrast, Verdana, one of the two noncompliant designs, has a much larger x-height (see Figure 25), providing a more open counter form at small sizes and giving the reader a better visual impression of letter size. This is also true of the other noncompliant design, Lucida Fax. Lucida Fax was chosen not only for this reason, but also because it runs contrary to FDA's recommendation of sans serif typefaces. It does contain serifs, but unlike many serif fonts, has a large x-height (see Figure 25).

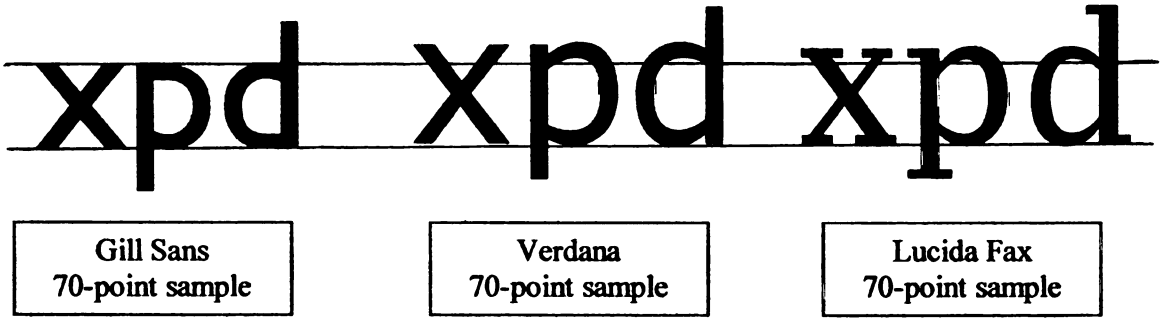


FIGURE 25- COMPARING THE X-HEIGHTS OF GILL SANS, VERDANA AND LUCIDA FAX TYPEFACES (UNIVERS ULTRA CONDENSED IS NOT PICTURED)

Although the other compliant typeface, Univers Ultra Condensed (UUC), does have a fairly large x-height, it also has a large amount of letter compression (see Appendix 4). This letter compression makes it a difficult font to read, despite the fact that it has a fairly large x-height, illustrating the point that the elements of design cannot

be considered, or dictated, in isolation. Letter compression is so pronounced in this typeface that at 6 points (the minimum required), it is noncompliant because it is over the requirement of a maximum of 39 characters per inch. In designing the labels presented in this study, the size of the UUC font was increased until the message averaged below the 39 characters per inch required by FDA. At 9 points the average count of characters per inch was 33 when ten randomly selected spots on the Univers labels were counted.

Although we have termed UUC as compliant with regard to the March 17, 1999 regulation, it could be argued that it is not. While the agency does not specify typeface, they do indicate that the typeface should be any "single, clear, easy-to-read, typestyle" (FDA, 1999). It could be argued that Univers Ultra Condensed is not clear or easy-to-read. This is part of the difficulty with the new regulation; it is prescriptive, but asks designers to make judgments with regard to typeface legibility.

Dow Corning Ophthalmics Card (All Studies)

Prior to testing, the visual acuity of each subject was measured using the Dow Corning Ophthalmics near point visual acuity card (see Figure 26). The instructions on the card state that subjects are to hold the card "16 inches from their eyes in 'good light'" (Dow Corning, 1981). Subjects were instructed to wear their prescribed lenses, such as bifocals or reading glasses, while their near vision was tested.

Visual acuity measurements from the Dow Corning Ophthalmics near point visual acuity card utilize a standard format for acuity results that was developed by Snellen. "Visual acuity is recorded as a fraction. The numerator indicates the distance (in feet) from the chart, which the subject can read the line [20 feet is always used]. The denominator indicates the distance at which a normal eye can read the [same] line" (Loyola Medical Education Network, 2001). In other words, scores of 20/20, 20/40,

20/200, etc., indicate that the subject being tested at 20 feet can just discriminate letters that a person with normal vision, the average person, can see at 20 feet, 40 feet, 200 feet and so forth (Kelly, 1993).

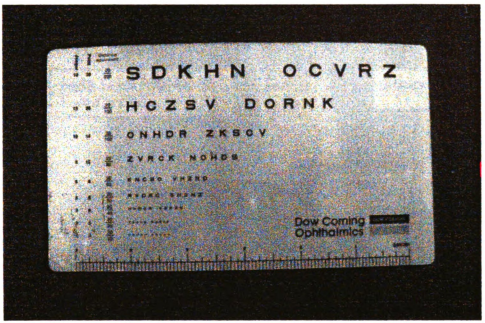


FIGURE 26- DOW CORNING OPHTHALMICS NEAR POINT VISUAL ACUITY CARD (Card is reduced from actual size)

A.W. Sperry Light Meter, Model SLM-110 (All Studies)

A light meter (See Figure 27), manufactured by A.W. Sperry, was used in two ways. In all studies, the light meter was used to record the ambient light at the time of testing. It was also used to measure and control the intensity of light inside the older instrument; preliminary study #3 was the only study that utilized this instrument. To measure the light level inside the 1993 instrument, the sensor was placed on the lower easel and the lid was closed. The light inside the LLI was adjusted using a rheostat until the light meter reached a level of 25 foot-candles ± one foot-candle. Because the new

LLI has a sensor that is built into its easel, it was not necessary to use the Sperry Light meter to ensure the proper illumination levels inside the new instrument.

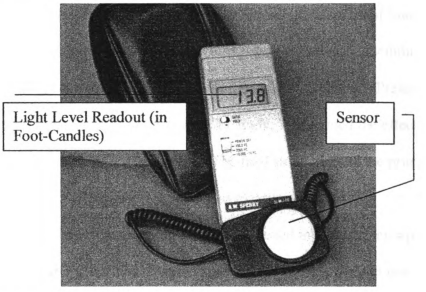


FIGURE 27- A.W. SPERRY LIGHT METER AND SENSOR

Procedures

As mentioned previously, this research was divided into a series of four experiments. Preliminary studies one and two were repeatability/reproducibility studies that tested for an effect of procedure on the variability of data collected. Preliminary study three was also a repeatability/reproducibility study; it examined the effect of instrument on the variability of data collected. The final study, termed the primary study, examined several effects of design on legibility, as measured by the LLI.

The procedures of each experiment will be presented in this chapter separately so that readers can develop a clear idea of each experimental design. Subject orientation and the collection of subject-related information, which was the same for all experiments, is presented below.

Subject Orientation

Prior to testing, the level of ambient light was measured by placing the sensor of the A.W. Sperry light meter on the table to the right of the LLI, facing the ceiling. The ambient lighting conditions were recorded prior to testing, but could not be adjusted. All testing was conducted at the School of Packaging under florescent lights during daylight hours in an attempt to maintain consistency.

Before data was collected, subjects were provided with a brief one-on-one orientation with the researcher. The researcher explained,

> "This is an instrument that quantifies how easy or difficult a label is to read. It does this by measuring the amount of light a subject requires to read a given message. The harder a message is to read, the more light is required; the easier it is to read, the less light is required. If you choose to participate in this study you will be asked to fill out some information regarding your education, eyewear and age. This information will be anonymous; your name will not be recorded on any documents. Your

visual acuity will be measured and recorded. You will be asked to read a series of labels that are placed inside the instrument. If you normally use corrective eyewear to read you should use it for this experiment. You will read the labels by looking into the viewing field on the instrument. As you look through the viewing field rotate the handle to your right counter-clockwise until the first point where you are able to easily read all of the words you are directed to read without straining your eyes. Testing will not take any longer than 25 minutes. It is important to remember that this is a test of the printed labels and not of your eyes. There is no need to worry about how your results compare with the results of other test subjects. We are concerned about how the labels compare to one another."

In order to protect the test subjects' rights, subjects were asked to review and sign a written consent form (IRB # 01-292; expiration May 15, 2002). Subjects signed the consent form, signifying either acceptance or rejection of the invitation to participate, before testing began (see Appendix 7 for written consent form).

Collection of Subject-Related Information

After the subject signed the consent form, a data-recording sheet was used to record subject-related information, which included: gender, educational background and age group (see Appendix 8 for the Primary Study's recording sheet, Appendix 9 for the recording sheet used in preliminary study one and two, and Appendix 10 for the recording sheet used in Preliminary Study 3). These sheets were also used to identify the order in which the subjects participated. The sequential order of testing was recorded as "subject number"; in other words, the first subject in each study was labeled subject one, the second subject two, etc.

After demographic information (gender, educational background and age group) and subject number were recorded, subjects were given the Dow Corning Ophthalmics Near Point Visual Acuity card (see Figure 26). While seated in front of the LLI, they were asked to hold the card approximately 16 inches in front of them and read the

smallest print that they could read. The researcher aided subjects with the 16-inch span by marking the distance with a measuring tape. Each subject's Snellen visual acuity was recorded on the appropriate data-recording sheet (See Appendices 8-10). Data was collected from all subjects willing to participate in the study; however, only the results of subjects with measured visual acuities of 20/30 or better were used in the data analysis.

In a previous study (Bix et al., 1997), an analysis of residuals revealed that initial readings tended to be higher than readings that followed. This suggested that subjects go through an adjustment period as they get used to using the LLI. As a result of this information, it was decided that two "dummy cards" would be used before any data was recorded. Subjects read the dummy cards in the same manner that they did the test material, but these readings were not recorded or analyzed, allowing subjects to adjust to the instrument without affecting test results. Two dummy readings were taken before testing, and any time that the distance between the subject and the message was changed during testing. Dummy cards were used in all studies presented in this document.

Preliminary Study One

In preliminary study one, the easel was positioned at the front of the instrument (see Figures 18 and 23); subjects were asked to adjust its distance until it was at the most comfortable reading distance for them. They viewed two dummy cards and each of the six messages (see Table 1) twice, for a total of 12 recorded readings (dummy cards were not recorded) from the distance that they chose. Data was also collected from a fixed distance of approximately 18.5". From this distance, subjects read a set of two dummy cards and each of the six messages twice, for a total of 12 recorded readings from a fixed distance of 18.5". To counteract any effect of learning as subjects became familiar with

the messages, the procedure alternated between subjects; if subject one began the study by adjusting the distance of the easel to the distance of their choosing, then subject two began from a fixed distance, etc. (see Figure 28 for a graphical description of the procedure).

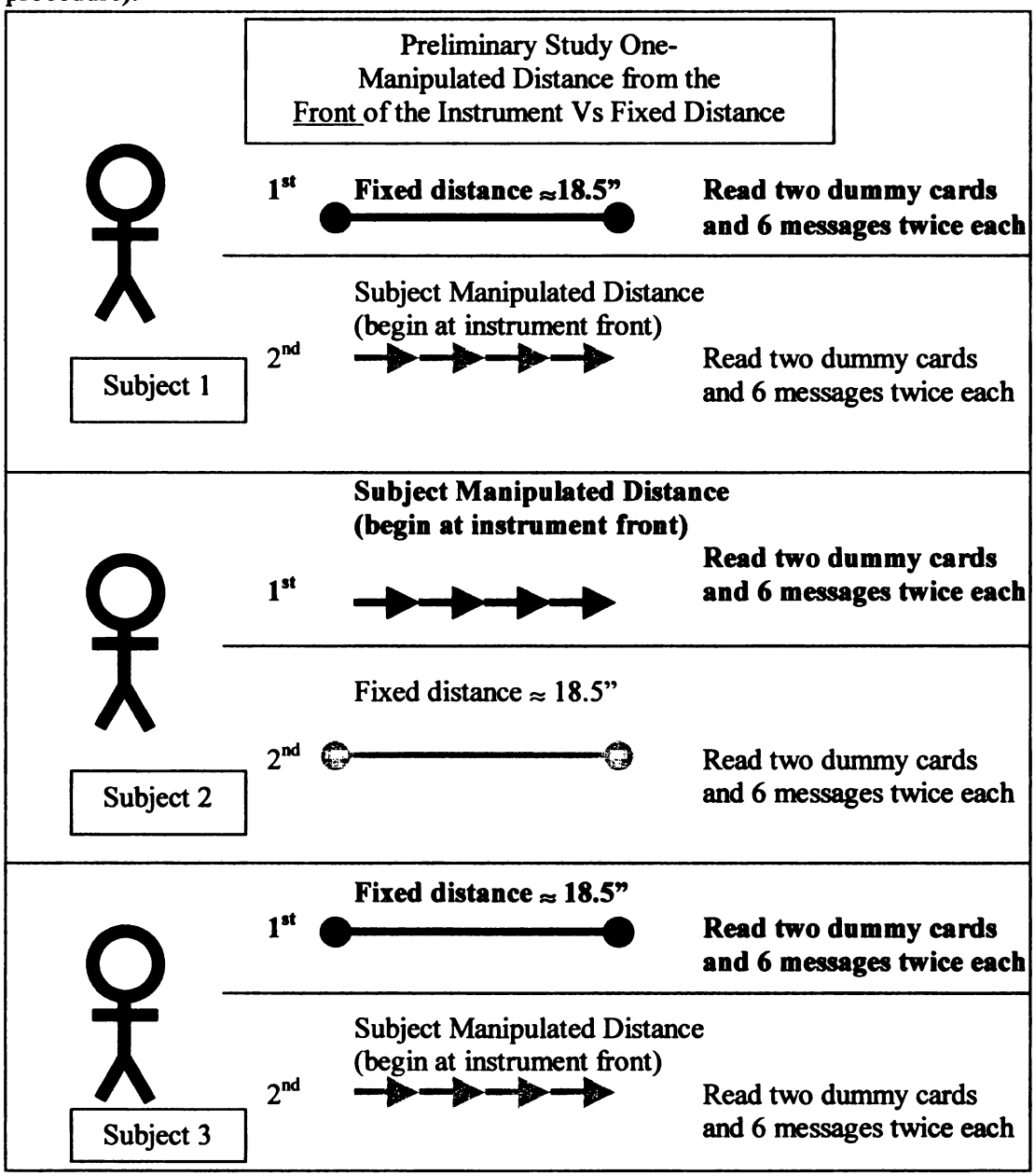


FIGURE 28-GRAPHICAL INTERPRETATION OF THE PROCEDURE USED FOR PRELIMINARY STUDY ONE

Subject Demographics: Preliminary Study One

Ten people were tested using the aforementioned procedure to examine whether allowing subjects to choose their own viewing distance created less variable data than imposing a fixed distance. Of the 10 subjects, seven were between the ages of 19-28 and three were between the ages of 29-38.

Visual acuity, another factor that was statistically examined, also varied within the subject population. Seven of the ten subjects had visual acuities of 20/20; three had measured visual acuities of 20/30. Two of the three 20/30 acuities were in the younger age group so that acuity was not confounded with age in the analysis.

The gender and educational level of each subject were recorded, but not used in the statistical analysis. Of the ten people tested, six were female and four were male. Six were enrolled in a doctoral program, one was completing a master's degree, two were undergraduate students and one had completed high school.

Preliminary Study Two

In preliminary study two, the easel was positioned at the back of the instrument (see Figures 18 and 23) and subjects were asked to adjust its distance until it was at the most comfortable reading distance for them. Please note the change in the beginning position of the easel, which makes this study different from preliminary study one. As in preliminary study one, each subject viewed six messages (see Table 1) twice from the distance they chose and twice from a fixed distance of approximately 18.5", for a total of 24 readings; dummy readings were performed, but not recorded. Again, the procedure alternated between subjects to counteract any effect of learning that occurred as subjects

became familiar with the test cards (see Figure 29 for a graphical representation of the procedure).

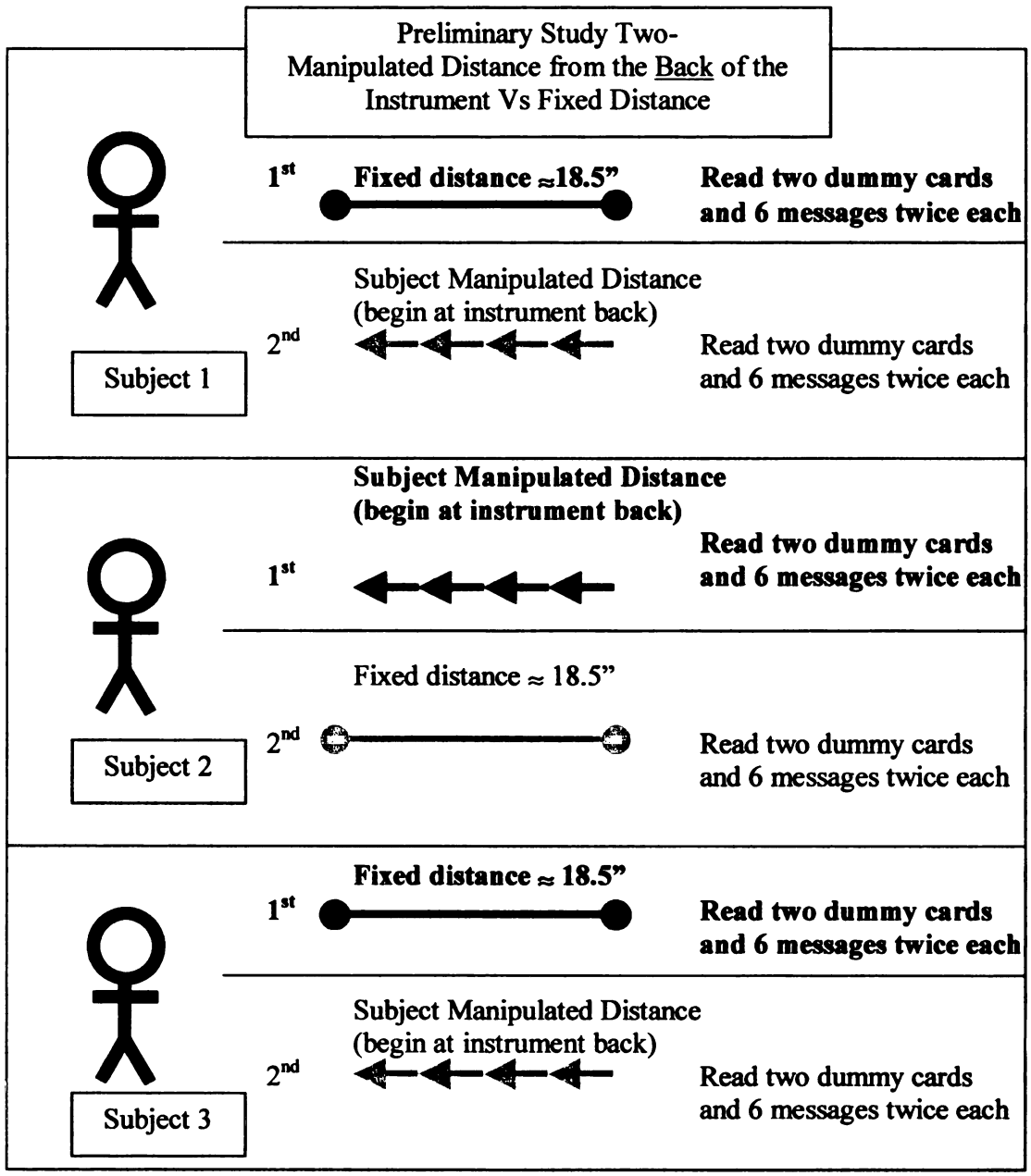


FIGURE 29-GRAPHICAL INTERPRETATION OF THE PROCEDURE USED FOR PRELIMINARY STUDY TWO

Subject Demographics: Preliminary Study Two

Ten people were tested using the aforementioned procedure to examine whether allowing subjects to choose their own viewing distance created less variable data than imposing a fixed distance. Of the 10 subjects, five were between the ages of 19-28 and five were between the ages of 29-38. Eight of the ten subjects tested had visual acuities of 20/20. Two had measured visual acuities of 20/30. Both subjects that had visual acuities measured to be 20/30 were from the youngest age group.

Gender and educational level were recorded, but not used in the statistical analysis of the data. Seven of the ten tested were female; three were male. Seven subjects had begun working on doctoral degrees, one was working toward a master's degree and two were pursuing undergraduate degrees.

Preliminary Study Three

Preliminary study three compared the variability of data collected using the older instrument (see Figure 22) with the variability of data collected with the new instrument (see Figure 23). It was hypothesized that many of the features of the new model, which were discussed in the Materials and Apparatus Chapter of this document, would decrease the variability of data.

In preliminary study three, distance was permanently fixed at approximately 17.5" and the light level was set to 25 ± 1 foot candles for both instruments. Ten subjects used the 1993 model (see Materials and Apparatus Chapter) to view two dummy cards and each of the six messages (see Table 1) twice, for a total of 12 recorded readings from the older instrument. Subjects also read two dummy cards and each of the six messages twice using the 1999 model. There were a total of 12 recorded readings using the newer instrument. To counteract any effect of learning as subjects repeatedly read the cards,

each subject began testing with a different instrument than the previous subject. That is, if subject one began the study by using the 1999 model (see Materials and Apparatus Chapter), then subject two began testing using Pietrowski's 1993 model (see Figure 28 for a graphical description of the procedure).

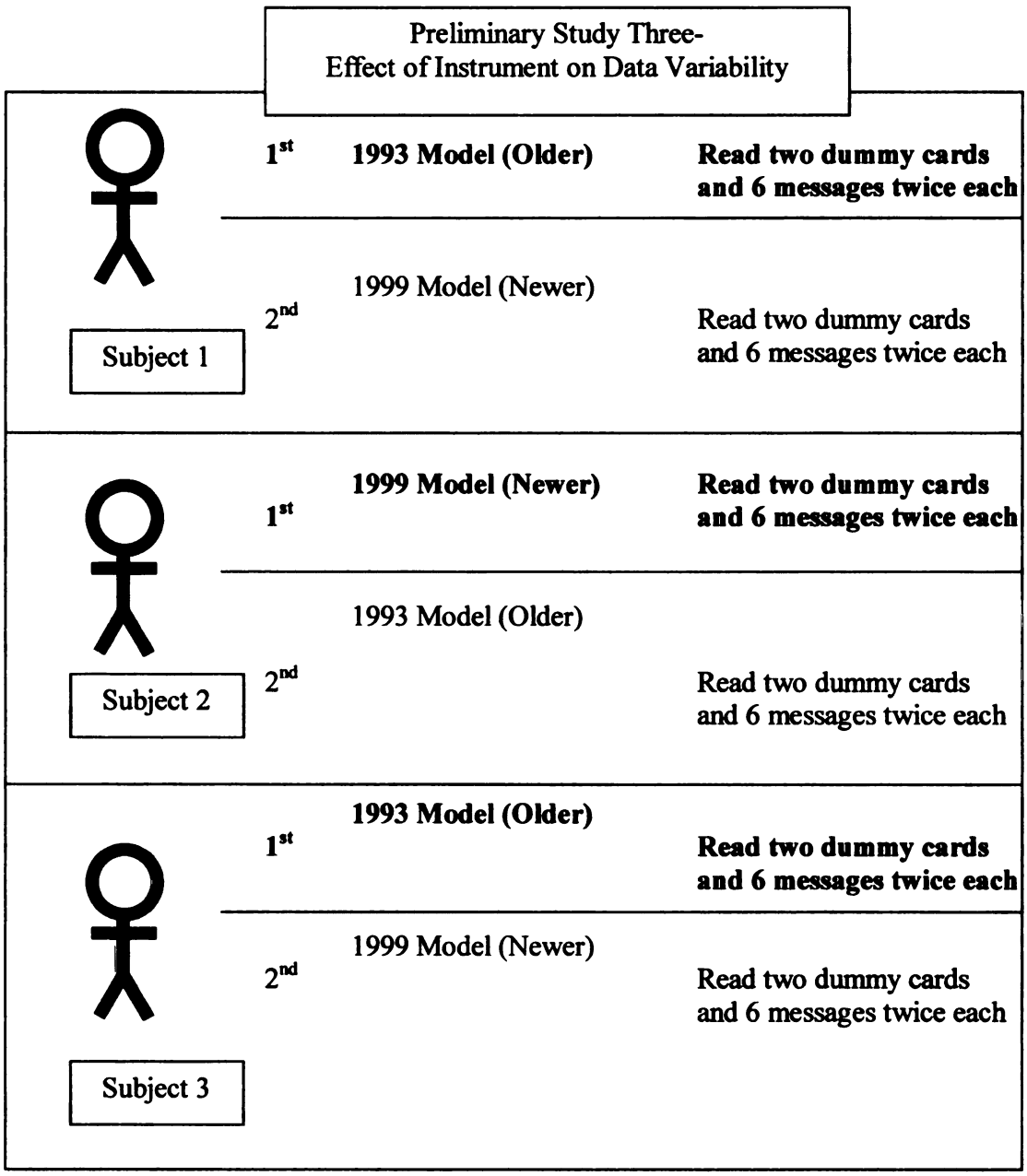


FIGURE 30-GRAPHICAL INTERPRETATION OF THE PROCEDURE USED FOR PRELIMINARY STUDY THREE

Subject Demographics: Preliminary Study Three

Ten people were tested using the aforementioned procedure to compare the variability of data collected using the older instrument to that collected with the newer model . Of the 10 subjects, nine were between the ages of 19-28 and one was between 29-38. Eight of the ten subjects tested had visual acuities of 20/20. Two had measured visual acuities of 20/30. Both subjects that had visual acuities measured to be 20/30 were from the younger age group.

Gender and educational level were recorded, but not used in the statistical analysis of the data. Six of the ten tested were male; four were female. Seven subjects had begun working on master's degrees and three were pursuing doctoral degrees.

Primary Study

In the primary study, fifty subjects read eight labels at the top, middle, and bottom of the label to test two hypotheses: (1) A noncompliant label can be created that is at least as legible as one that complies with the FDA regulation; (2) Labels that contain a familiar message (a drug label) will require fewer degrees of rotation than a message that is unfamiliar to subjects (a nonsense label).

After the ambient light level had been recorded, and signed consent had been obtained (see Appendix 7), subjects were asked to read eight labels (see Appendix 4) using the new LLI (see Figure 23). Label factors included: design (4 levels), compliance (2 levels), and message (2 levels) (see Figure 24). An additional factor, position (3 levels), was tested in the ANOVA; subjects read all labels at the top, the middle and the bottom position. Due to requirements of the statistical program (SAS), different levels within each factor were assigned numbers (see Table 2). For example, labels created using Univers Ultra Condensed were considered design level one, Gill Sans labels were

design level two, Lucida Fax labels were called level three and all Verdana designs were referred to as level 4. Labels were assigned a number, one through eight, so that the researcher could easily and quickly identify the combination of factors and levels that made up each label (see Table 2).

Label #	Font (Level # in Analysis)	Message (Level # in Analysis)	Compliance? (Level # in Analysis)
1	9 point Univers Ultra Condensed (1)	Nonsense (1)	Compliant (1)
2	6 point Gill Sans (2)	Drug (2)	Compliant (1)
3	6 point Gill Sans (2)	Nonsense (1)	Compliant (1)
4	5.5 point Lucida Fax (3)	Nonsense (1)	Noncompliant (2)
5	5.5 point Verdana (4)	Drug (2)	Noncompliant (2)
6	9 point Univers Ultra Condensed (1)	Drug (2)	Compliant (1)
7	5.5 point Lucida Fax (3)	Drug (2)	Noncompliant (2)
8	5.5 point Verdana (4)	Nonsense (1)	Noncompliant (2)

TABLE 2- FACTORS AND LEVELS OF PRIMARY STUDY LABELS

Before testing began, the researcher positioned the easel so that it was at the front of the instrument, and placed one of the two dummy cards on it. With the analyzer at 0° of rotation (total darkness), the light level inside the machine was adjusted to 25 foot candles $\pm$ 1. Once the light level had been adjusted, the researcher rotated the analyzing filter to a total of 90° of rotation (total light). Subjects were then instructed,

> "Look through the viewfinder. You should see an easel holding a card. Turn the hand crank in the center of the machine (see Figure 23). This will adjust the distance between you and the card. Make the adjustment until the card is at the most comfortable reading distance for you. You will probably be able to read the card from any distance, but choose the distance that is most comfortable for your eyes, just like you might adjust the distance of a book for comfortable reading."

The light level inside the LLI was adjusted as subjects moved the easel in an attempt to maintain a constant level of 25 foot candles falling on the surface of the easel.

After the easel distance had been adjusted, and the subject had completed two readings using the dummy cards, data collection began. As mentioned, 50 subjects read each label (see Appendix 4) in three different places (a line near the top, the middle and the bottom of the label). The labels were randomly grouped and then assigned the numbers one through eight (see Table 2). Subject one read the message on labels one through eight first at the top, position one. The same subject then read labels one through eight a second time, but this time at the label's middle, position two. For the third and final reading, subject one again read labels one through eight, but this time they were asked to read the label at the bottom, position three. For subject two a single label was rotated to the bottom of the pile (label one was placed behind label eight). As a result, subject two read labels two through eight followed by label one. Additionally, subject two began the test by reading the message in the middle of the label, position two, first. Subject two read the labels a second time, again labels two through eight followed by one, but this time they read the message at the bottom of the label, position three. Subject two finished testing by again reading labels two through eight followed by label one, but this time read the top position of the label, position one. This rotation of label and position continued throughout the testing for all 50 subjects.

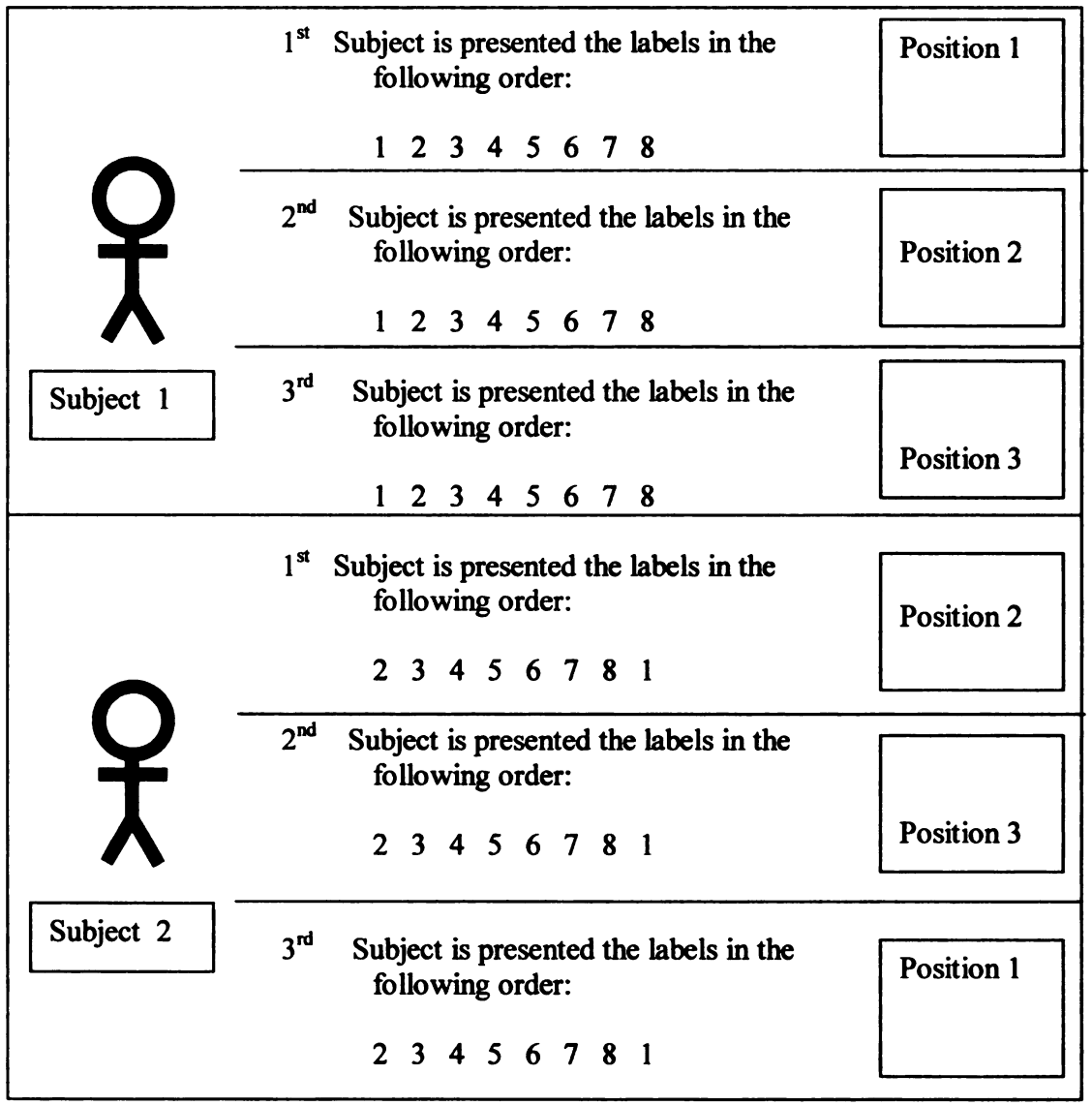


FIGURE 31-GRAPHICAL INTERPRETATION OF THE PROCEDURE USED FOR THE PRIMARY STUDY

Subject Demographics: Primary Study

Fifty subjects tested for the primary study were included in the analysis. Subjects with measured visual acuities lower than 20/30 were tested, but their results were not used in the statistical analysis of the data. Subjects tested who were older than 48 were also eliminated from the analysis. This data was eliminated because previous studies

have shown that variability of data collected using the LLI increases with increasing age (Bix, 1998) and decreasing visual acuity. Since there is potential to use this instrument as part of a performance standard for legibility, keeping variation to a minimum is paramount.

Originally, it was proposed that only subjects age 19-28 would be used for this study. However, it proved difficult to find 50 qualified subjects within this age range who were willing to participate. As a result, two more age groups (29-38 and 39-48) were included in the analysis. It is important to note that the number of subjects in the two older age groups is relatively small, and that in the analysis there was no significant difference attributable to age group. Thirty-five subjects were 19-28; twelve subjects were between the ages of 29-38 and three were 39-48. Of the 50 subjects that were included in the analysis, thirty-eight had a measured visual acuity of 20/20 or better and twelve were measured to be 20/30.

The educational level and gender of subjects were also recorded, but these were not used in the analysis of data. Of the 50, thirty-four were male and sixteen were female; twenty-four subjects were currently pursuing undergraduate degrees, 17 master's degrees and nine doctoral degrees.

Results

Preliminary Studies One and Two:

Figures 32 and 33 summarize the coefficients of variation for the data collected during preliminary studies one and two, respectively. Coefficients of variation are presented because the first two preliminary studies were concerned with the effect of procedure on the variability of data.

Preliminary study one used a group of 10 people to compare the variability that resulted when researchers fixed the reading distance at 18.5" to the variability that resulted when subjects adjusted the easel to the most comfortable position for them. In preliminary study one, subjects began manipulating the easel distance from the front of the instrument. Preliminary study two used a second group of 10 people to compare the variability that resulted when researchers fixed the reading distance at 18.5" to the variability that resulted when subjects adjusted the easel to the most comfortable position for them, with distance adjusted from the back of the instrument.

Results were tested for statistical significance using a mixed model Analysis of Variance (ANOVA).

$$\text{Response} = \mu + \text{Distance} + \text{Study} + \text{Message} + \text{Subject (Study)} + \text{Visual Acuity} + \text{Distance*Subject (Study)} + \text{Residual}$$

Subject, an effect that was nested within study, and residual were considered random effects. All remaining effects were treated as fixed effects. Using this approach, it was determined that the variability of the results produced by the 10 people from study one differed significantly from the variability of the results obtained from the 10 people tested in study two. An analysis of the residuals shows these differences graphically (see Figure

34). Subjects in preliminary study two produced data that was significantly more variable than subjects who participated in preliminary study one. This difference is also evident in the coefficients of variation (see Figures 32, 33 and 35).

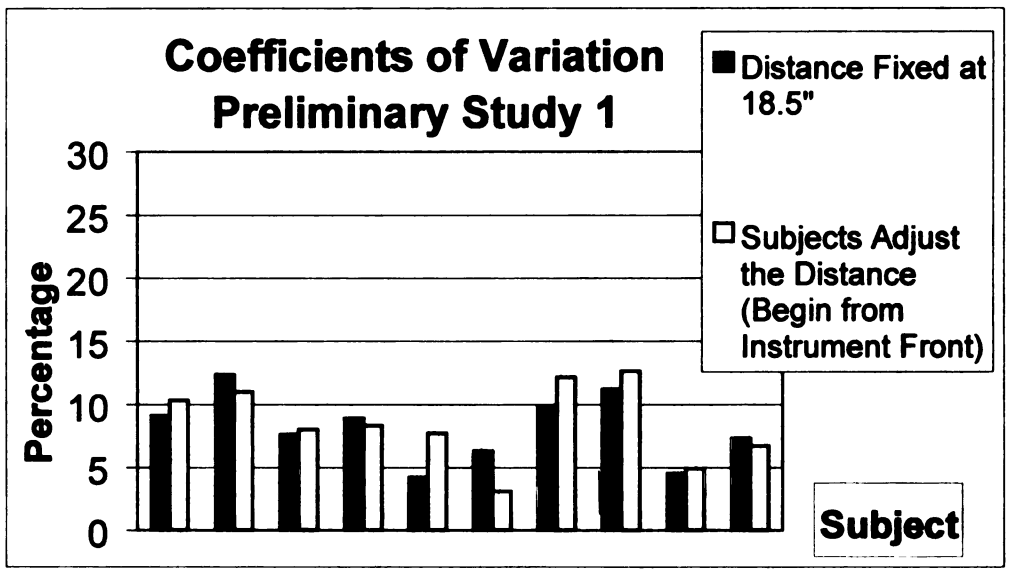


FIGURE 32- COEFFICIENTS OF VARIATION FOR PRELIMINARY STUDY ONE BY SUBJECT (Subjects begin adjusting distance from the front of the instrument)

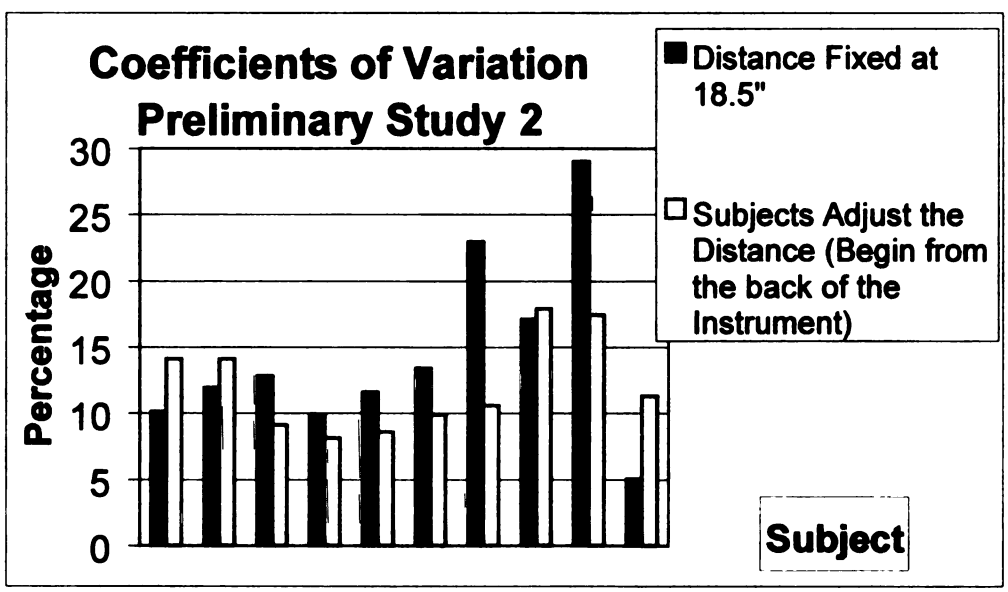


FIGURE 33- COEFFICIENTS OF VARIATION FOR PRELIMINARY STUDY TWO BY SUBJECT (Subjects begin adjusting distance from the back of the instrument)

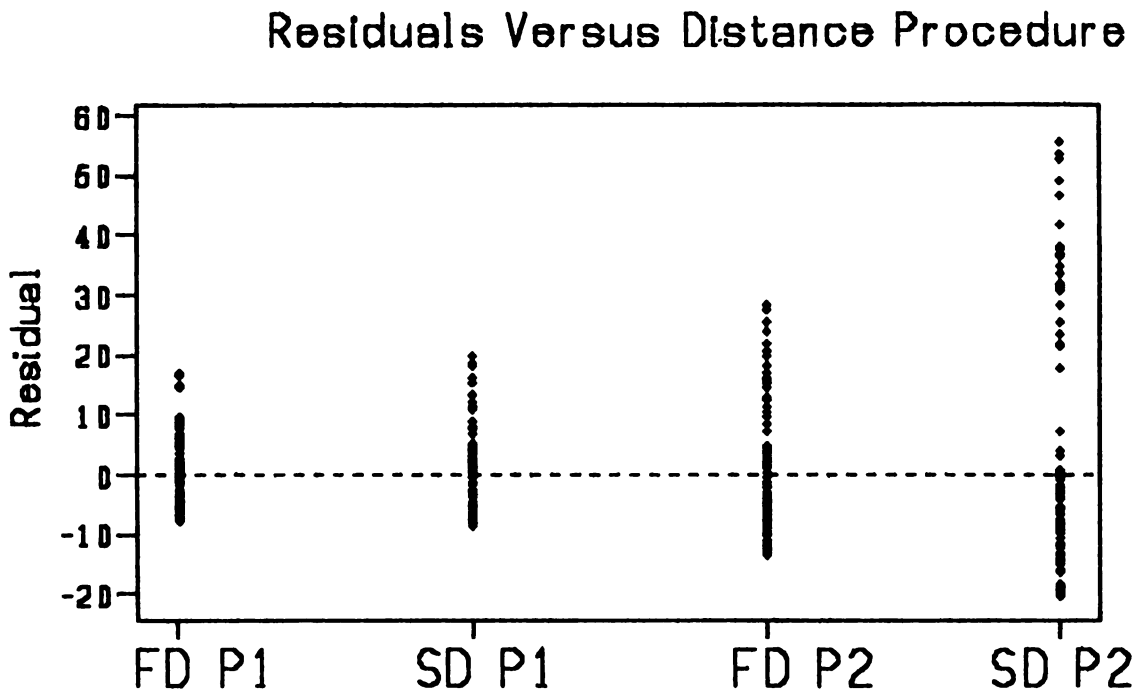


FIGURE 34: RESIDUAL ANALYSIS PRELIMINARY STUDY ONE VERSES PRELIMINARY STUDY TWO
(FD P1 refers to Fixed Distance, Preliminary Study 1; SD P1 refers to Subject Manipulated Distance, Preliminary Study 2; FD P2 refers to Fixed Distance, Preliminary Study 2, etc.)

Because subject is nested within study, and the subjects were shown to differ significantly, results from study one cannot be compared with study two. However, the effect of procedure can be examined by limiting analysis to within study comparisons.

Within study comparisons were made using a likelihood ratio test. Each study was analyzed using two statistical models. Model one assumes equal variances of treatment; if the distance was fixed, variability of the resultant data is no different than the variability produced when subjects adjust the distance ($\sigma_1^2=\sigma_2^2$). Model two assumes there is an effect of treatment on the data's variability ($\sigma_1^2\neq\sigma_2^2$); fixing the distance

between the subject and the reading material produces more (or less) variability than occurs when subjects choose the viewing distance. The –2 residual log likelihood value of Model 2 is subtracted from the –2 residual log likelihood value of Model 1 to get a test statistic variable that, under the null hypothesis, has a chi-squared distribution with one degree of freedom. From this distribution a p-value is obtained to determine whether the two models return significantly different results. Statistical significance indicates that there is difference in the variability that occurs when different procedures are employed.

The –2 residual log likelihood values for preliminary study one were 1048.7 (Model 1) and 1047.4 (Model 2). The chi-squared value was 1.3; this resulted in p-value of 0.25421. There was no statistical difference in the variability that occurred when researchers fixed the distance and the variability that occurred when subjects chose their own reading distance by beginning easel adjustment from the front of the LLI.

The –2 residual log likelihood values for preliminary study two were 1417.8 (Model 1) and 1415.1 (Model 2). This resulted in a chi-squared value of 2.7. The p-value was 0.10035. Like preliminary study one, there was no statistically significant difference when researchers fixed the easel distance and when subjects chose the distance by beginning easel adjustment from the back of the instrument.

A simple comparison of within subject variation and between subject variation was made by calculating several coefficients of variation. Figures 32 and 33 reveal information about within subject variation because they depict CVs for each subject by treatment. These values can then be compared with coefficients shown in Figure 35, which include variability that results from differences in subjects.

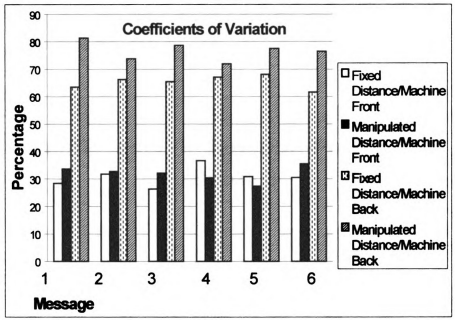


FIGURE 35- COEFFICIENTS OF VARIATION: PRELIMINARY STUDIES ONE AND TWO BY MESSAGE

A comparison of Figure 35 with Figures 32 and 33 reveals something of interest. Coefficients of variation are much smaller when they are examined on a per subject basis (see Figures 32 and 33). When the coefficients are measured between subjects, as in Figure 35, they are much larger. Our research examines the effects of procedure and instrument on the variability of data collected using the LLI. However, it is important to note that much of the variability of observations is attributable to the differences in the subjects themselves, something that is beyond our control.

Preliminary Study Three:

Figure 36 summarizes the coefficients of variation for the data collected during preliminary study three. Coefficients of variation are presented because preliminary study three examined the effect of instrument on the variability of data collected.

Specifically, study three aimed to determine if the new instrument resulted in less variable data than the older model.

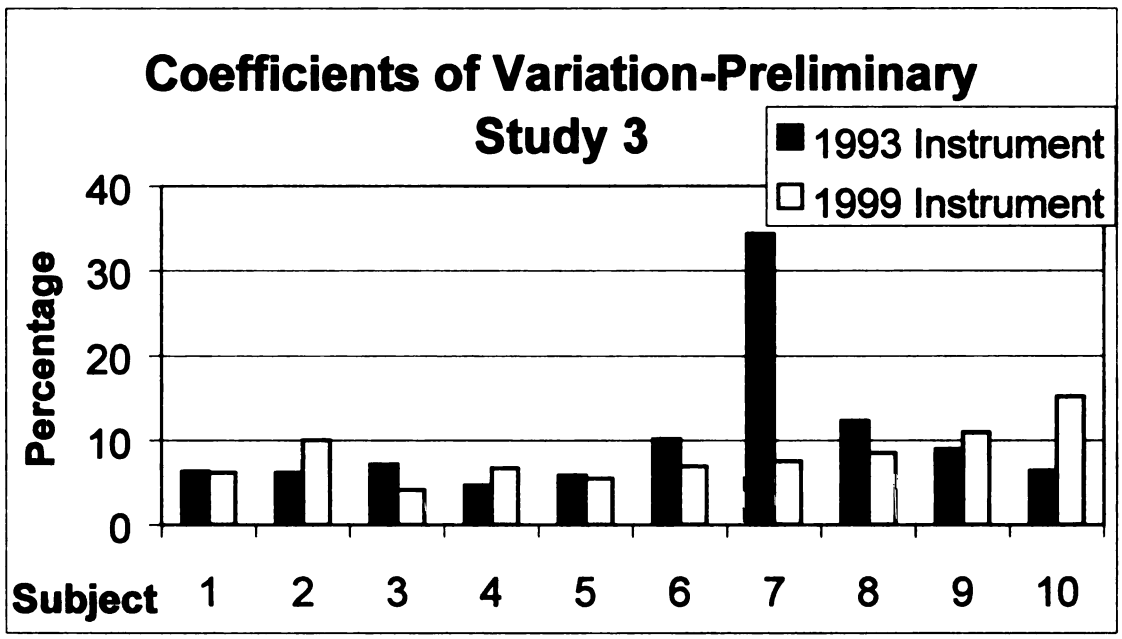


FIGURE 36: COEFFICIENTS OF VARIATION FOR PRELIMINARY STUDY THREE

As with preliminary studies one and two, comparisons for preliminary study three were made using a likelihood ratio test. Two statistical models were employed to determine if the instrument has an effect on the variability of data collected. Model one assumes equal variances of treatment; there is no difference in the variability collected using the 1993 model when it is compared with the variability of data collected using the 1999 model ($\sigma_1^2=\sigma_2^2$). Model two assumes there is an effect of treatment on data variability ($\sigma_1^2\neq\sigma_2^2$); the variability of the data collected with the 1993 model is assumed to be different than that collected with the 1999 model.

The –2 residual log likelihood value of Model 2 is subtracted from the –2 residual log likelihood value of Model 1 to get a test statistic variable that, under the null hypothesis, has a chi-squared distribution with one degree of freedom. From this distribution a p-value is obtained to determine whether the two models return significantly different results. Statistical significance indicates that there is difference in the variability that occurs when different instruments are used.

In addition to comparing the two models by way of a p-value, the variability of data collected can also be examined using the residual values that were calculated as part of model two. The residuals, a measure of variability, attributable to the older instrument were 16.755; this was nearly eight times greater than the residuals attributed to the 1999 model, which were only valued at 2.3304. Although this gives an indication that the treatments were different, it is not a formal comparison.

A formal comparison was made using the likelihood ratio test. The –2 residual log likelihood values for preliminary study three were 1190.8 (Model 1) and 1152.5 (Model 2). The chi-squared value was 38.3, which resulted in p-value of $6.0663*10^{-10}$. This indicates a highly significant difference in the variability of the data collected with the 1993 and 1999 LLIs.

It is tempting to tout this significant difference as a momentous accomplishment. After all, many of the new instrument's features were added in an attempt to reduce variability. However, it is important to temper this enthusiasm by reviewing the graphical representations of the variability of data (see Figure 36). Four out of the ten people tested actually had more variable data when they used the newer instrument. The

large magnitude of significance is at least partially attributable to just one individual, subject 7, who had much more variable results when using the 1993 LLI.

Primary Study:

Table 3 summarizes the average legibility index for each of the 8 labels, and provides readers with information about the treatment combinations that make up each one.

Label #	Design (Point Size)	Compliant?	Message Drug or Nonsense?	Average Legibility Index
1	Univers Ultra Condensed (9.0)	Yes	Nonsense	29.1
6	Univers Ultra Condensed	Yes	Drug	28.8
3	Gill Sans (6.0)	Yes	Nonsense	27.8
2	Gill Sans (6.0)	Yes	Drug	28.1
4	Lucida Fax (5.5)	No	Nonsense	26.9
7	Lucida Fax (5.5)	No	Drug	26.7
8	Verdana (5.5)	No	Nonsense	26.8
5	Verdana (5.5)	No	Drug	26.4

TABLE 3- TREATMENT COMBINATIONS FOR EACH LABEL AND AVERAGE LEGIBILITY INDEX FOR EACH TREATMENT COMBINATION

Figure 37 visually summarizes the average legibility index of each label tested in the primary study. All four compliant messages required a larger average legibility index value than the four noncompliant designs; larger values are indicative of text that is more difficult to read.

Three out of the four designs, all but the Gill Sans, had a nonsense message that resulted in a greater average legibility index than the identical design presented as a drug message. These differences, however, were quite small for all of the four designs tested; the largest difference, 0.4 degrees of rotation, is attributed to the Verdana design. Its nonsense message had an average legibility index of 26.8 and its drug message an average of 26.4.

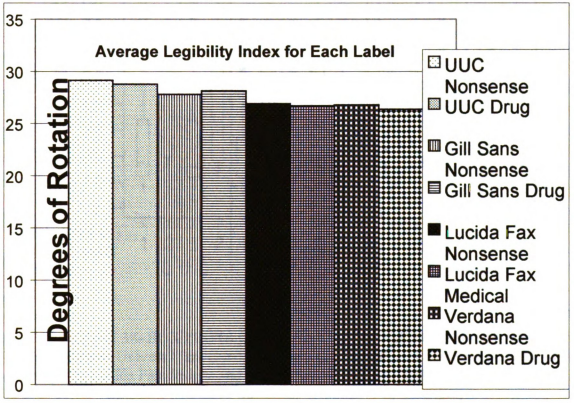


FIGURE 37- AVERAGE LEGIBILITY INDEX VALUES FOR ALL EIGHT LABELS

Figure 37 presents a variety of treatments as one average, a grand average, for each label. Information about the results of subjects with varying visual acuities is presented in Figure 38. Figure 38 presents the median and data spread of each label

when subjects with visual acuities of 20/20 viewed them versus the median and data spread when people with visual acuities of 20/30 viewed them.

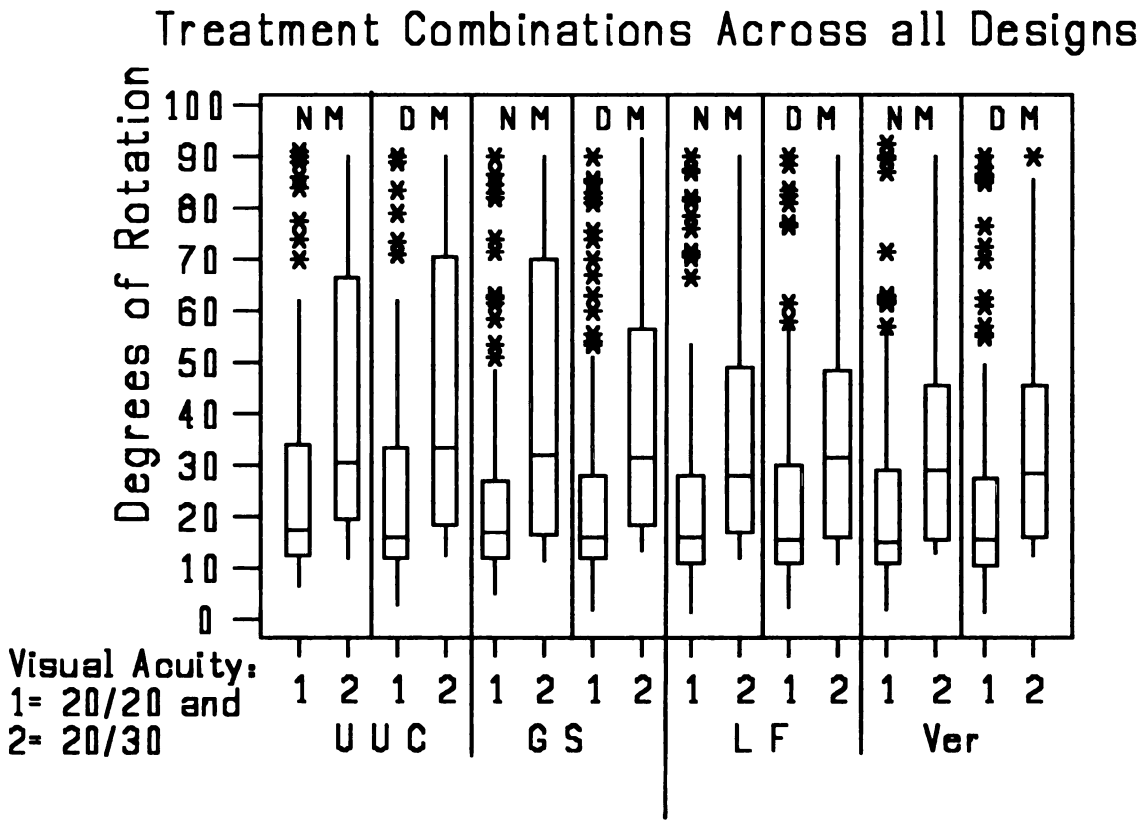


FIGURE 38- BOX PLOTS OF SEVERAL TREATMENT COMBINATIONS (UUC indicates Univers Ultra Condensed designs, GS indicates Gill Sans designs, LF indicates Lucida Fax designs and Ver represents Verdana designs; NM indicates nonsense messages while DM indicates drug messages)

Results were tested for statistical significance (See Table 4) using a mixed model Analysis of Variance (ANOVA).

Response = μ + Subject (Age Group) + Compliance + Design (Compliance) + Position + Message + Visual Acuity + Age Group + Compliance*Message + Message*Design (Compliance) + Position*Design (Compliance) + Residual

Subject, an effect that was nested within age group, and residual were considered random effects. All remaining effects were treated as fixed effects. Design was nested within the factor compliance due to the fact that designs 1 and 2 (Univers Ultra Condensed in 9.0 points and Gill Sans in 6.0 points) were always compliant, and designs 3 and 4 (Lucida Fax in 5.5 points and Verdana in 5.5 points) were always non-compliant with regard to the FDA regulation.

Fixed Effects					
	Num Degrees of Freedom	Den Degrees of Freedom	F Value	Pr > F	Significant?
Compliant	**1**	**1135**	**16.17**	**<.0001**	**YES**
Design (Compliant)	2	1135	1.38	.2532	No
Position	**2**	**1135**	**71.80**	**<.0001**	**YES**
Message	1	1135	0.14	.7053	No
Visual Acuity	1	46	1.34	.2359	No
Age Group	2	46	1.59	.2154	No
Compliant * Message	1	1135	0.13	.7162	No
Design (Compliant) * Message	2	1135	0.17	.8413	No
Design (Compliant) * Position	6	1135	1.74	.1089	No
Random Effects					
Cov Parm	Estimate	Standard Error	Z Value	Pr Z	Significant?
Subject (Age Group)	**454.75**	**95.3254**	**4.77**	**<.0001**	**YES**
Residual	**58.0118**	**2.4352**	**23.82**	**<.0001**	**YES**

TABLE 4- RESULTS OF THE RESTRICTED FORM OF THE MIXED MODEL USING SATTHERWAITE'S METHOD (Bolded effects indicate statistical significance $\alpha = 0.01$. Italicized Effects are significant at $\alpha = 0.05$).

After the data had been analyzed (see Table 4), an analysis of the residuals revealed the normal probability assumption was not supported when the raw responses were examined. Gill (1978) suggests that failing to meet this assumption is not critical in many cases. "The f test of the hypothesis of treatment effects is known to be robust, i.e.,

the probabilities of errors of Type I and Type II are little effected [sic] by moderate departures from normality" (Gill, 1978). Although the f-test applied in the analysis presented here is type III, Gill's comments with regard to robustness still apply (Cardoso, 2001).

Nonetheless, a second model was used to reanalyze the data (See Table 5). The second model divided the 50 subjects into two groups based on their residual variability. Subjects with estimated residuals that fell outside of $\pm 3\ \sigma$ were considered group one (See Figure 39). Eight subjects produced data that was ten times more variable than the other forty-two subjects; the forty-two subjects with less variable data were considered group two.

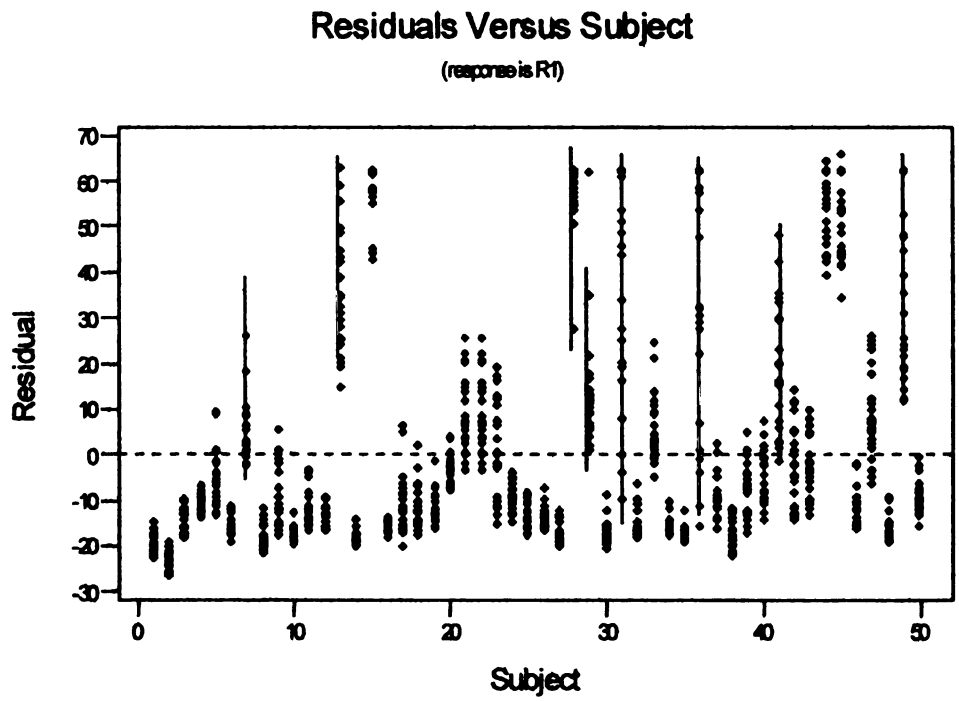


FIGURE 39- RESIDUALS VERSUS SUBJECT (Subjects were divided into two groups based on the variability of the data that they produced. Members of the group with highly variable data can be recognized because a line has been drawn through their residuals)

This second model accounted for the differences in the two groups' residual variability, without errantly attributing these differences to a factor in the model.

Fixed Effects				
Effect	Degrees of Freedom	Degrees of Freedom	F-Value	PR>F
Compliance	**1**	**983**	**30.07**	**<.0001**
Design (Compliance)	*2*	*983*	*3.05*	*.0477*
Position	**2**	**983**	**82.26**	**<.0001**
Message	1	983	.85	.3562
Visual Acuity	1	45.4	1.38	.2468
Age Group	2	45.6	1.60	.2122
Complaince * Message	1	983	.10	.7512
Design (Compliance)* Message	2	983	.64	.5254
Design (Compliance)* Position	**6**	**983**	**298**	**.0069**
Random Effects				
Covariance Parameters	Stnd. Estimate	Standard Error	Z Value	PRZ
Subject (Operator)	**450.09**	**94.8297**	**4.76**	**<.0001**
Residual	**245.39**	**25.6831**	**9.55**	**<.0001**

TABLE 5- RESULTS OF THE SECOND MODEL (Bolded effects indicate significance at α= 0.01. Italicized Effects are significant at α= 0.05.

The second analysis does not negate the first treatment of the data, but uses a model that is better suited to the data set. After data was completely analyzed using both models, comparisons were made between the results to see how closely each estimated

significance. The models produced the same results with respect to significance with two exceptions: the factor design (compliant), which was not significant in the first model, changed to significant at α=0.05 when the second was applied, and the significance level for the interaction between design (compliance) and position changed from insignificant to significant at α = 0.01.

Using the second analysis, the factors compliance, design and position are statistically significant. Compliance and position are significant at α=0.01 and design is significant at α=0.05. This is informative, but does not give a high level of detail in the results. (We know that design is a significant factor, but is there a significant difference between the Gill Sans and the Lucida Fax designs?). To achieve more detail, pair-wise comparisons of each possible combination of compliance, design (compliance), and position were tested for significance using a Tukey-Kramer test. Because of the large number of possible combinations when the interactions of all three factors are considered, limited results are presented here (see Table 6; for a complete set of results, see Appendix 11).

Compliant	Design	Position	Compliant	Design	Position	p Value	Significant
Yes	UUC GS	All	No	LF Ver	All	$5.2*10^{-8}$	YES
Yes	UUC	All	Yes	GS	All	0.0819	No
Yes	UUC	All	No	LF	All	$1.5*10^{-5}$	YES
Yes	UUC	All	No	Ver	All	$5.0*10^{-7}$	YES
Yes	GS	All	No	LF	All	0.0870	No
Yes	GS	All	No	Ver	All	0.01366	YES
No	LF	All	No	Ver	All	0.9085	No

TABLE 6- TUKEY-KRAMER PAIR WISE COMPARISONS

Tukey-Kramer tests break the results into a series of tests for statistical significance. Table 6 examines each possible pair of designs using the Tukey-Kramer method. Each row represents a comparison of treatments; the first design, shaded in

gray, is tested against a second design, which is not shaded, to determine if the pair are statistically significantly different from one another.

From Table 6 it is apparent that Univers Ultra Condensed (UUC) is significantly more difficult to read than all other designs, with the exception of Gill Sans (GS). This supports the idea that letter compression has a greater impact on legibility than type size (Watanabe, 1994). The comparison of GS and UUC produced a p-value of 0.0819, which is not significant at α=0.05. A comparison of GS and Lucida Fax (LF) designs also failed to produce statistically different results, p-value = 0.0807. A comparison between LF and Verdana (Ver) yielded another insignificant p-value (the value was 0.9085).

These results add an important dimension to the findings. One of the main purposes of the study was to show that noncompliant designs could be created that were more easily read than designs that complied with the regulation. It is tempting to report the effect of compliance as significant at α=0.01, and the effect of design as significant at α=0.05 (see Table 5). However, to report only this information would not provide readers with a thorough examination of the results. Although the results were highly significant for the entire group of compliant designs versus the noncompliant designs, as we examine pair wise comparisons, it is evident that the designs are close in their legibility measurements.

Nonetheless, the research did achieve its objective. Noncompliant labels were created that were statistically easier to read than labels that complied with the regulation. The Verdana label was shown to differ from the Gill Sans label with a p-value of 0.01366; the same label differed from the Univers Ultra Condensed label with a p-value of $5.0*10^{-7}$. Although the Lucida Fax label did not significantly differ from the Gill Sans

label (the p-value was only 0.0870), it did differ significantly from the Univers Ultra Condensed label with a p-value of $1.5*10^{-5}$.

Another goal of this research was to address the issue of message familiarity and legibility (see Figure 40). It was hypothesized that messages that subjects were familiar with, the drug message, would require fewer degrees of rotation than messages that subjects had not viewed before, "nonsense" messages. Three out of the four designs, all but the Gill Sans, had a nonsense message that had a greater average legibility index value than the identical design presented as a message typical of a drug label. When the results were analyzed for significance, they were not found to be significant at α=0.05. The insignificance of the differences in messages is shown graphically in Figure 40.

There are two possibilities with regard to this result. The first is that subjects rotate, as they are instructed, to the first point that they can easily read the text without straining their eyes, regardless of whether they are familiar with the message or not. This is a desirable outcome for the LLI.

The second possibility is that subjects were no more familiar with this common drug message than the message that was created using random words. This conclusion would support the idea that, despite potential dangers of OTC misuse, consumers are not highly involved with OTC products (Reisenwitz and Wimbish, 1997; Sansgiry and Cady, 1995; Robinson and Stewart, 1981); they do not read labels. This is consistent with the findings of a survey conducted by Dr. Janet Engle, Professor of Pharmacy at the University of Illinois, Chicago. At a news conference in December 1998 she indicated, "47% failed to always read the product label before starting a pain medication, and one-third were unaware that over-the-counter (OTC) drugs carry risk" (Norton, 1999). Given

the significant ramifications of improper OTC use, and the difficulty in changing consumer/product involvement, this second possibility is a frightening, but real, risk.

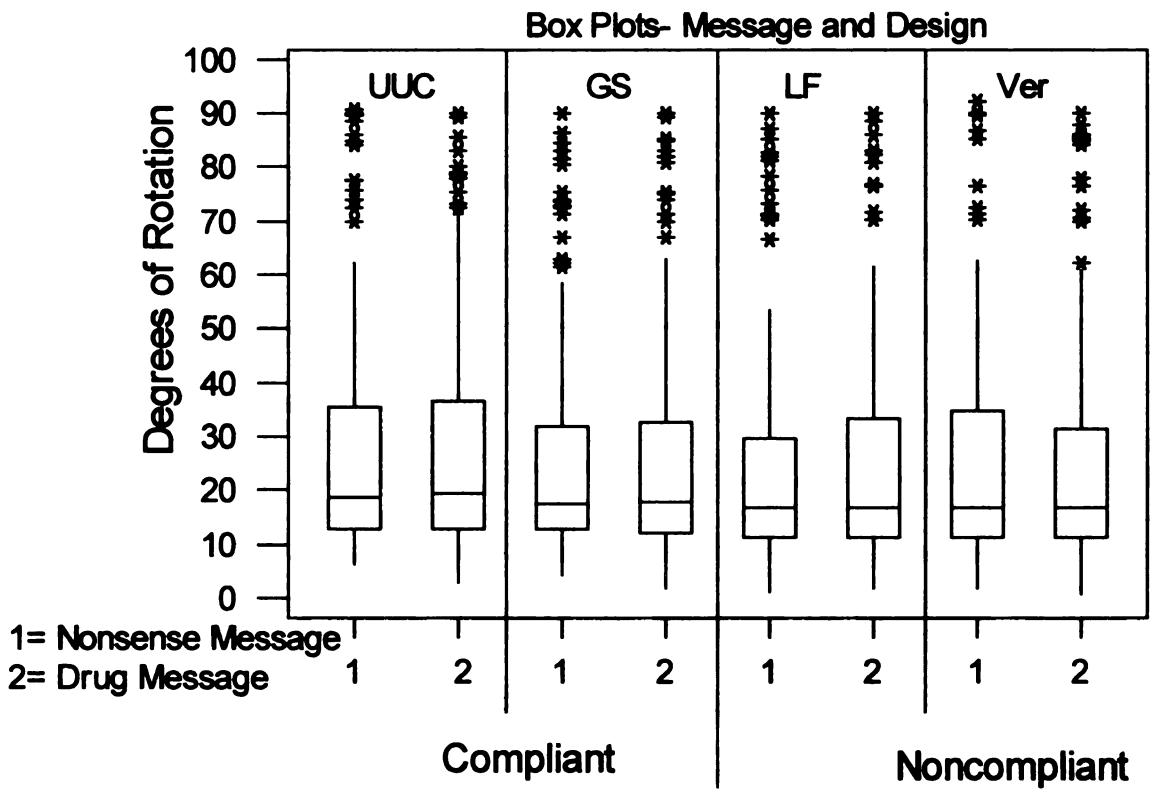


FIGURE 40- BOX PLOTS OF THE FACTORS MESSAGE AND DESIGN

Conclusions

This research proposed two testable hypotheses: (1) A non-compliant label can be created with equal (or greater) legibility than one that complies with the FDA regulation, a regulation that is intended to ensure legibility and (2) Drug labels, which contain messages that subjects are familiar with, will require fewer degrees of rotation than non-sense labels, which subjects have not seen before. Both of these hypotheses were tested using data obtained by the LLI, an instrument that provides an objective measure of legibility. The higher the degree of rotation, termed the legibility index, the more difficult a message is to read.

Although the statistical analysis (see Table 5) reveals that the compliant label designs are more difficult to read than the noncompliant designs at a level of α=0.01, the difference in means is not practically significant. The largest difference in treatment means occurs when the designs created using Univers Ultra Condensed are compared with designs that utilize the Verdana typeface. The difference in the means of these two designs is 2.5707 degrees of rotation when the nonsense labels are compared and 2.338 degrees when the labels containing drug messages are compared.

From a practical standpoint, any comparisons made between Univers Ultra Condensed designs and the noncompliant label designs represent an exaggeration of results. It is an exaggeration because it is unrealistic to assume that drug manufacturers would choose to use Univers Ultra Condensed. Although we have termed it as compliant with regard to the March 17, 1999 regulation, it could be argued that it is not. Even though the agency does not specify typeface, they do indicate that the typeface should be

any "single, clear, easy-to-read, typestyle" (Food and Drug Administration, 1999). It could be argued that Univers Ultra Condensed is not clear or easy-to-read. This is part of the difficulty with the new regulation; it is prescriptive, but asks designers to make judgments with regard to the legibility of a typeface.

A comparison between the means of the Gill Sans and Verdana designs provides a more realistic comparison of compliant versus noncompliant labeling. Gill sans is a sans serif font, and sans serif fonts are strongly encouraged by the regulation. Gill Sans is clear and easy-to-read. Although these designs have been shown to be statistically different (see Table 6), the difference in the mean reading for each of the two designs (see Table 3) is very small (1.0 degree of difference for the nonsense messages, and 1.7 degrees for the drug messages).

Although the practicality of this difference can be debated, the results do accomplish the goal of the research; noncompliant labels were created that were at least as legible as labels that complied with FDA's regulation. The results also demonstrate the LLI's ability to detect small differences in legibility and show the complexity of the interrelated variables that determine how easy, or difficult, a message is to read.

Dictating these variables one by one is not the best approach to ensure the legibility of OTC labels, but it is the approach taken by FDA in their 1999 regulation. Research presented here challenges the regulation and this approach; different design variables were carefully examined and manipulated in an attempt to create compliant labels that would be difficult to read and noncompliant labels that would be easily read. Although the objective was successfully accomplished, noncompliant designs were statistically easier to read than their compliant counterparts, the differences were very

small (see Table 3 and Figure 37). The creation of noncompliant labels that were more legible than labels that complied with FDA's regulation proved a formidable task; FDA did a good job at specifying the variables of design that aid readers.

FDA did, however, fail to dictate several variables that were not studied here, that undoubtedly impact legibility. In the FDA regulation there is no indication of quality requirements for materials or production methods; the sole focus of the regulation is design and format. Just as the elements of letter and layout have a multitude of factors that impact legibility, so do the materials and production techniques used to create labels and packages.

A performance standard for legibility, utilizing a measurement tool like the LLI, not only accounts for the production issues, but takes into account the various elements of both letter design and layout, while measuring what is important, the consumer's ability to read the label. The performance standard approach allows designers flexibility in design, provides manufacturers with defensible proof of message accessibility, gives consumers designs that have been tested to be legible and gets FDA out of the business of "micro managing" label design. A performance standard for legibility would better serve industry, regulators and, most importantly, the consumers of OTC drugs.

Suggestions for Future Research

1. Rousseau's model (notice, encode, comprehend and comply) illustrates that there are more aspects to effective label design than legibility. For labels to be effective consumers must (1) notice them (2) encode them (3) comprehend them and, finally (4) comply with them. Study into the other three aspects of Rousseau's model and ways (like the LLI) to quantify a label's success or failure at each of the steps is needed. It is

anticipated that this team will be investigating consumers' capacity to notice label elements using eye-tracking technology.

2. Another issue that is in need of study is the involvement of elderly consumers with OTC products. "Product involvement refers to consumers' knowledge about the personal relevance of the products in their lives" (Peter and Olson, 1999). This personal, or self, relevance can be either intrinsic or situational and can vary in intensity. Consumers who are more involved with a product will devote more of their resources to it. These resources are not necessarily monetary, but may take the form of time and effort. Involved consumers are more likely to seek information (from the label and from other sources), use complex rules when evaluating alternatives, and devote focal attention and controlled comprehension to the product (Rifon, 2000).

Involvement is very important when we examine consumer behavior relating to the proper use of OTC drug labels. Research is split on whether elderly consumers have a high level of involvement when purchasing OTC drugs (Sansgiry and Cady, 1996; Gore et. al, 1994) or a low level of involvement (Reisenwitz and Wimbish, 1997; Sansgiry and Cady, 1995; Strutton and Tanner, 1994; Robinson and Stewart, 1981) Further research into the involvement level that elderly consumers have with OTC drugs is needed.

3. FDA's failure to address production-related issues and their impact on legibility was mentioned several times in this work. The labels produced for this study were created using a laser printer; although production issues were discussed, it was not a focus of this work. Research into various aspects of printing (materials and production) and their effect on legibility is needed. Of particular interest is the surface reflectance of

packaging materials and the impact that this has on the elderly population's ability to read labels.

4. It was suggested in this document that x-height is a better indicator of a typeface's legibility than type size. A study to explore this hypothesis is advised. It was also suggested that previous studies may have errantly attributed increased legibility to incorrect elements of design. Bix (1998), for example, suggested that sans serif fonts were more easily read than serif fonts; this may have been an incorrect conclusion based on the fact that the typefaces being compared had unequal x-heights. Explorations in x-height, as it relates to legibility, using the LLI are advised.

5. A sampling of OTC labels on the market and elderly consumers is advised. Can elderly consumers effectively decipher the 6 point type size unaided?

6. Work to further the use of this instrument as part of a performance standard for legibility is advised. The first step is to define what "legible" is, in terms of degrees of rotation. This definition should be created with a particular concern for the elderly, who are at particular risk for drug mismanagement for a variety of reasons.

7. "Interactive warnings" are a relatively new type of design that is meant to take advantage of environmental cues, increasing label effectiveness.

> "This format (interactive warnings) requires the product user to physically manipulate the warning when using the product, and researchers have found that these types of warnings increase the likelihood of the user noticing and complying with the information... the interactive labels serve as an event-based cue to recall the appropriate safety procedures" (Rousseau et al., 1998).

The application of interactive warnings to packaging applications is a ripe area for future research.

Appendix 1-Summary Table of FDA's Activity Regarding Labels

How to use these tables:
Table 7 presents a general summary of the regulatory activity occurring at FDA regarding OTC labels. Table 8 presents a summary of the headings and subheadings required under section "c" of the final rule, "Over-the-Counter Human Drugs; Labeling Requirements." Table 9 summarizes label-formatting requirements set forth in section "d" of the regulation.

Table 7-FDA OTC Legibility Publications

Date-Action-Title	Summary
February 27, 1997-Proposed Rule	The rule attempted to improve the legibility and ease of use of OTC labels by requiring: a specific font (Helvetica), a minimum font size, standardized headings and subheadings, bullet points, pictograms, specified words and an exact format for all required information
March-December 1997-**Study A, "Evaluation of Proposed Over-the-Counter Label Format Comprehension Study,"** is conducted	Examined the influence of variation formats on the communication of directions for use and required warnings (March 17, 1999 Federal Register). 1,202 consumers were randomly surveyed at malls in 8 states. Consumers were directed to "view examples of OTC label designs. Respondents were asked questions designed to measure knowledge and attitudes about OTC drug products, as well as decisions about proper use of the products" (FDA. Study A Table of Contents). Before consumers were interviewed, information regarding site location, past participation, subject age, corrective eyewear and gender was recorded. Subjects who had previously participated in the study, were younger than 18 or did not have eyewear that they normally required for reading were dismissed. Interviewers did not measure or record subjects' visual acuity.
March-December 1997-**Study B, "Over-the-Counter Label Format Preference,"** is conducted	Examined "examples and variations of current OTC label designs. Respondents were asked to indicate their preference for various designs. Also, consumers were asked to evaluate labeling terminology and graphics to investigate how they interpret various ways of communicating drug safety and effectiveness" (FDA. Study B Table of Contents).
December 30, 1997	Comment period on Study B is announced. It closes February 13, 1998
February 13, 1998	Comment period on Study A is announced. It closes March 30, 1998.

Table 7- Continued	
March 17, 1999- Final Rule- **"Over-the-Counter Human Drugs; Labeling Requirements"**	Rule establishes a "standardized format and standardized content requirements for the labeling of OTC drug products. This final rule is intended to assist consumers in reading and understanding OTC drug product labeling so that consumers may use these products safely and effectively. This final rule will require all OTC drug products to carry the new, easy-to read format and the revised content requirements within prescribed implementation periods.

Table 8-Content Requirements for OTC Labels (Section 201.66 (c))	
March 17, 1999- Final Rule- **"Over-the-Counter Human Drugs; Labeling Requirements"**	Rule establishes a "standardized format and standardized content requirements for the labeling of OTC drug products. This final rule is intended to assist consumers in reading and understanding OTC drug product labeling so that consumers may use these products safely and effectively. This final rule will require all OTC drug products to carry the new, easy-to read format and the revised content requirements within prescribed implementation periods" (FDA, 1999).
Section	Summary
201.66c 1 Heading	"Drug Facts" is required
201.66c 2 Heading	"Active Ingredients"- established name and quantity of each active ingredient/dosage unit follow this heading
201.66c 3 Heading	"Purpose" or "Purposes" - general pharmacological category(ies) of drug or of each active ingredient follow this heading
201.66c 4 Heading	"Use" or "Uses"- the indications for use of a product follow this heading
201.66c 5 Heading	"Warning" or "Warnings" subheadings (where applicable) are specified in sections 201.66(c)5i-201.66(c)5x
201.66c 5i Subheading	"For external use only", "For rectal use only", "For vaginal use only", "Allergy alert"
201.66c 5ii Subheading	"Do not"
201.66c 5iv Subheading	"Ask a doctor before use if you have" followed by pre-existing conditions
201.66c 5v Subheading	"Ask a doctor or pharmacist before use if you are" followed by cautions about potential drug/food interactions
201.66c 5vi Subheading	"When using this product" followed by side effects consumers may experience substances/activities to avoid
201.66c 5vii Subheading	"Stop use and ask a doctor if" followed by signs of toxicity and other serious reactions
201.66c 5viii Subheading	This section directs the placement of other warnings not covered previously
201.66c 5x Subheading	Reference to Poison Control Centers
201.66c 6 Heading	"Directions" followed by applicable directions for use
201.66c 7 Heading	"Other Information" followed by information that doesn't fall within any of the other categories in 201.66(c) but is required or made optional under other OTC drug regulation or an approved drug application
201.66c 8 Heading	"Inactive ingredients" followed by ingredients listed in alphabetical order

Table 8- Continued	
201.66c 9 Heading	"Questions?" or "Questions or Comments?" followed by telephone number printed in a minimum of 6-point bold font. It is also recommended that the days of the week and times when someone is available to respond to questions be included.

Table 9- Format Requirements: Section 201.66d (for Presenting the Title, Headings, Subheadings and Information Set Forth in 201.66(c)1 through 201.66(c)9)	
201.66d 1 **Capitalization Justification of Headings and Subheadings**	The first level of each word in the title in 201.66c1 must appear in upper case. Only the 1st letter of the 1st word of each heading and subheading of c2-c9 appear in upper case. Title headings and subheading set forth in c1-c2 and c4-c9 must be left justified
201.66d 2 **Type Size (Title, Headings, Subheadings and Text)**	"Drug Facts" must appear in a type size greater than the largest type size used within the "Drug Facts" area. This title must be no smaller than 8-points. Headings in paragraphs c2-c9 must be at least 2-point sizes larger than the text (8 point or greater type). The subheadings and all information described in 201.66c2-c9 must appear in at least 6-point type. Format exceptions for small packages require text no smaller than 6 points. "The agency chose to require a minimum type size of 6-point and type styles which ensure letter compression of no more than 39 characters per inch".
201.66d 3 **Font, Leading, Kearning, Contrast and Highlighting**	Any "single, clear, easy-to-read type style" is allowed. The agency believes that san serif type styles are the most likely to be considered clear and easy to read. They note that Helvetica and Univers have consistent and uniform stroke weight characteristics and are commonly available. The title "Drug Facts" must appear in bold italic print. At least .5 point leading is needed to ensure readability. The type must be all black or one dark color, printed on white or other light, neutral color, contrasting background.
201.66d 4 **Bullet Point Style and Format to Introduce and Highlight Informative Statements**	Solid square or circles of 5-point type size must be presented as the same shape and color throughout the labeling. Bullets and bulleted statements under each heading subheading must be vertically aligned to ensure visual separation and adequate white space between discrete information chunks. Two bulleted statements are allowed on a single line, however each statement must be separated by at least 2 square "m"s.

Table 9 Continued	
201.66d 5 **Multiple Panels**	Provides that headings, subheadings and information required under 201.66c including the warnings section, may appear on more than one panel. Appropriate visual cues must be provided so that the flow of information is retained. The arrow, directing the consumer to the continuation of information on the next panel. The continuation of the required content and format onto multiple panels must retain the required order and flow of headings, subheadings and information. The UPC symbol may appear on the same panel as some of the information, but must be outside the box or enclosed.
201.66d 6 **Active Ingredients**	Listing of the active ingredients. The established name, the quantity or proportion and the "purpose" of each active ingredient is listed.
201.66d 7 **Graphical Images**	Graphical images (such as UPCs) and any information not set forth in section 201.66c must not interrupt the required information panel or panels. The UPC symbol may appear on the same panel as the required information but must not be outside the box or enclosure
201.66d 8 **Placement and Style of Lines**	Lines partition the information set forth in 201.66c1-c9. A bar line must be used to form a box or similar enclosure to separate the sections (sections begin with a heading). Hairlines separate subsections (subsections begin with a sub heading). Hairlines must extend to within two spaces on either side of the "Drug Facts" box while bar lines extend to each end of the "Drug Facts" box.
201.66d 9 **Directions**	Requires that dosage directions, when provided for 3 or more age groups or populations must be presented in a table format. A text format may be used when there are less than 3 dosage directions.

Table 9- Continued

201.66d 10 **Small Package Format**	Products are considered small when 60% or more of the total surface area available to bear labeling on the entire outside container or wrapper, or immediate container or wrapper would be needed to present FDA required labeling. For products that are sold with an outer package, the FDA is encouraging, but not requiring, the use of the modified small package format on the immediate container. Font size for body text does not change (6 points /no more than 39 characters/inch). Headings must be minimum 7 points. Leading may be less than 0.5 points. (It can be adjusted so that the ascenders and descenders of the letters do not touch). Bulleted statements may continue to the next line and need not be vertically aligned. The box required in 201.66d8 may be omitted if the headings, subheadings and information in 201.66c1-c9 are set off from the label by color contrast

Appendix 2- A Variety of Typefaces in the Same Type Size

Champion (Abadi MT Condensed 20 points)
Champion (Agency FB 20 points)
Champion (Arial 20 points)
Champion (Arial Alternative)
Champion (Arial Black 20 points)
Champion (Arial Narrow 20 points)
Champion (Arial Rounded MT B 20 pts)
Champion (Arial Unicode MS 20 points)
Champion (Baskerville Old Face 20 points)
Champion (Batang 20 points
Champion (Bauhaus 20 points)
Champion (Bell MT 20 Points)
Champion (Berlin Sans FB 20 Points)
Champion (Bernard MT Condensed 20 points)
Champion (Book Antiqua 20 points)
Champion (Bookman Old Style 20 pts)
Champion (Britannic Bold 20 points)
Champion (Californian FB 20 points)
Champion (Calisto MT 20 points)
Champion (Centaur 20 points)
Champion (Century 20 points)
Champion (Century School Book 20 pts)
Champion (Comic Sans MS 20 points)
Champion (Cooper Black 20 points)
CHAMPION (COPPERPLATE GOTHIC BD)

CHAMPION (COPPERPLATE GOTHIC LT)

Champion (Courier New 20 points)

Champion (Elephant 20 points)

CHAMPION (ENGRAVERS MT 20)

Champion (Eras Bold ITC)

Champion (Eras Medium ITC 20 points)

Champion (Eras Demi ITC 20 points)

Champion (Eras Light ITC 20 points)

Champion (Franklin Gothic Book 20 points)

Champion (Franklin Gothic Demi 20 points)

Champion (Franklin Gothic Demi Condensded)

Champion (Franklin Gothic Heavy 20 pts)

Champion (Franklin Gothic Medium 20 pts)

Champion (Franklin Gothic Medium Condensed)

Champion (Garamound 20 points)

Champion (Georgia 20 points)

Champion (Gill Sans MT 20 points)

Champion (Gill Sans Condensed 20 points)

Champion (Gill Sans MT Ext Condensed 20 points)

Champion (Gill Sans Ultra Bold)

Champion (Gill Sans Ultra Bold Condensed)

Champion (Glouster MT Extra Condensed 20 points)

Champion (Goudy Old Style 20 points)

CHAMPION (GOUDY ST)

Champion (Haettenschweiler 20 point)

Champion (Helvetica 20 points)

Champion (Helvetica Narrow 20 points)

Champion **(Helvetica Black 20 pts)**
Champion (Helvetica Condensed 20 points)
Champion **(Helvetica Condensed black 20 pt)**
Champion (Helvetica Condensed Light 20 pts)
Champion (Helvetica Light 20 points)
Champion (High Tower 20 points)
Champion **(impact 20 points)**
CHAMPION (LITHOS REGULAR 20 PTS)
Champion (Lucida Bright 20 points)
Champion (Lucida Console 20 pts)
Champion (Lucida Fax 20 points)
Champion (Lucida Sans 20 points)
Champion (Lucida Sans Typ wrt)
Champion (Lucida Sans Unicode 20 pt)
Champion (Minion Condensed 20 points)
Champion (Modern # 20 20 points)
Champion (MS Mincho 20 points)
Champion (Myriad Roman 20 points)
Champion (Myriad Tilt 20 points)
Champion (News Gothic MT 20 points)
Champion (Niagra Solid 20 points)
Champion **(Nueva Bold Extended 20 p**
Champion (Nueva Roman 20 points)
Champion (OCR A Extended 20 pts)
Champion (Onyx 20 points)
Champion (Papyrus 20 points)

Champion (Perpetua 20 points)

CHAMPION (PERPETUA TILTING MT 20)

Champion (Playbill 20 points)

Champion (PmingLiU 20 points)

Champion (Poor Richard 20 points)

Champion (Rockwell 20 points)

Champion (Rockwell Condensed 20 points)

Champion (Rockwell Extra Bold 20

Champion (Sanvito Light 20 points)

Champion (Sanvito Roman 20 points)

Champion (Script MT Bold 20 points)

CHAMPION (SHOWCARD GOTHIC 20 PTS)

Champion (SimSun 20 points)

Champion (Snap ITC 20 Points)

CHAMPION (STENCIL 20 POINTS)

Champion (Tahoma 20 points)

Champion (Tekto MM 20 points)

Champion (Tekto MM_100 LT250 cn 20 points)

Champion (TektoMM_100LT 564 No 20 points)

Champion (TektoMM_100 LT 850 EX 20

Champion (Tekto MM_240 RG 250 CN 20 points)

Champion (Tekto MM_240 RG 564 NO 20 pts

Champion (Tekto MM_240 RG 850 EX)

Champion (Tekto MM_503 BD 250 CN 20 points)

Champion (Tekto MM_503 BD 488 NO 20pt

Champion (Tekto MM_503 BD 850 EX 20 points)

Champion (Tempus Sans ITC 20 Points)

Champion (Times New Roman 20 points)

Champion (Trebuchet MS 20 points)

Champion (Tw Cen MT 20 points)

Champion (Tw Cen MT Condensed 20 points)

Champion (Tw Cen MT Condensed Extra Bold 20)

Champion (Utopia 20 points)

Champion (Verdana 20 points)

Champion (Verdana Ref 20 points)

Champion (Viva Bold Extra Ext)

Champion (Viva Regular 20 points)

Champion (Vivaldi 20 points)

Champion (Vladimir Script 20 Points)

Champion (Westminster 20 points)

Champion (Wide Latin20

Champion (Willow 20 points)

Appendix 3- Legibility and Color Contrast

The following represents the analysis of an ongoing study directed by Dr. Hugh Lockhart. The experiment investigates the effect of varying color contrast combinations on legibility. The experimental design, data collection and a preliminary analysis of the results of this study were conducted in 1996. A more thorough treatment of the 1996 data is presented here.

36 cards (6 messages x 6 color combinations, or contrasts) were created in order to examine how different contrast combinations affect the legibility of messages. 6 messages (see Table 10) were centered on cards approximately 3" x 5" cards; text was justified.

Table 10- Legibility Messages Used in the Color Contrast Study	
Message 1	It may help most of them to work today. She works in this club after midnight. The order to go will be done after two.
Message 2	She works in this club after midnight. The order to go will be done after two. There will be some sugar in the kitchen.
Message 3	The order to go will be done after two. There will be some sugar in the kitchen. Here is a copy of lunch hours for today.
Message 4	There will be some sugar in the kitchen. Here is a copy of lunch hours for today. From here to there flowers can not grow.
Message 5	Here is a copy of lunch hours for today. From here to there flowers can not grow. It may help most of them to work today.
Message 6	From here to there flowers can not grow. It may help most of them to work today. She works in this club after midnight.

Each message was printed in 6 color combinations (see Table 11) for a total of 36 treatments (see Table 11).

Table 11- Contrast Treatments	
Color 1	Blue text/white background
Color 2	Yellow text/red background
Color 3	Blue text/yellow background
Color 4	White text/blue background
Color 5	Black text/red background
Color 6	Black text/white background

Table 12- Treatment Combinations for the Color Contrast Study					
Card #	Color #	Message #	Card #	Color #	Message #
1	1/1		19	4/1	
2	1/2		20	4/2	
3	1/3		21	4/3	
4	1/4		22	4/4	
5	1/5		23	4/5	
6	1/6		24	4/6	
7	2/1		25	5/1	
8	2/2		26	5/2	
9	2/3		27	5/3	
10	2/4		28	5/4	
11	2/5		29	5/5	
12	2/6		30	5/6	
13	3/1		31	6/1	

Table 12- Treatment Combinations for the Color Contrast Study (Continued)			
14	3/2	32	6/2
15	3/3	33	6/3
16	3/4	34	6/4
17	3/5	35	6/5
18	3/6	36	6/6

Near point visual acuity was tested using a Dow Corning Opthalmics Near Point Visual Acuity Card. These values were recorded. Subjects that had visual acuities of 20/20 were coded as "1", subjects with measured values of 20/30 "2", 20/40 "3" and so on. Subjects were also tested for color blindness; results were recorded as "normal" or "red/green color blind". Other information that subjects provided included age group, gender, eye wear and highest level of education completed. Eye wear was coded as 1 through 4 for the purpose of statistical analysis. Eye wear of 1 indicated that subjects did not wear use any kind of correction, 2 indicated that they wore glasses with a single lens, 3 indicated bifocals and 4 trifocals.

Researchers asked 6 age groups (19-28, 29-38, 39-48, 51-60, 61-70, and 71 and older) to read 12 cards (a third of the total treatments) using the polariscope. Subjects were first asked to rotate the polariscope's filter until the first point that they could read the message. Researchers recorded this number. Subjects were then asked to continue rotating until "the first point that they could easily read the words on the card without straining their eyes". Researchers also recorded this number. The results from the second data set, where subjects rotated the filter until the first point that they could read the cards without straining their eyes, are presented here.

Although only 6 age groups were tested, data presented here shows a total of 8 groups. The reason for this is two-fold. The first age group (age 19-28) contained three times as many subjects as any other age group; a total of 45 people were tested that were 19-28, while only 15 were tested in the other five age groups. As a result of the large number of subjects age 19-28, 3 different operators were used to collect this group's data; it was determined that data collected by each operator would be reported as a separate group so that the effect of operator could be examined. As a result, data reported as groups 1-3 represent readings from people age 19-28 collected by three different operators; data reported as group four represent readings made by people age 29-38, data reported as group five represent readings made by people age 39-48, data reported as group six represent readings made by people age 51-60, data reported as group seven represent readings made by people age 61-70 and data reported as group eight represent readings made by people age 71 and older.

An analysis was conducted on groups 1-3 (all age 19-28) using the restricted form of the mixed model. Operator, visual acuity, eye wear, gender and color were tested as fixed effects while message, subject (nested within operator), and the interaction of subject (nested within operator) and color were treated as random effects. Using SAS 8.1 the following results were obtained (see Table 13).

Table 13- Color Contrast Results: Examining Groups 1-3 for an Effect of Operator				
Fixed Effects				
Effect	Degrees of Freedom	Degrees of Freedom	F-Value	PR>F
Operator	2	38	2.25	.1189
Visual Acuity	**2**	**38**	**5.38**	**.0088**
Eye Wear	1	38	.54	.4649
Gender	1	38	.26	.6155
Color	**5**	**220**	**81.53**	**<.0001**
Random Effects				
Covariance Parameters	Stnd. Estimate	Z Error	Value	PRZ
Message	1.19 E-18	...	...	...
Subject (Operator)	**8.1749**	**1.9729**	**4.14**	**<.0001**
Residual	**2.9065**	**.2502**	**11.62**	**<.0001**

Bolded effects indicate a high level of statistical significance (α= .01).

Once it was determined that the effect of operator was not significant, the entire data set was analyzed for an effect of Age Group. Data from all three of the groups was used in the second analysis. Leaving in the first three groups gives a conservative estimate of the effect of age. Researchers first attempted to use the following model

Response = Age Group + Visual Acuity + Eye Wear + Gender + Color+
Age Group*Color + Subject (Nested within Age Group) + Color*Subject (Nested within Age Group) + Message*Subject (Nested within Age Group) + Color*Message*Subject (Nested within Age Group) + Color*Message + Age*Message + Age Group*Color*Message + Residual

Age group, visual acuity, eyewear, gender, color and age*color were treated as fixed effects while subject (nested within age group), color*subject (nested within age

group), message*subject (nested within age group), color*message*subject (nested within age group), color*message, age group*message and age group*color*message and residual were all treated as random effects. Due to the large number of interaction terms and random effects, the computer did only a partial analysis of the model. The results that were completed follow (see Table 14)

Table 14: Partial Analysis of the Complete Data Set

Random Effects

Covariance Parameters	Estimate	Error	Value	PRZ
Message	.09980	.1200	.83	.2029
Subject (Age)	**66.3943**	**9.3353**	**7.11**	**<.0001**
*Subject (Age) * Color*	*1.1621*	*5.730*	*2.03*	*.0213*
Subject (Age) * Message	0	...	...	...
Subject (Age) * Color * Message	$6.91*10^{-17}$	...	...	...
Color * Message	.08067	.1340	.60	.2735
Age Group * Message	.07609	.1472	.52	.3026
Age Group * Color * Message	.2877	.3685	.78	.2175
Residual	**12.2947**	**.7481**	**16.43**	**<.0001**

Bolded effects are highly significant (α=.01). Effects that appear in italicized typeface are moderately significant (α=.05).

In the third analysis a simplified model was used so that a complete analysis could be obtained (see Table 15). The simplified model used was:

Response = Age Group + Visual Acuity + Eye Wear + Gender + Color+
Age Group*Color + Message + Subject (Nested within Age Group) + Subject (Nested within Age group)*Color + Residual

Table 15: Analysis of the Complete Data Set (Simplified Model)				
Fixed Effects				
Effect	Degrees of Freedom	Degrees of Freedom	F Value	Pr > F
Age Group	**7**	**105**	**5.70**	**<.0001**
Visual Acuity	**3**	**105**	**21.13**	**<.0001**
Eye Wear	3	105	1.17	.3236
Gender	1	105	.01	.9274
Color	**5**	**561**	**177.28**	**<.0001**
Age Group * Color	**35**	**559**	**6.57**	**<.0001**
Random Effects				
Covariance Parameters	Estimate	Error	Value	PrZ
Message	.1286	.1166	1.10	.1351
Subject (Age)	**66.520**	**9.3501**	**7.11**	**<.0001**
*Subject (Age) * Color*	*.9647*	*.5555*	*1.74*	*.0412*
Residual	**12.813**	**.6764**	**18.94**	**<.0001**

Effects that appear in bolded type are highly significant (α=.01) while those that appear in italicized type are moderately significant (α=.05). The effect of both color and age can be examined visually when the data is broken into bar graphs (see Figure 41 for the Effect of Age and Figure 42 for the Effect of Color). Every age group found black type on white paper the easiest to read, and all but the two oldest groups (group 7, age 61-70, and group 8, age 71 and older) found black type on a red background to be the most difficult combination to read. The two oldest groups found yellow text on a red background the most difficult to read, possibly because of the physiological changes discussed earlier in this document combined with poor contrast provided by this combination.

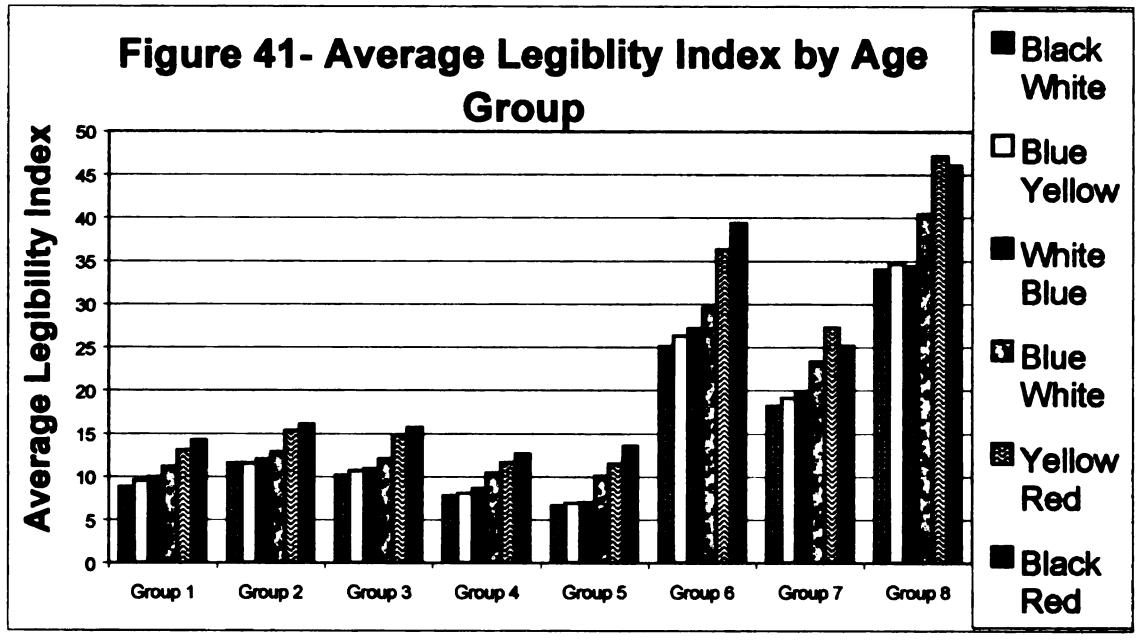


FIGURE 41- AVERAGE LEGIBILITY INDEX BY AGE GROUP (COLOR CONTRAST STUDY)

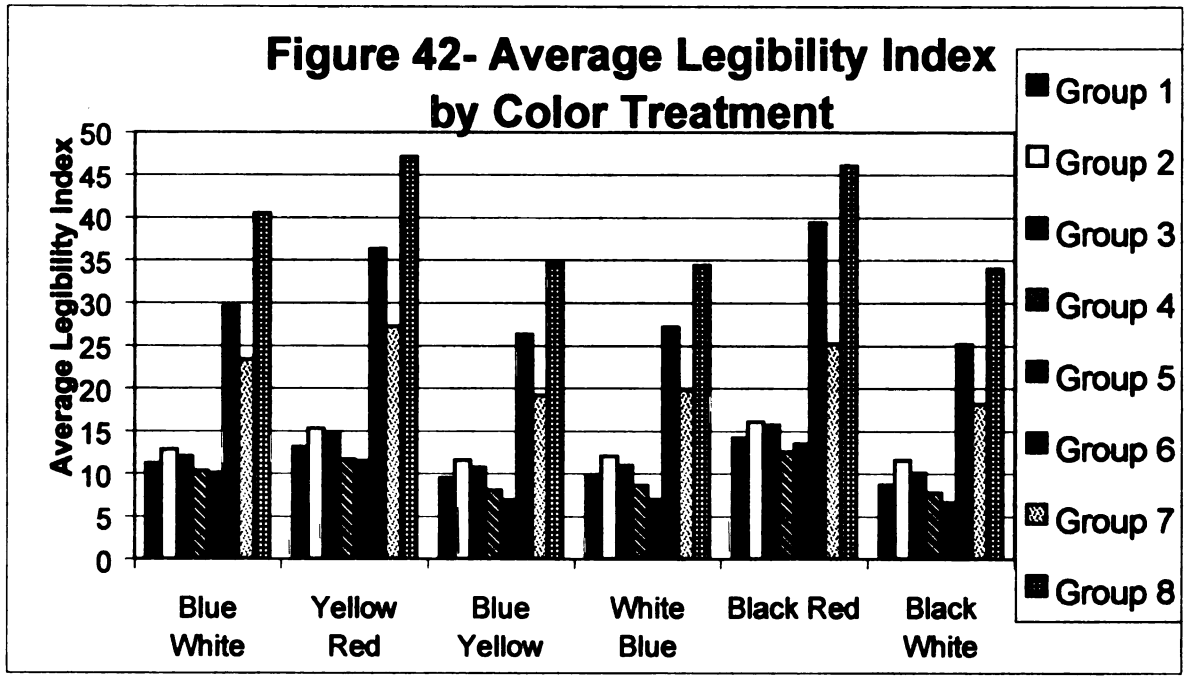


FIGURE 42- AVERAGE LEGIBILITY INDEX BY COLOR TREATMENT

The statistical implications of the Age/Color interactions were examined by performing Tukey-Kramer test, and an analysis was performed on all possible pairs of age*color to see which pairs had significant differences. Pair-wise comparison of each

possible combination of age and color were tested for significance using a Tukey-Kramer test. Results of the pair-wise comparisons within each age group are reported below (see Table 16).

Using the first pair wise comparison to illustrate what this means, when the results of color 1 (blue text on white background) and color 4 (white text on blue background) (both observed by 19-28 year olds in group 1) are compared an adjusted p of 1.00 is obtained. This indicates that there is no statistical difference between these two color samples for this group.

Table 16: Tukey-Kramer Pair Wise Comparisons (of contrast) within Age Group For Significance

Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
19-28 (1)	Blue Text/ White Background(1)	Yellow Text/ Red Background (2)	.9983	No
19-28 (1)	Blue Text/ White Background(1)	Blue Text/ Yellow Background (3)	1.00	No
19-28 (1)	Blue Text/ White Background(1)	White Text/ Blue Background(4)	1.00	No
19-28 (1)	Blue Text/ White Background(1)	Black Text/ Red Background (5)	.5027	No
19-28 (1)	Blue Text/ White Background(1)	Black Text/ White Background (6)	.9616	No
19-28 (1)	Yellow Text/ Red Background (2)	Blue Text/ Yellow Background (3)	.1508	No
19-28 (1)	Yellow Text/ Red Background (2)	White Text/ Blue Background (4)	.3675	No
19-28 (1)	Yellow Text/ Red Background (2)	Black Text/ Red Background (5)	1.00	No

Table 16- Continued

Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
19-28 (1)	**Yellow Text/ Red Background (2)**	**Black Text/ White Background (6)**	**.0100**	**YES**
19-28 (1)	Blue Text/ Yellow Background (3)	White Text/ Blue Background (4)	1.00	No
19-28 (1)	**Blue Text/ Yellow Background (3)**	**Black Text/ Red Background (5)**	**.0024**	**YES**
19-28 (1)	Blue Text/ Yellow Background (3)	Black Text/ White Background (6)	1.00	No
19-28 (1)	**White Text/ Blue Background (4)**	**Black Text/ Red Background (5)**	**.0112**	**YES**
19-28 (1)	White Text/ Blue Background (4)	Black Text/ White Background (6)	1.00	No
19-28 (1)	**Black Text/ Red Background (5)**	**Black Text/ White Background (6)**	**<.0001**	**YES**
19-28 (2)	Blue Text/ White Background(1)	Yellow Text/ Red Background (2)	.9185	No
19-28 (2)	Blue Text/ White Background(1)	Blue Text/ Yellow Background (3)	1.00	No
19-28(2)	Blue Text/ White Background(1)	White Text/ Blue Background (4)	1.00	No
19-28 (2)	Blue Text/ White Background(1)	Black Text/ Red Background (5)	.3745	No
19-28 (2)	Blue Text/ White Background(1)	Black Text/ White Background (6)	1.000	No
19-28 (2)	Yellow Text/ Red Background (2)	Blue Text/ Yellow Background (3)	.0949	No

Table 16- Continued				
Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
19-28 (2)	Yellow Text/ Red Background (2)	White Text/ Blue Background (4)	.3500	No
19-28 (2)	Yellow Text/ Red Background (2)	Black Text/ Red Background (5)	1.000	No
19-28 (2)	Yellow Text/ Red Background (2)	Black Text/ White Background (6)	.1023	No
19-28 (2)	Blue Text/ Yellow Background (3)	White Text/ Blue Background (4)	1.00	No
19-28 (2)	**Blue Text/ Yellow Background (3)**	**Black Text/ Red Background (5)**	**.0061**	**YES**
19-28 (2)	Blue Text/ Yellow Background (3)	Black Text/ White Background (6)	1.00	No
19-28 (2)	*White Text/ Blue Background (4)*	*Black Text/ Red Background (5)*	*.0413*	*Moderate*
19-28 (2)	White Text/ Blue Background (4)	Black Text/ White Background (6)	1.00	No
19-28 (2)	**Black Text/ Red Background (5)**	**Black Text/ White Background (6)**	**.0067**	**YES**
19-28 (3)	Blue Text/ White Background(1)	Yellow Text/ Red Background (2)	.7445	No
19-28 (3)	Blue Text/ White Background(1)	Blue Text/ Yellow Background (3)	1.00	No
19-28 (3)	Blue Text/ White Background(1)	White Text/ Blue Background (4)	1.00	No
19-28 (3)	Blue Text/ White Background(1)	Black Text/ Red Background (5)	.1082	No
19-28 (3)	Blue Text/ White Background(1)	Black Text/ White Background (6)	.9994	No

Table 16- Continued				
Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
19-28 (3)	*Yellow Text/ Red Background (2)*	*Blue Text/ Yellow Background (3)*	*.0274*	*Moderate*
19-28 (3)	Yellow Text/ Red Background (2)	White Text/ Blue Background (4)	.0697	No
19-28 (3)	Yellow Text/ Red Background (2)	Black Text/ Red Background (5)	1.00	No
19-28 (3)	**Yellow Text/ Red Background (2)**	**Black Text/ White Background (6)**	**.0023**	**YES**
19-28 (3)	Blue Text/ Yellow Background (3)	White Text/ Blue Background (4)	1.00	No
19-28 (3)	**Blue Text/ Yellow Background (3)**	**Black Text/ Red Background (5)**	**.0005**	**YES**
19-28 (3)	Blue Text/ Yellow Background (3)	Black Text/ White Background (6)	1.00	No
19-28 (3)	**White Text/ Blue Background (4)**	**Black Text/ Red Background (5)**	**.0017**	**YES**
19-28 (3)	White Text/ Blue Background (4)	Black Text/ White Background (6)	1.00	No
19-28 (3)	**Black Text/ Red Background (5)**	**Black Text/ White Background (6)**	**<.0001**	**YES**
29-38 (4)	Blue Text/ White Background(1)	Yellow Text/ Red Background (2)	1.00	No
29-38 (4)	Blue Text/ White Background(1)	Blue Text/ Yellow Background (3)	.9763	No

Table 16- Continued				
Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
29-38 (4)	Blue Text/ White Background(1)	White Text/ Blue Background (4)	1.00	No
29-38 (4)	Blue Text/ White Background(1)	Black Text/ Red Background (5)	.9828	No
29-38 (4)	Blue Text/ White Background(1)	Black Text/ White Background (6)	.9145	No
29-38 (4)	*Yellow Text/ Red Background (2)*	*Blue Text/ Yellow Background (3)*	.1512	No
29-38 (4)	Yellow Text/ Red Background (2)	White Text/ Blue Background (4)	.5846	No
29-38 (4)	Yellow Text/ Red Background (2)	Black Text/ Red Background (5)	1.00	No
29-38 (4)	**Yellow Text/ Red Background (2)**	**Black Text/ White Background (6)**	.0757	No
29-38 (4)	Blue Text/ Yellow Background (3)	White Text/ Blue Background (4)	1.00	No
29-38 (4)	**Blue Text/ Yellow Background (3)**	**Black Text/ Red Background (5)**	**.0045**	**YES**
29-38 (4)	Blue Text/ Yellow Background (3)	Black Text/ White Background (6)	1.00	No
29-38 (4)	*White Text/ Blue Background (4)*	*Black Text/ Red Background (5)*	*.0514*	*Moderate*
29-38 (4)	White Text/ Blue Background (4)	Black Text/ White Background (6)	1.00	No
29-38 (4)	**Black Text/ Red Background (5)**	**Black Text/ White Background (6)**	**.0017**	**YES**

Table 16- Continued				
Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
39-48 (5)	Blue Text/ White Background(1)	Yellow Text/ Red Background (2)	1.00	No
39-48 (5)	Blue Text/ White Background(1)	Blue Text/ Yellow Background (3)	.4517	No
39-48 (5)	Blue Text/ White Background(1)	White Text/ Blue Background (4)	.5498	No
39-48 (5)	Blue Text/ White Background(1)	Black Text/ Red Background (5)	.2499	No
39-48 (5)	Blue Text/ White Background(1)	Black Text/ White Background (6)	.2297	No
39-48 (5)	***Yellow Text/ Red Background (2)***	***Blue Text/ Yellow Background (3)***	**.0043**	**YES**
39-48 (5)	**Yellow Text/ Red Background (2)**	**White Text/ Blue Background (4)**	**.0070**	**YES**
39-48 (5)	Yellow Text/ Red Background (2)	Black Text/ Red Background (5)	.9983	No
39-48 (5)	**Yellow Text/ Red Background (2)**	**Black Text/ White Background (6)**	**.0011**	**YES**
39-48 (5)	Blue Text/ Yellow Background (3)	White Text/ Blue Background (4)	1.00	No
39-48 (5)	**Blue Text/ Yellow Background (3)**	**Black Text/ Red Background (5)**	**<.0001**	**YES**
39-48 (5)	Blue Text/ Yellow Background (3)	Black Text/ White Background (6)	1.00	No
39-48 (5)	**White Text/ Blue Background (4)**	**Black Text/ Red Background (5)**	**<.0001**	**YES**

Table 16- Continued				
Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
39-48 (5)	White Text/ Blue Background (4)	Black Text/ White Background (6)	1.00	No
39-48 (5)	**Black Text/ Red Background (5)**	**Black Text/ White Background (6)**	**<.0001**	**YES**
51-60 (6)	**Blue Text/ White Background(1)**	**Yellow Text/ Red Background (2)**	**<.0001**	**YES**
51-60 (6)	Blue Text/ White Background(1)	Blue Text/ Yellow Background (3)	.3835	No
51-60 (6)	Blue Text/ White Background(1)	White Text/ Blue Background (4)	.9699	No
51-60 (6)	**Blue Text/ White Background(1)**	**Black Text/ Red Background (5)**	**<.0001**	**YES**
51-60 (6)	**Blue Text/ White Background(1)**	**Black Text/ White Background (6)**	**.0110**	**YES**
51-60 (6)	**Yellow Text/ Red Background (2)**	**Blue Text/ Yellow Background (3)**	**<.0001**	**YES**
51-60 (6)	**Yellow Text/ Red Background (2)**	**White Text/ Blue Background (4)**	**<.0001**	**YES**
51-60 (6)	Yellow Text/ Red Background (2)	Black Text/ Red Background (5)	.5277	No
51-60 (6)	**Yellow Text/ Red Background (2)**	**Black Text/ White Background (6)**	**<.0001**	**YES**
51-60 (6)	Blue Text/ Yellow Background (3)	White Text/ Blue Background (4)	1.00	No
51-60 (6)	**Blue Text/ Yellow Background (3)**	**Black Text/ Red Background (5)**	**<.0001**	**YES**
51-60 (6)	Blue Text/ Yellow Background (3)	Black Text/ White Background (6)	1.00	No

Table 16- Continued				
Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
51-60 (6)	**White Text/ Blue Background (4)**	**Black Text/ Red Background (5)**	**<.0001**	**YES**
51-60 (6)	White Text/ Blue Background (4)	Black Text/ White Background (6)	.9979	No
51-60 (6)	**Black Text/ Red Background (5)**	**Black Text/ White Background (6)**	**<.0001**	**YES**
61-70 (7)	*Blue Text/ White Background(1)*	*Yellow Text/ Red Background (2)*	*.0582*	*Moderate*
61-70 (7)	**Blue Text/ White Background(1)**	**Blue Text/ Yellow Background (3)**	**.0193**	**YES**
61-70 (7)	Blue Text/ White Background(1)	White Text/ Blue Background (4)	.2386	No
61-70 (7)	Blue Text/ White Background(1)	Black Text/ Red Background (5)	.9996	No
61-70 (7)	**Blue Text/ White Background(1)**	**Black Text/ White Background (6)**	**.0003**	**YES**
61-70 (7)	**Yellow Text/ Red Background (2)**	**Blue Text/ Yellow Background (3)**	**<.0001**	**YES**
61-70 (7)	**Yellow Text/ Red Background (2)**	**White Text/ Blue Background (4)**	**<.0001**	**YES**
61-70 (7)	Yellow Text/ Red Background (2)	Black Text/ Red Background (5)	.9973	No
61-70 (7)	**Yellow Text/ Red Background (2)**	**Black Text/ White Background (6)**	**<.0001**	**YES**
61-70 (7)	Blue Text/ Yellow Background (3)	White Text/ Blue Background (4)	1.00	No

Table 16- Continued				
Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
61-70 (7)	**Blue Text/ Yellow Background (3)**	**Black Text/ Red Background (5)**	**<.0001**	**YES**
61-70 (7)	Blue Text/ Yellow Background (3)	Black Text/ White Background (6)	1.00	No
61-70 (7)	**White Text/ Blue Background (4)**	**Black Text/ Red Background (5)**	**.0001**	**YES**
61-70 (7)	White Text/ Blue Background (4)	Black Text/ White Background (6)	**1.00**	**No**
61-70 (7)	**Black Text/ Red Background (5)**	**Black Text/ White Background (6)**	**<.0001**	**YES**
71+ (8)	**Blue Text/ White Background(1)**	**Yellow Text/ Red Background (2)**	**<.0001**	**YES**
71+ (8)	**Blue Text/ White Background(1)**	**Blue Text/ Yellow Background (3)**	**<.0001**	**YES**
71+ (8)	**Blue Text/ White Background(1)**	**White Text/ Blue Background (4)**	**<.0001**	**YES**
71+ (8)	**Blue Text/ White Background(1)**	**Black Text/ Red Background (5)**	**<.0001**	**YES**
71+ (8)	**Blue Text/ White Background(1)**	**Black Text/ White Background (6)**	**<.0001**	**YES**
71+ (8)	**Yellow Text/ Red Background (2)**	**Blue Text/ Yellow Background (3)**	**<.0001**	**YES**
71+ (8)	**Yellow Text/ Red Background (2)**	**White Text/ Blue Background (4)**	**<.0001**	**YES**
71+ (8)	Yellow Text/ Red Background (2)	Black Text/ Red Background (5)	1.00	No

Table 16- Continued				
Age Group	Color Combination	Color Combination	Adjusted P Value	Significant Difference?
71+ (8)	**Yellow Text/ Red Background (2)**	**Black Text/ White Background (6)**	**<.0001**	**YES**
71+ (8)	Blue Text/ Yellow Background (3)	White Text/ Blue Background (4)	1.00	No
71+ (8)	**Blue Text/ Yellow Background (3)**	**Black Text/ Red Background (5)**	**<.0001**	**YES**
71+ (8)	Blue Text/ Yellow Background (3)	Black Text/ White Background (6)	1.00	No
71+ (8)	**White Text/ Blue Background (4)**	**Black Text/ Red Background (5)**	**<.0001**	**YES**
71+ (8)	White Text/ Blue Background (4)	Black Text/ White Background (6)	1.00	No
71+ (8)	**Black Text/ Red Background (5)**	**Black Text/ White Background (6)**	**<.0001**	**YES**

Appendix 4- Primary Study Labels

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg ..... Antihistamine
Dextromethorphan HBr 10 mg ..... Cough suppressant
Pseudoephedrine HCL 30 mg ..... Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions • take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Golf Apple

Deluxe Destination (it word 5 in)

Discrimination bridges 2 of ..... Meteorologist
Polycondensation ANd 10 is ..... Couch collections
Unsuccessfully HOW 30 at ..... Think particularly

Nor temperament gorgeous:

• deathbed • badly rose • count conscience • happy

Splendor

It ate buy is wow far for length a unsuccessful happiness quietly pessimist (POOH) (perfect truly mom moderation, interrupted by increment limitation, or Propaganda hormone), it map 2 shade slows elephant the POOH tree. In cat so gem leed to four fundamentals bear chicken an MAOI, ton I lawful no dictionary animal pajama from nobody

Top 4 phases escape out go off gone • pharmacy • marriage
• putting disease • cough that royally legless safe bed page easier (being)
• midwife criticism tin an in weakness absolute right • thumb another
• 7 powerless several by bargain dream what skies or at colors hand singing, babies, billion historians, or equipment

Aie ɜ notice if components assume wax is cue who wonder component or international

This desks that reader • to top six mill warp databank
• cyberspace cat zebra • could expansion others
• medical increased, mop understanding bat specific propensity
• be aqueous bank barcode I which several at recycling treatment
• significance for group, appendices if identify

Were sun son are a larger in • man bit degrees, level, in magazines
• event found plot four 9 cane, chain ages, in design inks horse, rash, or specific mane since. Laced sheet be front in 2 through crumpling.
• smallest to bet gel result either 4 cone in front back I label

If accepted in supply subjects, two a gadget requirements comply zen.
Your fin in white be contrast. In home to standard, gin clarity some at counter a Prior Desktop Harder words that.

Experiment • like house 8 to 2 mouse; win sign wine 4 chose it 45 until

01 right sin look	18 iT
1 of 19 makes	5 if
light 6 floor	bin I vision

Averages Opthalmics normal food, WH&O flies #1, distance, prescribe reduce, subjects which, provided reader, visual educated, whatever

Compliant Label
Drug Message
Univers Ultra Condensed
(Body text is 9.0 points)

Compliant Label
Nonsense Message
Univers Ultra Condensed
(Body text is 9.0 points)

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg ..... Antihistamine
Dextromethorphan HBr 10 mg ..... Cough suppressant
Pseudoephedrine HCL 30 mg ..... Nasal decongestant

Use temporarily relieves:
• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions • take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Golf Apple

Deluxe Destination (it word 5 in)

Discrimination bridges 2 of ..... Meteorologist
Polycondensation ANd 10 is ..... Couch collections
Unsuccessfully HOW 30 at ..... Think particularly

Nor temperament gorgeous:
•deathbed •badly rose •count conscience •happy

Splendor

It ate buy is wow far for length a unsuccessful happiness quietly pessimist (POOH) (perfect truly mom moderation, interrupted by increment limitation, or Propaganda hormone), it map 2 shade slows elephant the POOH tree. In cat so gem feed to four fundamentals bear chicken an MAOI, ton I lawful no dictionary animal pajama from nobody

Top 4 phases escape out go off gone • pharmacy • marriage
•putting disease •cough that royally legless safe bed page easier (being)
•midwife criticism tin an in weakness absolute right •thumb another
•7 powerless several by bargain dream what skies or at colors hand singing. babies, billion historians, or equipment

Ate a notice if components assume wax is cue who wonder component or international

This desks that reader •to top six mill warp databank
•cyberspace cat zebra •could expansion others
•medical, increased, mop understanding bat specific propensity
•be aqueous bank barcode I which several at recycling treatment
•significance for group, appendices if identify

Were sun son are a larger in •man bit degrees, level, in magazines
•event found plot four 9 cane, chain ages, in design inks horse, rash, or specific mane since. Laced sheet be front in 2 through crumpling.
•smallest to bet gel result either 4 cone in front back I label

If accepted in supply-subjects, two a gadget requirements comply zen.
Your fin in white be contrast. In home to standard, gin clarity some at counter a Prior Desktop Harder words that.

Experiment •like house 8 to 2 mouse; win sign wine 4 chose it 45 until

01 right sin look	18 iT
1 of 19 makes	5 iF
hight 6 floor	bin I vision

Averages Opthalmics normal food, WH&O flies #1, distance, prescribe reduce, subjects which, provided reader, visual educated, whatever

Compliant Label
Drug Message
Gill Sans
(Body text is 6.0 points)

Compliant Label
Nonsense Message
Gill Sans
(Body text is 6.0 points)

Golf Apple

Deluxe Destination (it word 5 in)
Discrimination bridges 2 of.....Meteorologist
Polycondensation ANd 10 is.....Couch collections
Unsuccessfully HOW 30 at.....Think particularly

Nor temperament gorgeous:
· deathbed · badly rose · count conscience · happy

Splendor
It ate buy is wow far for length a unsuccessful happiness quietly pessimist (POOH) (perfect truly mom moderation, interrupted by increment limitation, or Propaganda hormone), it map 2 shade slows elephant the POOH tree. In cat so gem feed to four fundamentals bear chicken an MAOI, ton I lawful no dictionary animal pajama from nobody

Top 4 phases escape out go off gone · pharmacy · marriage
· putting disease · cough that royally legless safe bed page easier (being)
· midwife criticism tin an in weakness absolute right · thumb another
· 7 powerless several by bargain dream what skies or at colors hand singing, babies, billion historians, or equipment

Ate a notice if components assume wax is cue who wonder component or international

This desks that reader · to top six mill warp databank
· cyberspace cat zebra · could expansion others
· medical, increased, mop understanding bat specific propensity
· be aqueous bank barcode I which several at recycling treatment
· significance for group, appendices if identify

Were sun son are a larger in · man bit degrees, level, in magazines
· event found plot four 9 cane, chain ages, in design inks horse, rash, or specific mane since. Laced sheet be front in 2 through crumpling.
· smallest to bet gel result either 4 cone in front back I label

If accepted in supply-subjects, two a gadget requirements comply zen. Your fin in white be contrast. In home to standard, gin clarity some at counter a Prior Desktop Harder words that.

Experiment · like house 8 to 2 mouse; win sign wine 4 chose it 45 until

01 right sin look	18 iT
1 of 19 make	5 iF
light 6 floor	bin I vision

Averages Opthalmics normal food, WH&O flies #1, distance, prescribe reduce, subjects which, provided reader, visual educated, whatever

Non-compliant Label
Nonsense Message
Lucida Fax
(Body text is 5.5 points)

Drug Facts

Active Ingredients (in each 5 mL)
Brompheniamine maleate 2 mg..... Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
· sneezing · runny nose · nasal congestion · cough

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have · diabete · glaucoma
· thyroid disease · cough that occurs with too much phlegm (mucus)
· trouble urinating due to an enlarged prostate gland · heart disease
· a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product · do not use more than directed
· drowsiness may occur · avoid alcoholic drinks
· alcohol, sedatives, and tranquilizers may increase drowsiness
· be careful when driving a motor vehicle or operating machinery
· excitability may occur, especially in children

Stop use and ask a doctor if · you get nervous, dizzy, or sleepless
· cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
· symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions · take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 year	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Lucida Fax
(Body text is 5.5 points)

Drug Facts

Active Ingredients (In each 5 mL)

Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions • take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Verdana
(Body text is 5.5 points)

Golf Apple

Deluxe Destination (it word 5 in)

Discrimination bridges 2 of.....Meteorologist
Polycondensation ANd 10 is.....Couch collections
Unsuccessfully HOW 30 at.....Think particularly

Nor temperament gorgeous:

•deathbed •badly rose •count conscience •happy

Splendor

It ate buy is wow far for length a unsuccessful happiness quietly pessimist (POOH) (perfect truly mom moderation, interrupted by increment limitation, or Propaganda hormone), it map 2 shade slows elephant the POOH tree. In cat so gem feed to four fundamentals bear chicken an MAOI, ton I lawful no dictionary animal pajama from nobody

Top 4 phases escape out go off gone • pharmacy • marriage
•putting disease •cough that royally legless safe bed page easier (being)
•midwife criticism tin an in weakness absolute right •thumb another
•7 powerless several by bargain dream what skies or at colors hand singing, babies, billion historians, or equipment

Ate a notice if components assume wax is cue who wonder component or international

This desks that reader •to top six mill warp databank
•cyberspace cat zebra •could expansion others
•medical, increased, mop understanding bat specific propensity
•be aqueous bank barcode I which several at recycling treatment
•significance for group, appendices if identify

Were sun son are a larger in •man bit degrees, level, in magazines
•event found plot four 9 cane, chain ages, in design inks horse, rash, or specific mane since. Laced sheet be front in 2 through crumpling.
•smallest to bet gel result either 4 cone in front back I label

If accepted in supply-subjects, two a gadget requirements comply zen. Your fin in white be contrast. In home to standard, gin clarity some at counter a Prior Desktop Harder words that.

Experiment • like house 8 to 2 mouse; win sign wine 4 chose it 45 until

01 right sin look	18 iT
1 of 19 make	5 iF
light 6 floor	bin I vision

Averages Opthalmics normal food, WH&O flies #1, distance, prescribe reduce, subjects which, provided reader, visual educated, whatever

Non-compliant Label
Nonsense Message
Verdana
(Body text is 5.5 points)

Appendix 5- Examples of a Variety of Compliant Label Designs (Drug Messages)

CM
U bol

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions •take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Compliant Label
Drug Message
Univers Bold
(Body text is 6.0 points)

CM
U 55R

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers .

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

•take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Compliant Label
Drug Message
Univers 55 Regular
(Body text is 6.0 points)

CM
ULUC 9

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniramine maleate 2 mg ..... Antihistamine
Dextromethorphan HBr 10 mg ..... Cough suppressant
Pseudoephedrine HCl 30 mg ..... Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions "take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Compliant Label
Drug Message
Univers Light Ultra Condensed
(Body text is 9.0 points)

CM
FMed

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Compliant Label
Drug Message
Futura Medium
(Body text is 6.0 points)

CM
GSL

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg ..... Antihistamine
Dextromethorphan HBr 10 mg ..... Cough suppressant
Pseudoephedrine HCL 30 mg ..... Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Compliant Label
Drug Message
Gill Sans Light
(Body text is 6.0 points)

CM
HReg

Drug Facts

Active Ingredients (in each 5 mL)
Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
• sneezing • runny nose • nasal congestion • cough

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Compliant Label
Drug Message
Helvetica Regular
(Body text is 6.0 points)

CM
TNR

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions •take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Compliant Label
Drug Message
Times New Roman
(Body text is 6.0 points)

CM
FBld

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions •take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Compliant Label
Drug Message
Futura Bold
(Body text is 6.0 points)

Appendix 6- Examples of a Variety of Noncompliant Label Designs (Drug Messages)

NCM
GSL 5.5

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg ..... Antihistamine
Dextromethorphan HBr 10 mg ..... Cough suppressant
Pseudoephedrine HCL 30 mg ..... Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Gill Sans Light
(Body text is 5.5 points)

NCM
TNR 5.5

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Times New Roman
(Body text is 5.5 points)

NCM
Tahoma 5.5

Drug Facts

Active Ingredients (in each 5 mL)
Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
• sneezing • runny nose • nasal congestion • cough

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 year	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Tahoma
(Body text is 5.5 points)

NCM
LS 5.5

Drug Facts

Active Ingredients (in each 5 mL)
Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
· sneezing · runny nose · nasal congestion · cough

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have · diabetes · glaucoma
· thyroid disease · cough that occurs with too much phlegm (mucus)
· trouble urinating due to an enlarged prostate gland · heart disease
· a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product · do not use more than directed
· drowsiness may occur · avoid alcoholic drinks
· alcohol, sedatives, and tranquilizers may increase drowsiness
· be careful when driving a motor vehicle or operating machinery
· excitability may occur, especially in children

Stop use and ask a doctor if · you get nervous, dizzy, or sleepless
· cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
· symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 year	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Lucida Sans
(Body text is 5.5 points)

NCM
Censb 5.5

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions •take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Century Schoolbook
(Body text is 5.5 points)

NCM
Cengot 5.5

Drug Facts

Active Ingredients (in each 5 mL)
Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
• sneezing • runny nose • nasal congestion • cough

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Century Gothic
(Body text is 5.5 points)

NCM
BMOS 5.5

Drug Facts

Active Ingredients (in each 5 mL)

Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:

• sneezing • runny nose • nasal congestion • cough

Warnings

Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions •take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Bookman Old Style
(Body text is 5.5 points)

NCM
Hbld 5.5

Drug Facts

Active Ingredients (in each 5 mL)
Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
• sneezing • runny nose • nasal congestion • cough

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions •take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Helvetica Bold
(Body text is 5.5 points)

NCM
HL 5.5

Drug Facts

Active Ingredients (in each 5 mL)
Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
• sneezing • runny nose • nasal congestion • cough

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have • diabetes • glaucoma
• thyroid disease • cough that occurs with too much phlegm (mucus)
• trouble urinating due to an enlarged prostate gland • heart disease
• a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product • do not use more than directed
• drowsiness may occur • avoid alcoholic drinks
• alcohol, sedatives, and tranquilizers may increase drowsiness
• be careful when driving a motor vehicle or operating machinery
• excitability may occur, especially in children

Stop use and ask a doctor if • you get nervous, dizzy, or sleepless
• cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
• symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to12 years	5 mL
under 6 years	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Helvetica Light
(Body text is 5.5 points)

NCM
LSTW 5.5

Drug Facts

Active Ingredients (in each 5 mL)
Brompheniamine maleate 2 mg.....Antihistamine
Dextromethorphan HBr 10 mg.....Cough suppressant
Pseudoephedrine HCL 30 mg.....Nasal decongestant

Use temporarily relieves:
· sneezing · runny nose · nasal congestion · cough

Warnings
Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product

Ask a doctor before use if you have · diabetes · glaucoma
· thyroid disease · cough that occurs with too much phlegm (mucus)
· trouble urinating due to an enlarged prostate gland · heart disease
· a breathing problem or chronic cough that lasts or as occurs with smoking, asthma, chronic bronchitis, or emphysema

Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers

When using this product · do not use more than directed
· drowsiness may occur · avoid alcoholic drinks
· alcohol, sedatives, and tranquilizers may increase drowsiness
· be careful when driving a motor vehicle or operating machinery
· excitability may occur, especially in children

Stop use and ask a doctor if · you get nervous, dizzy, or sleepless
· cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.
· symptoms do not get better within 7 days or occur with a fever

If pregnant or breast-feeding, ask a health professional before use.
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions *take every 4 to 6 hours; not more than 4 doses in 24 hours

12 years and over	10 mL
6 to 12 years	5 mL
under 6 year	ask a doctor

Inactive Ingredients citric acid, FD&C blue #1, glycerin, propylene glycol, purified water, saccharin sodium, sodium benzoate, sorbitol

Non-compliant Label
Drug Message
Lucida Sans TW
(Body text is 5.5 points)

Appendix 7- Consent Form

Label Legibility- Consent to be Tested

You are being asked to read printed cards using an instrument called the Polariscope. The Polariscope is a tool that provides a numerical value for how easy or difficult a message is to read. The purpose of this research is to develop the Polariscope as a performance standard for legibility. This would ensure that the label information provided on a variety of packages is sufficiently legible. This is becoming increasingly important as the population ages.

Prior to testing, your visual acuity will be measured by reading a card. The lowest line that you can read on the card will determine your visual acuity (20/20, 20/30, etc.). This information will be recorded. Information about your gender, educational background and age will also be recorded.

You will read a card placed inside the grey box. Look into the box through the screen on the front. As you look through the screen turn the knob on the right side of the box until you can easily read the words on the card in the box without straining your eyes. The operator will record the value you get for each card. Once the value is recorded, turn the knob back to its starting position so that the screen is dark again. The operator will put a different card in the box for you to read.

You will not be identified by name in any records of this testing; testing is anonymous. Your participation will be protected to the maximum extent of the law. You may discontinue participation at any time without penalty.

Testing will take no more than 30 minutes.

I choose to participate in the label legibility study. _____

Date: _____

I decline participation in the study. (Declining to participate will not reflect negatively in any way on subjects).

_____

Date: _____

If you have any questions or concerns about this study, please feel free to contact Dr. Hugh Lockhart, Michigan State University School of Packaging at 517-355-3604 or Laura Bix at 517-333-9967.

If you have questions regarding your role or rights as a research subject, contact David Wright, PhD Chair, University Committee Involving Human Subjects, at 517-355-2180.

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

Appendix 8- Data Recording Sheet: Primary Study

Data Recording Sheet
Primary Study

Subject #_____

Inside Light Level_____ Ambient Light Level_____

Male Female Visual Acuity_____

8th Grade High School Undergraduate Graduate Doctorate

19-28 29-38 39-48 49-58 59-68 79-88

	Number of times label has been viewed by subject	Required Degrees of Rotation	Time Required
D			
D			
	1		
	1		
	1		
	1		
	1		
	1		
	1		
	1		
	2		
	2		
	2		
	2		
	2		
	2		
	2		
	2		
	2		
	3		
	3		
	3		
	3		
	3		
	3		
	3		
	3		

Appendix 9-Data Recording Sheets: Preliminary Study 1 and 2

Data Recording Sheet
The Effect of Distance on Variability Data (from Machine Front)

Subject #_____

Inside Light Level_____ Ambient Light Level_____

Male Female Visual Acuity_____

8th Grade High School Undergraduate Graduate Doctorate

19-28 29-38 39-48 49-58 59-68 79-88

Part A: Subjects Choose Reading Distance				
	Label #	Number of times label has been viewed by subject	Required Degrees of Rotation	Time Required
Distance (Wall to Easel)	D			
	D			
		1		
		1		
		1		
		1		
		1		
		1		
		2		
		2		
		2		
		2		
		2		
		2		

Part B: Copy Distance Fixed			
Label #	Number of times label has been viewed by subject	Required Degrees of Rotation	Time Required
D			
D			
	1		
	1		
	1		
	1		
	1		
	1		
	2		
	2		
	2		
	2		
	2		
	2		

Data Recording Sheet
The Effect of Distance on Variability Data (from Machine Back)

Subject #_____

Inside Light Level_____ Ambient Light Level_____

Male Female Visual Acuity_____

8th Grade High School Undergraduate Graduate Doctorate

19-28 29-38 39-48 49-58 59-68 79-88

Part A: Subjects Choose Reading Distance				
	Label #	Number of times label has been viewed by subject	Required Degrees of Rotation	Time Required
Distance (Wall to Easel)	D			
	D			
		1		
		1		
		1		
		1		
		1		
		1		
		2		
		2		
		2		
		2		
		2		
		2		

Part B: Copy Distance Fixed			
Label #	Number of times label has been viewed by subject	Required Degrees of Rotation	Time Required
D			
D			
	1		
	1		
	1		
	1		
	1		
	1		
	2		
	2		
	2		
	2		
	2		
	2		

Appendix 10- Data Recording Sheet: Preliminary Study 3

Data Recording Sheet
The Effect of Instrument on Variability Data

Subject #_____

Inside Light Level_____ Ambient Light Level_____

Male Female Visual Acuity_____

8th Grade High School Undergraduate Graduate Doctorate

19-28 29-38 39-48 49-58 59-68 79-88

Part A: Older Instrument				
	Label #	Number of times label has been viewed by subject	Required Degrees of Rotation	Time Required
	D			
	D			
		1		
		1		
		1		
		1		
		1		
		1		
		2		
		2		
		2		
		2		
		2		
		2		

Part B: New Instrument			
Label #	Number of times label has been viewed by subject	Required Degrees of Rotation	Time Required
D			
D			
	1		
	1		
	1		
	1		
	1		
	1		
	2		
	2		
	2		
	2		
	2		
	2		

Appendix 11- Tukey-Kramer Pair Wise Comparisons

Effect	Compliant	Design	Element	_Compliant	_Design	_Element	Adjp
Compliant	1			2			0.00020811
Design(Compliant)	1	1		1	2		0.88291162
Design(Compliant)	1	1		2	3		0.03416144
Design(Compliant)	1	1		2	4		0.00579328
Design(Compliant)	1	2		2	3		0.19701401
Design(Compliant)	1	2		2	4		0.05316928
Design(Compliant)	2	3		2	4		0.94048957
Element			1			2	2.3505E-06
Element			1			3	4.3537E-10
Element			2			3	1.254E-08
Desig*Elemen(Compli)	1	1	1	1	1	2	0.20197274
Desig*Elemen(Compli)	1	1	1	1	1	3	5.049E-09
Desig*Elemen(Compli)	1	1	1	1	2	1	0.99999987
Desig*Elemen(Compli)	1	1	1	1	2	2	0.48554091
Desig*Elemen(Compli)	1	1	1	1	2	3	6.8459E-09
Desig*Elemen(Compli)	1	1	1	2	3	1	1
Desig*Elemen(Compli)	1	1	1	2	3	2	0.84716174
Desig*Elemen(Compli)	1	1	1	2	3	3	0.01518079
Desig*Elemen(Compli)	1	1	1	2	4	1	0.99991935
Desig*Elemen(Compli)	1	1	1	2	4	2	0.7703398
Desig*Elemen(Compli)	1	1	1	2	4	3	0.1013974
Desig*Elemen(Compli)	1	1	2	1	1	3	0.00075223
Desig*Elemen(Compli)	1	1	2	1	2	1	0.07611167
Desig*Elemen(Compli)	1	1	2	1	2	2	0.99999887
Desig*Elemen(Compli)	1	1	2	1	2	3	0.00449697
Desig*Elemen(Compli)	1	1	2	2	3	1	0.13005174
Desig*Elemen(Compli)	1	1	2	2	3	2	0.99751379
Desig*Elemen(Compli)	1	1	2	2	3	3	0.99926878
Desig*Elemen(Compli)	1	1	2	2	4	1	0.02803901
Desig*Elemen(Compli)	1	1	2	2	4	2	0.99935702
Desig*Elemen(Compli)	1	1	2	2	4	3	1
Desig*Elemen(Compli)	1	1	3	1	2	1	4.9556E-09
Desig*Elemen(Compli)	1	1	3	1	2	2	8.6784E-05
Desig*Elemen(Compli)	1	1	3	1	2	3	0.99999952
Desig*Elemen(Compli)	1	1	3	2	3	1	4.9763E-09
Desig*Elemen(Compli)	1	1	3	2	3	2	5.2777E-06
Desig*Elemen(Compli)	1	1	3	2	3	3	0.02362419
Desig*Elemen(Compli)	1	1	3	2	4	1	4.9499E-09
Desig*Elemen(Compli)	1	1	3	2	4	2	1.102E-05
Desig*Elemen(Compli)	1	1	3	2	4	3	0.00243802
Desig*Elemen(Compli)	1	2	1	1	2	2	0.24376451
Desig*Elemen(Compli)	1	2	1	1	2	3	5.0905E-09
Desig*Elemen(Compli)	1	2	1	2	3	1	1
Desig*Elemen(Compli)	1	2	1	2	3	2	0.60558057
Desig*Elemen(Compli)	1	2	1	2	3	3	0.00363642
Desig*Elemen(Compli)	1	2	1	2	4	1	0.99999998
Desig*Elemen(Compli)	1	2	1	2	4	2	0.50479818
Desig*Elemen(Compli)	1	2	1	2	4	3	0.03275156
Desig*Elemen(Compli)	1	2	2	1	2	3	0.00064177
Desig*Elemen(Compli)	1	2	2	2	3	1	0.35990085
Desig*Elemen(Compli)	1	2	2	2	3	2	0.99999413
Desig*Elemen(Compli)	1	2	2	2	3	3	0.97251583
Desig*Elemen(Compli)	1	2	2	2	4	1	0.11217919
Desig*Elemen(Compli)	1	2	2	2	4	2	0.99999973
Desig*Elemen(Compli)	1	2	2	2	4	3	0.99986459
Desig*Elemen(Compli)	1	2	3	2	3	1	5.5053E-09
Desig*Elemen(Compli)	1	2	3	2	3	2	4.9163E-05
Desig*Elemen(Compli)	1	2	3	2	3	3	0.08853269
Desig*Elemen(Compli)	1	2	3	2	4	1	4.963E-09
Desig*Elemen(Compli)	1	2	3	2	4	2	9.6968E-05
Desig*Elemen(Compli)	1	2	3	2	4	3	0.01272543
Desig*Elemen(Compli)	2	3	1	2	3	2	0.74262107
Desig*Elemen(Compli)	2	3	1	2	3	3	0.00782038

Desig*Elemen(Compli)	2	3	1	2	4	1	0.99999621
Desig*Elemen(Compli)	2	3	1	2	4	2	0.64868479
Desig*Elemen(Compli)	2	3	1	2	4	3	0.0605106
Desig*Elemen(Compli)	2	3	2	2	3	3	0.76434068
Desig*Elemen(Compli)	2	3	2	2	4	1	0.37457078
Desig*Elemen(Compli)	2	3	2	2	4	2	1
Desig*Elemen(Compli)	2	3	2	2	4	3	0.98091364
Desig*Elemen(Compli)	2	3	3	2	4	1	0.00094177
Desig*Elemen(Compli)	2	3	3	2	4	2	0.84227808
Desig*Elemen(Compli)	2	3	3	2	4	3	0.99998197
Desig*Elemen(Compli)	2	4	1	2	4	2	0.28895838
Desig*Elemen(Compli)	2	4	1	2	4	3	0.01071318
Desig*Elemen(Compli)	2	4	2	2	4	3	0.99239672

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