THE EFFECT OF PACKAGE DISPENSER AND LABEL ON SUNSCREEN APPLICATION

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ABSTRACT

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As skin cancer rates rise, sunscreen use is recommended as a way to decrease the risk of developing skin cancer. Studies show that most consumers of sunscreen do not apply the recommended amount of sunscreen to achieve full protection from UV rays. This study investigates the effect of using two different package dispenser types on human behavior in the context of sunscreen application in an effort to quantify differences in application volume. Additionally, labeling interventions designed to either encourage or discourage application of sunscreen were placed on the bottle to test the effectiveness of using label messaging to influence application amounts. Participants were asked to apply sunscreen from different package styles to their arms and legs and complete a survey regarding the perceived risk of developing skin cancer and frequency of sunscreen use and other demographic factors. Results indicate that participants applied more sunscreen from the squeeze bottles than the pump bottles ($p<.0001$), and that there was no evidence of a discernable difference between different labels. Of the personal characteristics included in the model (including age, gender, skin tone saturation, history of sun burn, and study location) worry about developing skin cancer and frequency of sunscreen use were also significant at $\alpha=.05$. The overall findings of this study was packaging design affects sunscreen application practices, but labeling warnings are less influential.

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" To all the little girls watching… never doubt that you are valuable and powerful and deserving of every chance and opportunity in the world."

- Hillary Rodham Clinton

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Chapter 1 Introduction

Protecting the skin from the sun is not a modern notion. Ancient Egyptians, Greeks, and Native Americans utilized a variety of plants and oils in attempts to protect their skin from the sun (Aldahan, AS et. all). Modern sunscreen has advanced in formulation and added a secondary function. The earliest and primary function of sunscreen is to prevent sunburn, and the second is to prevent skin cancer and premature signs of aging. The precursors to modern sunscreen, lotions designed to prevent sunburn, were developed in the 1930's, modern broad-spectrum sunscreen was developed in the 1970's (Aldahan, AS et. all). Broad Spectrum refers to the ability of the lotion to protect the skin from both ultraviolet A radiation (UVA) and ultraviolet B radiation (UVB). While both UVA and UVB can cause skin cancer, premature aging, and sunburn, UVB is the primary source of sunburn (FDA Sheds Light on Sunscreen 2011). UVA has been found to have a stronger link to skin cancer than UVB. (Kuritky, L. A and Beeker J., 2015). There are two subtypes of broad-spectrum sunscreen: physical sunscreens with the ingredients zinc or titanium oxide that work by physically blocking radiation from penetrating the skin, and chemical sunscreens with UV filtering chemical compounds derived from carbon that work by absorbing the harmful radiation (Mitchell, Heidi, 2014). The level of protection the sunscreen product provides is measured in the unit of Sun Protection Factor (SPF), and the relationship between the SPF value and the amount of protection provided is exponential (Faurschou & Wulf, 2007).

Regular use of sunscreen is recommended to reduce the risk of sunburn and the development of skin cancers. Routine use of sunscreen starting in childhood has

been found to reduce the risk of developing non-melanoma skin cancers by as much as 78%, (Stern, Weinstein, & Baker, 1986) but, like most drug products, there are also inherent risks to consumers which accompany the benefits.

There are multiple, documented risks associated with sunscreen usage. The primary risk is that people do not apply adequate amounts of sunscreen, demanded via application requirements, to achieve the appropriate SPF. SPF is calculated based on the assumption that consumers will apply a layer of sunscreen that is 2mg/cm, but in reality consumers have been measured to apply approximately 0 .5 mg/cm^2 (Srinivas, C et. all, 2006)(Isedeh, Osterwalder, & Lim, 2013).Improper dosage of sunscreen can lead to a myriad of unwanted effects associated with a lack of full protection. Without the application of a full dosage amount, the sunscreen is rendered less effective at preventing skin cancer, premature signs of aging, and sunburn (Stern, Weinstein, & Baker, 1986).The amount of sunscreen applied by the average consumer has been indicated to be the equivalent of applying a sunscreen with a quarter of the SPF reported on the label (Kuritky, L. A and Beeker J., 2015). In addition to proper dosage, in order to maintain full sun protection, reapplication of sunscreen is recommended every 2 hours, or after sweating or swimming (FDA Sheds Light on Sunscreen, 2011).

Secondary risks linked to sunscreen use concern factors related to both consumer health and the environment. It has been suggested that the UV filtering ingredients contained within some sunscreens have the potential to, in high doses, act as endocrine disruptors. Recently published research on the effect of UV filtering ingredients on the development of Chironomus riparius, a common insect used for

chemical testing, found an increased risk of disruption of stress and sex hormones during the embryotic phase compared to the larvae stage (Ozáez, Morcillo, & Martínez-Guitarte, 2016)(Krause et al., 2012). While evidence is not conclusive that endocrine disruptors are a proven risk to humans, there is evidence that compounds found in sunscreen act as harmful endocrine disruptors in small mammals, amphibians, insects and fish populations (Waring & Harris, 2005). The specific UV filtering ingredients that are thought to be Endocrine Disruptors are: benzophenone-3 (BP-3), 3-benzylidene camphor (3-BC), 3-(4- methyl-benzylidene) camphor (4-MBC), 2-ethylhexyl 4-methoxy cinnamate (OMC), Homosalate (HMS), 2-ethylhexyl 4-dimethylaminobenzoate (OD- PABA) and 4-aminobenzoic acid (PABA). These ingredients are absorbed through the skin when sunscreen is applied, and have been found in urine and breast milk samples. [8] Additionally, current research is exploring whether or not vulnerable populations, such pediatric users, are at particular risk of harm.

Research Objectives

Since there are potential risks associated with both applying either too little sunscreen or too much sun protection, we became interested in the factors that affect application amount; specifically, the influence of label warnings and the physical structure of the package. What is the effect of packaging type on the amount of sunscreen applied? What is the effect of an alarmist label that alerts the consumer to possible risks associated with nanoparticles compared to a label encouraging generous application on sunscreen usage? What is the combined effect of packaging and labeling? What subject characteristics influence application? Namely, does personal history (e.g. skin tone, family history of skin cancer, experience with severe sunburns) significantly affect the amount of sunscreen applied? This research will investigate these questions.

Chapter 2 Literature Review

Regulation of Sunscreen

In the United States, the Food and Drug Administration (FDA) regulates sunscreen as an over the counter drug (OTC). Sunscreen was first regulated as a drug in 1978 (FDA "Sunscreen Drug Products for Over-The-Counter Human Use," 1978). The Final Rule [21 CFR Part 352], "Sunscreen Drug Products for Over-The-Counter Human Use," details the ingredients generally recognized as safe (GRAS), labeling requirements specific to products with varied levels of UV protection, and testing procedures for getting new products approved, but does not include product packaging suggestions or discussion (FDA "Sunscreen Drug Products for Over-The-Counter Human Use,"1978). Labeling requirements include:

- A drug facts panel
- The sun protection factor (SPF) within a range of SPF 15 to SPF 50+
- Water resistance claims with specific time limits
- A warning alerting the consumer the product does not protect against skin cancer or aging if the product has an SPF between 2-14.

Additionally, the regulation indicates that manufacturers may not use the phrases "sunblock", "sweat proof", or "waterproof" since those terms have been deemed misleading to the consumer (FDA Sheds Light on Sunscreen, 2011). In addition to these labeling guidelines, there are guidance documents published in the Federal Register with lists of approved ingredients and current best practices for manufacturing (FDA "Sunscreen Drug Products for Over-The-Counter Human Use", 1978) More recently (2011), the FDA expressed interest in better understanding the

relationship of packaging for these products and consumer behavior. Specifically, how different dispenser types, primarily lotion dispensers, compare to both manual and aerosol spray dispensers, and, ultimately, the influence they have on consumers' usage of sunscreen products (Tan, 2011). Our review of the literature found a dearth of information on this topic, in spite of the need expressed by the Agency.

There are a variety of sunscreen products available on the market, but the FDA only allows those products in oil, cream, lotion, gel, butter, paste, ointment, stick, or spray form without special approval. The FDA recognizes the following delivery mechanisms for sunscreen as needing special approval before marketing: powder, wipe, towellete, shampoo or body wash form (Tan, 2011). The number of different application forms available makes the question of how varied package designs influence consumer adherence to protection guidelines important.

Perception of Warning Labels

The warning process is described by Rogers, Lamson, and Rousseau as "four components: notice, encode, comprehend, and comply," (Rogers, Lamson, & Rousseau, 2000). Other models, such as the Model of the Effects of Product Warning Labels proposed by DeTurck, Rachlin, and Young, have expanded the four steps to include a preliminary step of exposure (deTurck, Rachlin, & Young, 1994). The Model of the Effects of Product Warning Labels is composed of the following steps: exposure, awareness, comprehension, perception of risk, and compliance (deTurck, Rachlin, & Young, 1994). Under these models, steps are serialized; that is, each is prerequisite to the next. Researchers have expanded on the notion of the different stages of the warning process to include the idea that warnings consist of three

parts: a signal word to alert, a description of the hazard, and instructions for compliance (Rogers, Lamson, & Rousseau, 2000). The signal word, related to the noticing or awareness step is intended to attract attention to the warning, which will include a description, information about any risks and instructions for mitigating the same. The ultimate intention is compliance, whereby the consumer uses actionable steps to mitigate the risk.

Rogers et al. propose there are two, broad categories of input variables that affect warning perception: personal variables, which are specific to the individual viewers, and warning variables, that are unique to the specific warnings being perceived. Some examples of personal and warning attributes are included below in Table 1, but these lists are not exhaustive (Rogers, Lamson, & Rousseau, 2000).

Table 1. Attributes that Impact Warning Perception[1]

Personal Attributes		Warning Attributes	
Age	Symbol Comprehension	Color	Font size
Familiarity	Information Seeking	Emphasis	Layout
Hazard Perception	Control Perception	Interactivity	Length
Gender	Modeling	Placement	Text Complexity
Vision	Risk-taking Style	Shape	Tone
Cost of Compliance		Size	Signal Word
		Type Style	Explicitness
		Statement of Hazard	Symbology

Personal variables include things like: age, familiarity, hazard perception, gender, vision, cost of compliance, risk-taking style, and level of health literacy

[1] Adapted from Rogers et al

(Rogers, Lamson, & Rousseau, 2000)(Davis et al., 2006). Warning variables are attributes of how the warning is presented. Examples include: color, emphasis, interactivity, placement, shape, size, signal word, explicitness, font size, layout, length, text complexity, and tone (Rogers, Lamson, & Rousseau, 2000). Attributes of both the warning and its target audience interact to produce different outcomes. For example, if a person with vision impairment is the target of the warning, warning variables such as font size are of paramount importance. Similarly, if a person with low literacy skills is presented a warning at a reading level beyond their capabilities, the effectiveness of the symbology utilized is vital.

One of the most important factors in warning perception is hazard perception. Hazard perception is defined as a "subjective level of danger" (Rogers, Lamson, & Rousseau, 2000), which can be described as the perceived likelihood of risk or how dangerous a person perceives an object or action to be, as opposed to how dangerous an object or action actually is. Wogalter, Brelsford, Desaulniers and Laughery found that the willingness of a person to read the warning is positively correlated with the perception of hazard despite level of familiarity (Wogalter, Brelsford, Desaulniers, & Laughery, 1991). This is crucial to warning perception because the literature shows that people tend to be less likely to notice warnings on products they are comfortable with (Rogers, Lamson, & Rousseau, 2000).This phenomenon could partially explain the number of people that noticed, and encoded the warnings on the sunscreen bottles tested in this study, since familiarity with sunscreen was one of the screening requirements for the subject pool. (This will be discussed in more detail in Chapters 3 and 4.)

Fear Motivation and Risk Perception

Fear motivation describes behavior driven by an aroused emotional state due to the threat of impending harm (Maddux & Rogers, 1983). Feather defines Fear Motivation as "motivation to avoid a negative incentive or punishment,"(Feather, 1963).This theory assumes humans will act in their own self-interest, through actions with the goal of protecting themselves from the impending harm (Maddux & Rogers, 1983). Within the context of this study, Fear Motivation relates to acting to avoid the negative consequences of unprotected UV exposure, such as a sunburn or skin cancer. Whether or not they choose to act depends on their self-efficacy, or belief about their own capability to perform the behavior presented to them as necessary. Bandura argues that the stronger the self-efficacy, the more likely they are to make a change (Bandura & Adams, 1977). Thus, self-efficacy is positively linked to behavioral change, meaning as self-efficacy increases, the likelihood that a person will follow through on changing a behavior also increases (Feather, 1963). Similarly, whether or not one continues to act in a manner motivated by fear depends on whether or not their fears are confirmed(Maddux & Rogers, 1983). In the context of this study, someone who does not wear sunscreen regularly but does not get sunburned, might not be motivated to apply sunscreen, even if avoiding sunburn did not influence their risk of developing skin cancer.

Related to the Theory of Fear Motivation is the Theory of Risk Perception. Risk Perception is the study of how humans behave based on how likely they perceive the potential for harm. The fourth wave of risk perception research focused on subjective attributes of individuals, such as having the intent to act cautiously or

perceive hazards (Kluckhohn, 1962). Risk perception is seen as a tie between planned behavior and desired health outcomes, and has been shown to be an important factor in both the planning and execution of sun protection behaviors (Craciun, C et. all 2010). Self-efficacy mediates risk perception and planned behavior. If something, such as sun exposure, is perceived as risky and the person has high self-efficacy, meaning they believe they are capable of mitigating that risk, planned behavior is more likely to be implemented (Feather, 1963).

There are many ways of manipulating risk perception. One of the major approaches to manipulate perception of risk, and germane to this study, is via dissemination of information regarding the possibility of risk and how that information affects the behavioral outcome. How familiar a consumer is with the nature of the product and what information is included on the product warning labels affect the perception of risk (Leonard & Hill, 1993). In a study examining consumer perception of risks associated with genetically engineered soy beans, researchers found that if the benefits associated with a product or technology are high, the product or technology was perceived as low risk. Meaning, perceived risk can be manipulated by a third factor, simply changing the perceived benefits (Lynne & Ping (2003). This idea has been extrapolated to sunscreen by examining the change in perceived risks based only on the inclusion of warning labeling. One study used labeling of sunscreens made with nanotechnology as a proxy variable for the labeling of genetically modified foods (Siegrist & Keller, 2011).

Siegrist and Keller split participants into six groups and varied the labeling stimuli each group was exposed to. The different stimuli were: a picture of a

sunscreen bottle without a nanotechnology label (control), a picture of a sunscreen bottle with a nanotechnology label, and then four different combinations of the picture of a sunscreen bottle with the nanotechnology label and either literature describing: nanotechnology in general terms, the same general information combined with information about the risks, only the risk literature, or literature on the benefits of nanotechnology. Thus, there were six treatments: control, the treatment picture without literature, and then four different treatment pictures and literature combinations. While there was a statistically significant difference between the control sunscreen label and the experimental labels alerting the consumer to the presence of nanoparticles, no statistical difference was evident between the perceived risks of the five bottles of sunscreen with the label indicating nanotechnology, despite the different educational pamphlets included with the different treatments. In other words, simply adding the label alerting consumers to the presence of nanoparticles increased the perceived risk, whether or not additional literature about risks or benefits was included (Siegrist & Keller, 2011).

Warning and Personal Characteristics in Packaging

There are many components of packaging that influence a person's perception of the product. The size, shape, color, labeling, and context all convey different information about what the package contains, how to access the product, what to do with the empty package after its contents are used, and many more possible messages (Silayoi & Speece, 2007). An optimally designed package immediately conveys information about opening, dispensing, usage, closing, storage, and disposal (De La Fuente, Gustafson, Twomey, & Bix, 2015). The context

surrounding a task, for instance, time constraints facing the consumer and the number of alternatives surrounding the product, affect the interaction that occur and the behaviors that are exhibited (Silayoi & Speece, 2007). The definition of context need not be narrowly defined as those encompassed in the physical environment, but can also include things within the social context including who the product will be used by or the opinion of others (De La Fuente, 2013).

One theory about the interactions between human processing systems and package messaging systems is the Human Package Interaction Model (HPIM). Proposed by de la Fuente (De La Fuente, 2013). The model purports people interact with packaging using perception, cognition, and motor functions to process information using five steps exposure, perception, encodation, comprehension, and execution to accomplish a given task, such as dispensing the product (De La Fuente, 2013).

HPIM, when applied in the context of package dispensing mechanisms, interacts with Affordance Theory to provide a theory that explains consumer behavior and package use. According to Affordance theory, as applied to physical objects by Don Norman, an affordance can be defined as, "the relationship between a physical object and a person…An affordance is a relationship between the properties of an object and the capabilities of the agent that determine just how the object could possibly be used,"(Norman, D. A. 2013). In an earlier article, Norman states, " Affordances specify the range of possible activities, but affordances are of little use if they are not visible to the users," (Norman, 1999). A perceived affordance differs from the traditional idea of an affordance by having the additional

requirement of allowing for the perception of a specific intended action, rather than traditional idea of only the capability to preform an action (Norman, 2004). For example, a handle affords gripping or a button affords pushing. Within the context of this study, the pump bottle will afford metered dispensing of the product more strongly than the bottle without a pump.

The different components of a package communicate different information about the different actions the package affords the user to take, which is why the messaging, both covert and overt, is important to consider during the design process (Norman, 2004). Thus, the label on the bottle is not the only component of a sunscreen package that communicates information to the consumer, each component should be chosen carefully.

The Children and Sunscreen Study

In 2012, researchers at the University of Queensland, in the public health department launched an investigation into the application of children's sunscreen. Researchers investigated the effects the package dispenser type and the age of the child on the thickness of the application (Diaz, Neale, Kimlin, Jones, & Janda, 2012). Families that participated were given three packaging alternatives filled with sunscreen, and the directions to use one each week for a period of three weeks. The package alternatives were a squeeze bottle, a pump bottle and a roll on; all alternatives were different sizes and volumes. The child participants were instructed to apply the sunscreen to themselves as their first daily application. The children that participated in this study ranged in age from 7-12 years old.

The methods used in the Queensland study to calculate the amount of sunscreen applied by the children involved weighing the packages and using a formula to calculate the surface area of the entire body using height and weight. The sunscreen was weighed before it was distributed to the participants, and again at the end of the study. The differences in weight of the packages were used in conjunction with the surface area of the body to calculate an average application thickness. Since no researchers supervised or weighed the packages while the participants were using them, and the packages were with the families for a period of three weeks, the thickness of the individual applications unable to be known.

The study concluded that package type statistically significantly affected the amount of sunscreen the children applied to themselves, regardless of age or other demographic variables. The pump had the thickest average application, followed by the squeeze bottle. The roll on had the thinnest average application. The children still only applied about half of the recommended dosage; even with the pump bottle (Diaz et al., 2012). The study presented herein differs from the Children and Sunscreen Study by targeting an adult population and looking at the covariant of labeling. The hypothesis that the package type will influence application thickness is based on The Children and Sunscreen Study.

Chapter 3 Methods and Materials

In order to better understand the potential effects of packaging and labeling on the amount of sunscreen applied by users, 96 research participants were recruited to participate in the study presented herein during the summer of 2016. Forty-eight participants between the ages of 18- 36 were recruited using the College of Communication Arts and Science SONA system and tested in laboratories at Michigan State University (MSU). A second population of subjects was recruited California Polytechnic State University through in-class announcement provided in the Graphic Communications course "Consumer Packaging", the Industrial Technology and Packaging courses "Packaging Fundamentals" and "Supply Chain Management in Manufacturing and Services", and the Business course "Information Systems".

The objective of this study was to investigate the effects of packaging and labeling to better understand how consumers of sunscreen determine the amount of sunscreen to use, and what factors influence that amount of sunscreen they self-apply. Specifically, a dosing pump system was compared to a non-dosing squeeze bottle; these were crossed with two levels of label messaging (Figure 1), for a total of four test treatments.

Materials

- 8 oz. Natural Low Density Polyethylene Boston Round Bottles, SKS Bottle & Packaging International (Watervliet, New York)
- Polypropylene Pumps, SKS Bottle and Packaging International
- Polypropylene Flip Top Spout Caps, SKS Bottle and Packaging International
- Fisher Science Education ™ Portable Balance, Capacity: 300g, Readability: 0.001g
- Rocky Mountain Sunscreen's SPF 30 Kids Broad Spectrum Sunscreen
- Adhesive Vinyl labels, FedEx (Memphis, Tennessee)
- Measuring Tape
- Baby Wipes

Recruitment of Participants

A total of 96 participants were recruited from the two locations of test, Michigan State University and California Polytechnic State University SLO. Participants were recruited through multiple methods in accordance with the Internal Review Board (IRB) approvals from both Michigan State and California Polytechnic State University of San Luis Obispo documented as **#16-574.** At Michigan State University, the primary method of recruiting students was the College of Communication Arts and Science SONA System. The study was posted to the paid pool with an incentive of $10 and to the student pool with an incentive of 0.75 SONA credit. At California Polytechnic State University SLO, participants were recruited by presenting the opportunity to participate in the study in the multiple classes listed above and received $10 as an incentive to participate in the study.

In order to be eligible to participate in the study, subjects had to be between the ages of 18 and 36 years old, be sunscreen users, and have no history of a skin condition such as eczema. Participants between the ages of 18 and 36 belong to the "Millennial" generation[2]. This generational cohort was chosen to assure that consumers were familiar with the application of sunscreen, since they were all born after sunscreen was first regulated by the FDA and were, thus, likely to have lifetime sunscreen usage. Exclusion of participants with history of skin conditions was to protect subjects with sensitive skin from using an unfamiliar product that could potentially result in an adverse reaction. Participants were asked to wear clothing that would facilitate the application of sunscreen to their entire arms and lower legs. T-shirt or tank tops and shorts or knee length skirts were recommended, but it was stressed that any clothing that could be rolled up to allow comfortable application of sunscreen to the entire arm and lower leg was also allowed.

The IRB approved documents, including the consent form that details eligibility criteria, the data sheet created for the study, and the demographic and health history questionnaire the participants were asked to fill out as part of their participation, are included in Appendix A.

[2] Millennial Generation was defined as born between 1980 and 1998. This cohort was chosen because it the oldest members were born after sunscreen was first regulated by the FDA and adopted for wider use, and the youngest members are of the age of majority (18 years old).

Sample Preparation

Four complete sets of the test packages were assembled. Each set of four included a bottle with a pump (hereafter interchangeable with "Dosing Package") and a label advising the application of 9 teaspoons of sunscreen to the entire body (hereafter referred to as "Encouraging Label")(Figure 2), a bottle with a pump and a label indicating the product contained nanoparticles (hereafter referred to as "Discouraging Label")(Figure 3), a bottle with a flip top (hereafter interchangeable with "Non-Dosing Package") advising the application of 9 teaspoons of sunscreen, and a bottle with a flip top indicating it contained nanoparticles.

Figure 1. Package Label Combinations

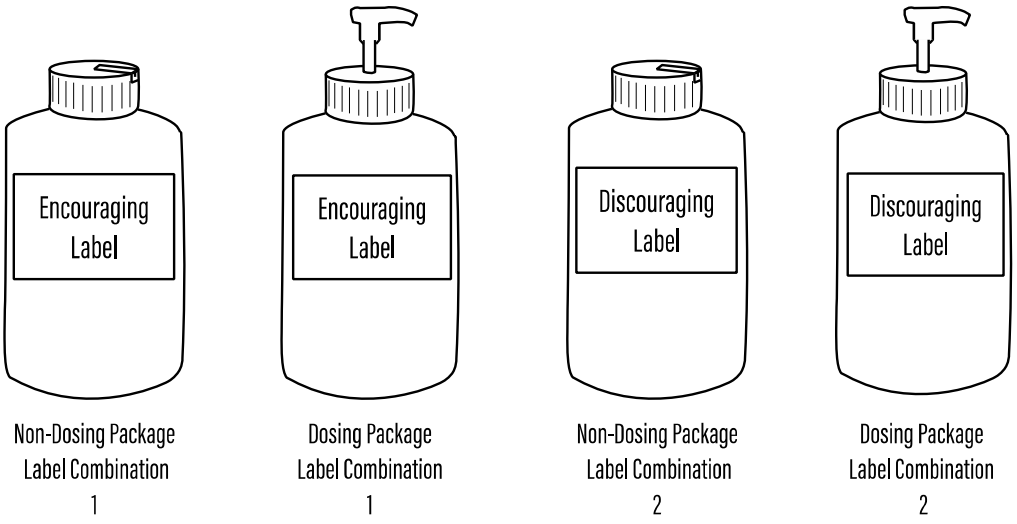
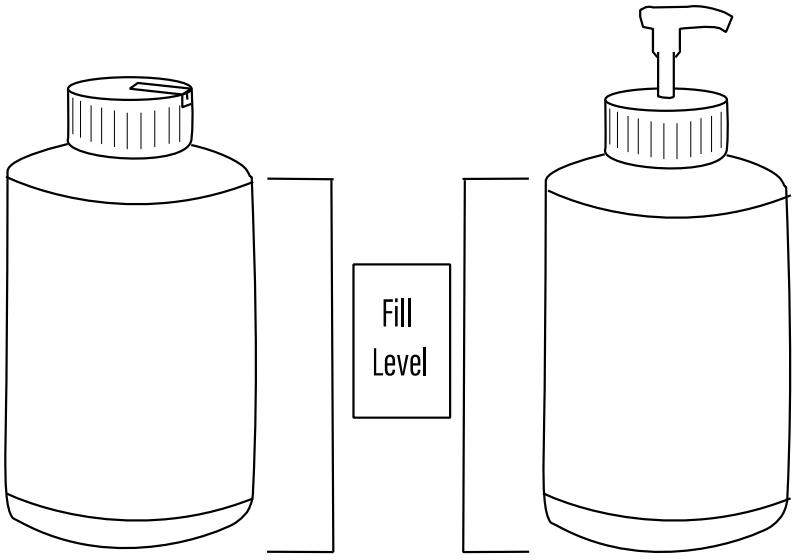


Figure 2. "Encouraging Label" describing effective dosing

Figure 3. "Discouraging Label" describing the presence of nanoparticles

While each block of test packages consisted of four unique bottle/label/dispenser combinations, (two levels of physical structure crossed with two levels of label treatment), a total of sixteen test packages were prepared to rotate throughout the testing in case of any damage to the sunscreen bottles or labels. All bottles were filled to the top of the display panel (i.e. at the shoulder of the bottle, see Figure 4) with the Rocky Mountain Sunscreen between uses. Physical structure of the bottles was chosen as the fill level to account for undetectable inconsistencies with label application and the level of fill was chosen to account for any displacement from adding the pump. The full bottle of sunscreen weighed approximately 298 g. The labels were designed to be the exact height of the display panel of the bottle and wrapped fully around the circumference of the bottle.

Figure 4. Fill Levels of Sunscreen Bottles



As part of staging between participants, filled bottles of sunscreen were weighed and weight was recorded on the data sheet with the corresponding participant number. Staging also included laying out the labels for the order of

sunscreen application to each limb (see Appendix C for the detailed list of the orders sunscreen were applied), and refilling the bottles if their weight dropped below 280g.

Additional preparation for the study included preparing stimuli for the label recall task in the survey by laminating actual size print outs of four additional labels in an attempt to verify that subjects actually viewed each label. Laminated labels indicated as A-F and displayed with laminated print outs of the labels used in the study where the participants sat to fill in the demographic survey. Lastly, in order to help the participants remember the order of body parts to apply the sunscreen to, place cards were for the sunscreen to clarify the application area (left arm, right arm, right leg, left leg). The place cards were rotated as part of the staging for each participant to reflect the order in which they were to apply the sunscreen.

Testing

When participants arrived at the testing facility, the researcher provided them with a consent form and verbally indicated the screening criteria, time commitment, incentive and that they could withdraw at anytime or refuse any testing that made them uncomfortable without penalty. The sunscreen was set up, with the labels facing the participant, in the predetermined application order (based on the predetermined counterbalanced scheme- see Appendix C) presented to them in the order from left to right, on a table. The bottles of sunscreen were set upon place cards with the body part the sunscreen was intended for. The table also had baby wipes, access to a trashcan, and a chair or stool.

After the participants read and signed the consent form, the researcher asked their handedness and walked them through a short exercise in order to determine laterality. The term laterality, often interchangeable with "limb preference" is ,"used to express the preferential use of one limb in voluntary motor acts," (Sadeghi, Allard, Prince, & Labelle, 2000). An example of laterality would be the leg that tends to be on top while sitting cross-legged or the thumb that is on top when hands are clasped. Laterality was determined by asking the participants to clasp their hands together and report which thumb was on top and then to cross their arms and report which arm was on top. This was measured to potentially use as a variable in the model if order of application, and thus which limbs were used to apply the sunscreen, influenced application amount . Handedness was reported as right, left, or ambidextrous. Laterality was reported as "right-right", "right-left", "left-right", or "left-left." For example, if the right thumb was on top when the hands are clasped, and the left arm is on top when the arms are crossed, laterality would be "right-left". This information was recorded on the data collection sheet in Appendix A.

The final information collected before the application of sunscreen was measurements of the circumference of the upper arm (right above the start of the bicep), circumference of the wrist, the length of the arm (from shoulder to wrist), the circumference of the calf (directly below the knee), the circumference of the ankle, and the length of the lower leg (from the bottom of the knee to the ankle). These measurements were recorded from a tape measure with accuracy to the nearest 1/8 of an inch. This information was collected to estimate the surface area where the participants would be applying sunscreen.

The participants were directed to, “Apply the sunscreen to their arms and lower legs as if they would be spending the entire day outside on a sunny day”. Due to the similarity of the label designs, the researcher also instructed the participants, ”While these packages all look the same at first glance, they are different. Please look at each package before applying the sunscreen.” The test plan was developed with the intention of analyzing the differences within each participant rather than across each participant. Because of this, each participant was provided each package-label combination to apply. Since there are four packages with different dispenser-label combinations, each package would be applied a single time, and each limb would receive one application of sunscreen. The sunscreen bottles were refilled between participants once the weight of the package was below 280g.

Each possible order in which each participant could apply the four packages of sunscreen was assigned randomly to a number between 1 and 24. Likewise, the order of which limb the sunscreen could be applied to was also assigned to a number between 1 and 24. The participant number within each block of 24 participants corresponded with the application orders. The test plan is included in Appendix C to better illustrate how the order of application rotated throughout each block of 24 participants. In order to clearly communicate the instructions to the participants, the sunscreen packages were placed on labels with the body part receiving the sunscreen laid out in the order of application starting from right to left. To further clarify which package of sunscreen to use next, the researcher removed the bottles as the participants finished each round of application. Baby wipes were

provided to the participants to clean their hands between each application of sunscreen.

After applying the sunscreen, participants were asked to complete a twelve-question survey. The survey is included in Appendix A as part of the IRB-approved documents. In an effort to screen subjects that had failed to access the label information, the survey started by asking the participants to identify which sunscreens they applied out of six possible sunscreen label possibilities. These six included the two labels that subjects had, indeed seen (figures 2 and 3), and four that they had not (Appendix B). The survey also contained questions pertaining to their personal history of sun burns and skin cancer, frequency regarding sunscreen usage, their perception of risk for developing skin cancer, and demographic questions related to age, gender, skin tone, and parental status. Skin tone was determined by asking the participants to self identify the option that best matched their skin tone from Pantone SkinTone Guide (Pantone LLC Carlstadt, NJ), and record the corresponding value.

The sunscreen packages were weighed after the application of sunscreen, and the final weight was recorded. Notes and observations were also recorded if anything out of the ordinary happened in that particular trial. For example, one participant mistakenly applied sunscreen to the same leg twice, and that error was noted. The total amount of sunscreen applied was calculated by subtracting the final weight of the packaging from the initial weight of the package, as recorded at the prior to the participant's arrival. Any data that was determined to have an

application amount of less than zero grams of sunscreen was removed from analysis due to human error in the recording of the data.

Experimental Design

The experiment was designed as a Counterbalanced Randomized Complete Block. Participants were randomly assigned to the order in which to apply the sunscreens to their limbs based on when they arrived to participate in the study. Since there were 24 possible combinations for both the order of using the different package-label combinations and the order of the limbs sunscreen was applied to, blocks of 24 participants were recruited. Each order of package-label was married to the order of limbs sunscreen was applied to. Post-hoc analysis did not reveal a run order effect on the amount of sunscreen applied and the response was analyzed in units of thickness of application in order to eliminate any application differences due to limb size differences.

Statistical Analysis

The collected data was analyzed using R (R Core Team 2016). Data was fit to a Random Effects Model (Also referred to as a Mixed Linear Model). The response variable of amount of sunscreen applied was analyzed as a thickness in the unit of mg/cm^2, and the categorical predictor variables were selected based on correlations with the response and variability within the collected data. Some variables were reverse coded in order to correspond correctly with the other variables included in the model. The Binomial Distribution was used to calculate the probability of 55% correctly identifying the labels by random chance in order to include the labels as a predictor variable.

Surface Area Estimation

The surface area of the limbs the sunscreen was applied to was estimated by taking measurements and then treating arms and legs mathematically as truncated cones.

Equation 1. Surface Area of a Truncated Cone

$$Surface\ Area = \pi[s(R + r) + R2 \quad + r^2]$$

Where: R= Greater Radius *r= less radius* *s= slant height*

The measurements used in the arm surface area estimations are: the circumference of the upper arm (around the bicep), circumference of the wrist, and the length from shoulder to wrist. The measurements used in the leg surface area estimations are: the circumference of the calf directly below the knee, the circumference of the ankle, and the length of the shin (from the bottom on the knee to the ankle). The circumferences were used to solve for the radii to use in the surface area of a truncated cone equation, and the length of the arm or shin was used as the slant height. This estimation of surface area was used to standardize the amount of sunscreen applied by the participants to the units of mg/cm^2 commonly used in sunscreen research.

The data was fit to a Random Effects Model (also referred to as a linear mixed model) using R (Vienna, Austria). In the model illustrated by Equation 1, y is a vector of the number of participants (94) multiplied by the number of observations per participant (4). X is made up of a matrix of the predictor variables; the number of participants (94) multiplied by the number of predictor variables (10). β is the fixed effects vector made up of the coefficients for the predictor variables, and Z is

the matrix for the random effects that make this model different from a traditional linear model. The error term, to explain the parts of Y that are not explained by the rest of the model is ε, the vector of the residuals (Jones, G. 2011).

Equation 2. Random Effects Model

$$\boldsymbol{y} = \boldsymbol{X\beta} + \boldsymbol{Z\gamma_i} + \boldsymbol{\varepsilon}$$

$$Z \sim N(0, \hat{\sigma}_a^2) \qquad \hat{\sigma}_a^2 = .6644062$$

$$\varepsilon \sim N(0, \hat{\sigma}_e^2) \qquad \hat{\sigma}_e^2 = .5885008$$

The response variable was the thickness of the sunscreen application, determined by dividing the weight of the applied sunscreen by the estimated surface area of the body part the sunscreen was applied to, and the factors included in the analysis were: package type, label messaging, whether or not they recognized the labels during the survey, frequency of worry about developing skin cancer, skin tone saturation, whether they know someone with skin cancer, frequency of applying sunscreen when spending more than two hours outside in the sun, gender, location of participation in the study, and age.

In order to select which of the factors generated by the survey data to include in the statistical model, Pearson Correlations were run with all of the survey response variables. To avoid redundancy and artificially inflating the number of significant variables, if variables were highly correlated only one was selected to be in the model. While interactions between the factors were tested while developing the statistical model, no interaction terms were included in the final model because none of the tested interactions were significant.

Chapter 4 Results and Discussion

Summary Statistics

Data collected from 94 participants were used for analysis after 2 participants were excluded from the final data set due to recording error; namely, the weights recorded after usage were higher than those prior to use. Of those included in the analysis, 47 participants were recruited from MSU and 47 participants from Cal Poly. The mean age for the total sample was 23 years old with a median age of 21. The mean and median ages for the MSU portion of the sample were 25 and 24 years old respectively, and the mean and median ages for the Cal Poly sample were calculated as 20. The overall sample was 41% male and 59% female, with the MSU portion of the sample being 29% male and 71% female and the Cal Poly portion of the sample being 52% male and 48% female. Two participants reported having children. All data was collected between July 6th August 26th 2016.

Table 2. Age and Sex of Participants by Location

	Total Sample	MSU Sample	Cal Poly Sample
Sample Size	94 (96)*	47 (48)*	47 (48)*
Mean Age (years)	23	25	20
Median Age (years)	21	24	20
Male	41%	29%	52%
Female	59%	71%	48%

*94 participants were included in the statistical analysis since two were excluded from the study due to error in data recording.

Of the sample of 94 participants, 52 (55%) correctly identified the labels of the sunscreen they applied and 42 (45%) did not. Sixteen participants (17%) reported having experienced severe sunburns, 37 (39%) reported knowing someone with skin cancer, and the most prevalent skin tone saturations, matched from a Pantone SkinTone Guide (Pantone LLC Carlstadt, NJ) on a scale of 1(fair) to 15 (deep), each with 12 respondents, were saturation levels 2, 3, and 8.

When comparing the actual amount applied by participants in the study to the amount recommended in the FDA guidelines for testing[2], only 8 of the 94 participants (9%) applied sunscreen in the thickness denoted by the FDA (≥2 mg/cm^2) for all four of their applications. In other words, less than 10% of study participants consistently applied enough sunscreen in each application to truly have 30 SPF as the protection level from UV rays. None of the predicted means (see figure 5 below) were above the recommended level for sunscreen thickness.

Statistical Model

After fitting the random effects model to the data using the maximum likelihood method, a type three analysis of variance (ANOVA) was run to determine if there were any significant factors. The results of this ANOVA are reported below in Table 3. The significant factors: package type, self-reported worry about developing skin cancer, and self-reported frequency of sunscreen use when outside for more than two hours on a sunny day, are reported in bold as determined by an evaluation threshold of α=0.05.

Table 3. Results from ANOVA of the Full Random Effects Model

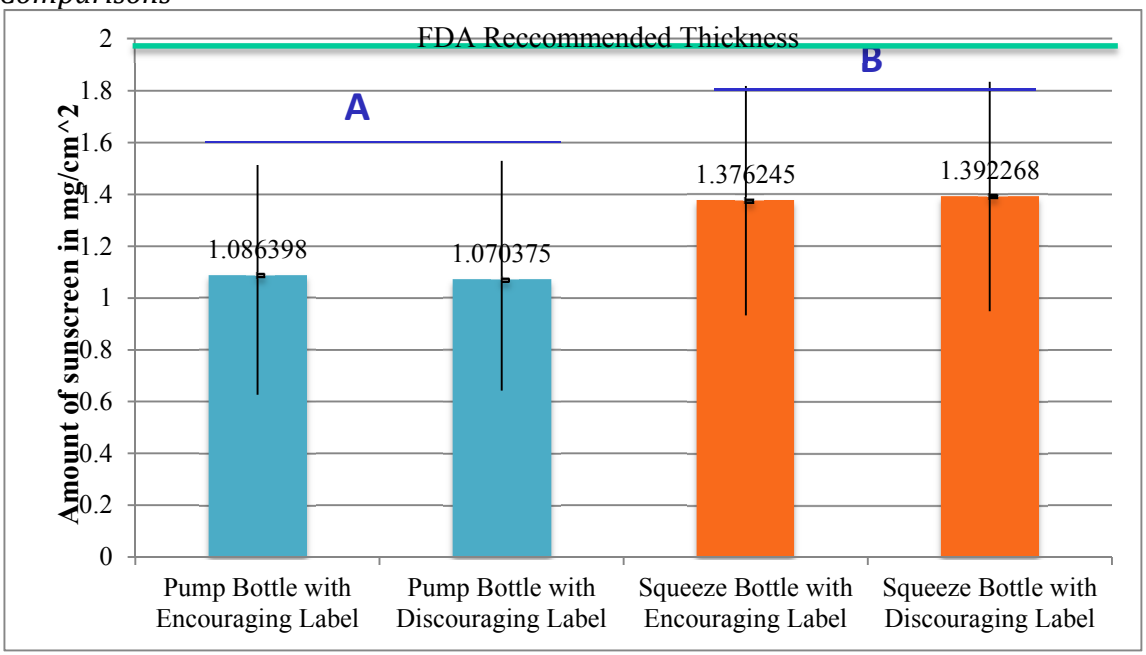
Factor	Num. DF	Den. DF	F-value	P-value
Package Type (Pump or Squeeze)	**1**	**280**	**23.5016**	**<. 0001**
Label Type	1	280	0.0645	0.7997
Gender	1	68	0.0488	0.8259
Know Someone with Skin Cancer	1	68	0.0528	0.8189
Worry about developing Skin Cancer	**3**	**68**	**3.2871**	**0.0258**
Recognize Labels	1	68	1.5688	0.2147
Self-reported frequency of Sunscreen Use When Outside for 2 hours	**4**	**68**	**2.9601**	**0.0258**
Skin Tone Saturation	13	68	1.4044	0.1803
Age	1	68	0.6098	0.4376
Location	1	68	0.1942	0.6608

The significant factors from the model will be discussed individually in further detail. The predicted means were calculated using the Least Square Means function in R.

Package Effect

The first significant factor that will be discussed is the effect of the different physical structure on the amount of sunscreen that participants applied. The model indicates that regardless of the label, participants applied 30% less sunscreen when using the pump as compared to the squeeze bottle ($p<.0001$). This is further illustrated in figure 5. Pairwise comparisons of treatments are shown in different colors at $\alpha=0.05$. This is an interesting finding because one of the hypotheses was that a dosing dispensing system (i.e. a bottle outfitted with a pump dispenser) could encourage consumers to use more of the product since it would be dispensed in a relatively consistent amount each time, at similar fill levels.

Figure 5. Predicted Mean Amount of Sunscreen, Package and Label Pairwise Comparisons



The type of package was found to significantly affect the thickness of sunscreen application, whereby participants applied more sunscreen from the squeeze bottles when compared to the pump bottles. A ranking of the four

sunscreen package and label combinations shows participants applied the most sunscreen from the squeeze bottle with the discouraging label, followed by the squeeze bottle with the encouraging label, the pump bottle with the encouraging label, and the least from the pump bottle with the discouraging label, but the difference between the amounts applied from the same package with different labels did not suggest significant differences.

Table 4. Predicted Mean Application Amounts

Package Label Combination	**Predicted Mean Application Amount (mg/cm^2)**
Pump Bottle with Encouraging Label	1.086398A*
Pump Bottle with Discouraging Label	1.070375A
Squeeze Bottle with Encouraging Label	1.376245B
Squeeze Bottle with Discouraging Label	1.392268B
*Means followed by the same letter are not significantly different from each other using Tukey's HSD at a significance level of 0.05.	

Affordance theory can be leveraged to offer insight into this finding about the effect of the physical dispensing structure on the amount that participants applied. It is possible that consumers interpreted the amount the pump metered out each time it was pressed down as the correct amount of sunscreen to apply, despite one single pump not being adequate to provide full protection to the arms or legs of most adults. A 95% confidence interval for the amount of sunscreen in one pump from the bottle is 491mg to 523mg; this suggests it would take approximately 3 pumps to adequately cover an arm or lower leg with the average surface areas represented in this sample, 808.41cm^2 and 691.04cm2 respectively.

The pump could be considered a misleading or false perceived affordance, and thus ended up under-dosing when compared to the squeeze bottle in this experiment. While the pump affording dispensing the product does not change

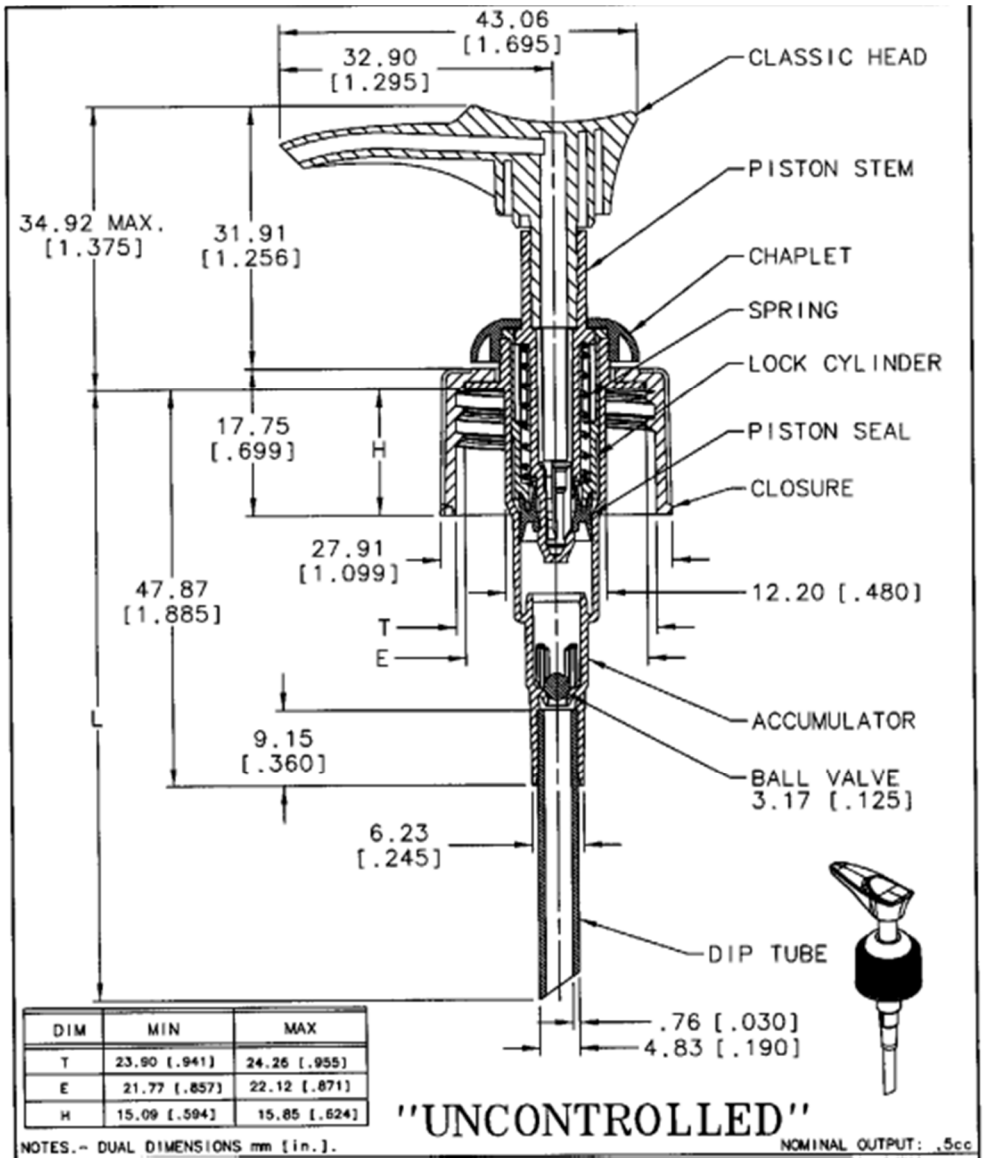
based on the amount in each pump, the perceived correct amount could be affected, and that signal would lead to consumers stopping the dispensing process before complying with application recommendations. The potential ramification of the under-dosing pump was 91% of the participants were noncompliant with FDA sunscreen application guidelines. Without further replication, the data implies a squeeze bottle should be the preferred package for sunscreen to ensure greater usage.

By contrast, results from Davis et al indicate that the use of a pump bottle results in significantly greater amounts of product application as compared with a squeeze tube and roll on dispenser. [30] We postulate two reasons the findings presented here run counter to those reported by Davis et al. Firstly, the study presented here utilized adults applying sunscreen to themselves while Davis et al. investigated how packaging influences the sunscreen application behaviors of children. Secondly, the average volume dispensed by the pump used on the pump package in the Children and Sunscreen Study was not disclosed in the paper, so it is unknown the exact difference in volume between the pump the children used and the pump used in this study.

Figure 6, a specification graphic created by SKS Bottle & Packaging Inc, below shows a cross section of the pump used in this study to dispense the sunscreen. When the pump is primed, meaning the accumulator fills with product on each stroke of the pump rather than air, the pump dispenses .5mL per stroke. For the product used in this study, .5mL was equal to the roughly .5 grams dispensed per pump. If the volume of the accumulator is greater, more product is drawn up the dip

tube with each stroke of the pump, and more product is dispensed. There are many different pumps available to be used for products, and thus without the disclosure of the delivery volume per stroke, it is unknown if the package used in the Children and Sunscreen study dispensed more or less per pump than the package used in this study.

Figure 6. Anatomy of the SKS Pump 2585 Series[3]



[3] Pumps (2585 Series) reproduced with permission from SKS Bottle & Packaging Inc

At similar fill levels, a pump with a greater delivery volume per stroke would implicitly communicate through affordances a greater quantity for the correct dosage, and thus be more efficient at promoting compliance with sunscreen application guidelines. While the fill level could influence how much is dispensed per stroke by also drawing air up the dip tube, that impact is primarily for lower levels of fill, when it is difficult to dispense the last bit of the product from most packages.

Label Recognition

While the model did not show label messaging to be statistically significant, it is important to note that there is evidence to indicate some participants did interact with the labels. One of the questions in the survey (included in Appendix A) asked participants to identify the two labels of the sunscreens applied during their participation in the study out of six possible options. This question was included as a mechanism to determine whether or not it would be appropriate to conduct statistical analysis examining differences in application amount due to the two different labels. Out of the 94 participants included in the final analysis, 55% of the participants were able to correctly recall both of the sunscreen labels. Fifty-five% correct identification was compared to the probability of randomly selecting the correct responses (33.6%) using the Binomial Probability Distribution with $p<0.0001$ ($p=0.000004578957$).

A contrast was applied to the model to determine if recognition had a significant effect on the label's effect on sunscreen application, and that finding was also inconclusive. Despite the lack of significance that label message effected the

amount of sunscreen used in an application, the percentage that correctly identified the labels is different from random chance, which is evidence that the participants did interact with the labels to at least a limited extent. One potential reason for this is that not all of the participants interacted with the labels in the same way. While 55% of the participants were able to correctly identify the labels, 45% were not able to correctly identify the labels despite being specifically asked to look at the entire package prior to applying the lotion. Perhaps a different warning message could have performed differently because of the tendency for consumers to perceive a risk when a warning was placed on the label, perhaps it would have been better for the negative warning to be about the damage UV rays can cause, emphasizing the benefits of proper sunscreen usage to mitigate that damage, rather than an ingredient warning

Worry Effect

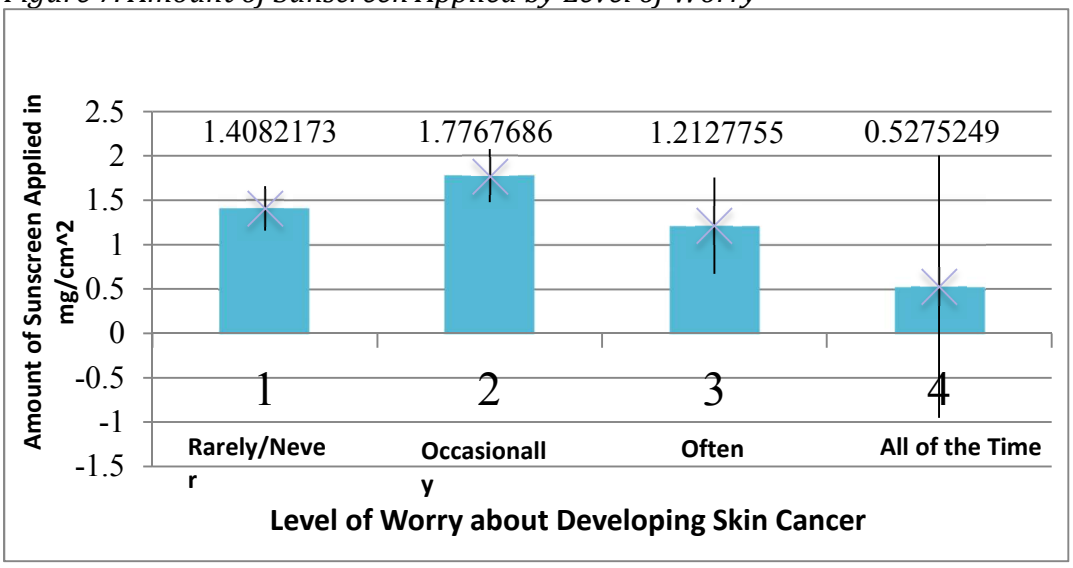
The second significant factor in the model was the level of worry about developing skin cancer scaled from 1 (Rarely/Never) to 4 (All of the Time), see Appendix A to reference survey question 9 which was used to measure worry. While worry about developing skin cancer was a significant factor within the statistical model, multiple comparisons using Tukey's Honestly Significant Difference (HSD) did not find any significant differences in the amount of sunscreen that was applied based on the levels of worry at the .05 significance level. The numerical value of the HSD is dependent on the number of replications of each treatment. Thus, the small proportion of the sample that experience increased levels of worry limits inferences about Worry's effect on sunscreen application.

Table 5. Predicted Means Level of Worry

Level of Worry	Predicted Mean (mg/cm²)	Lower Limit to 95% Confidence Interval	Upper Limit to 95% Confidence Interval	Frequency of Participants at self-reported level of worry
1	1.4082173	1.1572449	1.659190	49
2	1.7767686	1.4784189	2.075118	35
3	1.2127755	0.6693801	1.756171	9
4	0.5275249	-0.9509662	2.006016	1

Table 5 presents the predicted means based on the level of worry, but as the confidence intervals are all different sizes due to different number of people responding to each level of worry, they all overlap and none are significantly different from each other. Since the number of participants who selected the lower levels of worry is so much greater than those who selected the higher amount of worry, the power is reduced and the confidence intervals are wider for the higher level of worry and it is not possible to determine a statistically significant difference. Specific testing of this effect is recommended for further research.

Figure 7. Amount of Sunscreen Applied by Level of Worry



The discrepancy in sample size between levels of worry about developing skin cancer and the predicted amount of sunscreen that would be applied is illustrated in figure 7. The worry level 4 has a wide confidence interval that extends both higher than all of the other levels and below zero into a negative amount of sunscreen applied.

Frequency of Sunscreen Use Effect

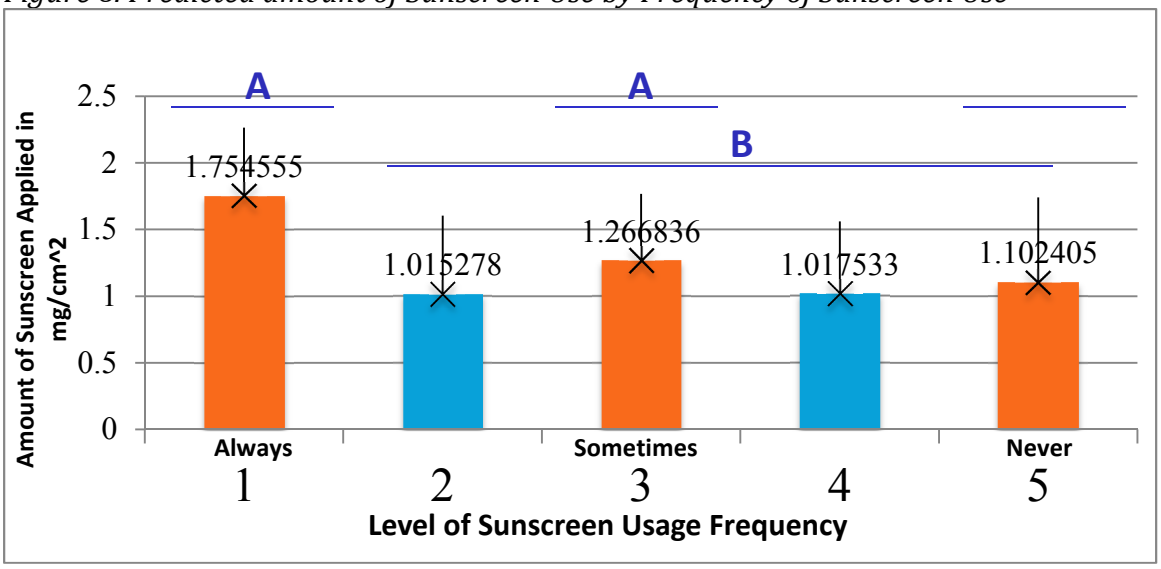
The final significant factor influencing the amount of sunscreen participants applied was their self-reported frequency of sunscreen use when planning on spending 2 or more hours outside in the sun. This factor was scaled from 1/Always to 5/Never, with 2, 3/Sometimes, and 4 as the intermediate options, as collected by question 5 in the survey in Appendix A. The distribution of the responses was more even for frequency of sunscreen use than it was for worry, Pairwise comparisons of the application thickness by varied levels of use were conducted using Tukey's HSD (see Figure 8). The predicted mean application amounts and the statistically significant differences are reported below in table 6.

Table 6. Tukey's HSD for Frequency of Sunscreen Use

Frequency of Sunscreen Use	**Predicted Mean Application Thickness (mg/cm²)**	**Frequency of Participants at self-reported frequency of Sunscreen Use**
1 (Always)	1.754555* A	14
2	1.015278 B	16
3 (Sometimes)	1.266836 AB	36
4	1.017533 B	21
5 (Never)	1.102405 AB	9
*Means followed by the same letter are not significantly different from each other at the .05 significance level using Tukey's HSD.		

Participants tended to center their answers on the scale; as such, no evidence of statistical significance resulted when comparisons of application were made by use levels 2, 3, and 4. By contrast, people who reported always using sunscreen when spending 2 hours or more outside on a sunny day had signifanctly higher predicted amounts of sunscreen applied. The people who selected the intermediate levels of the scale applied significantly less. Figure 8 illustrates the different amounts of sunscreen applied, with 95% confidence intervals, by participants with different levels of frequency of sunscreen usage when spending 2 hours of more outside on a sunny day. None of the participants who responded that they have experienced severe sunburn selected "never" using sunscreen when going outside for more than 2 hours on a sunny day, but the number of people in the sample who experienced severe burns is limited, and thus it was not also included in the model.

Figure 8. Predicted amount of Sunscreen Use by Frequency of Sunscreen Use



One finding from this study is that the frequency of use of sunscreen when spending 2 hours or more outside on a sunny day is a predictor for how much sunscreen one will apply. Familiarity with the product can come from repeated use,

and a self-report of “Always” using sunscreen when spending two hours or more outside on a sunny day proposes repeated use. Additionally, it would follow that consumers who are more likely to burn when out in the sun for 2 hours or more are more likely to be repeat users of sunscreen products. This familiarity with a product used to prevent sunburns might also be related to the consumer being more cognizant of the amount they personally use to prevent burning.

Chapter 5 Conclusions, Limitations and Ideas for Future Research

Overall, this study reinforced that users of sunscreen do not apply the amount that is tested to determine SPF level, and thus do not receive the full benefits associated with sunscreen use. A key finding of this study is the magnitude of the effect the packaging can have on sunscreen application, despite it being a relatively ignored factor in the literature surrounding sunscreen use and skin cancer prevention as well as the FDA guidelines for sunscreen manufacturers. While the information provided on a label is important for consumers, the packaging of sunscreen is also an important contributor to providing consumers the tools to protect their skin from UV rays and thus should also be considered by regulators and manufacturers of sunscreen products. The findings of this study indicate that even though packaging influences the amount of sunscreen people use, not enough research has been done to compare the different product package systems for their influence on compliance with sunscreen use guidelines, and the work is not complete. These findings may be useful in understanding what factors are associated with increased sunscreen use and how packaging can better encourage healthy skin protection practices, but they are only the starting point.

Ideas for Future Research

This study attempted to fill in the knowledge gap of how packaging influences the amount of sunscreen consumers apply, but it did not answer all of the questions relevant to this line of inquiry. Some relevant directly related research questions I would recommend pursuing are: influences of packaging on the application of nontraditional sunscreens such as spray bottles, aerosol sprays,

powders, or sticks, how consumers learn to apply sunscreen and if their application process changes over time, self application verses application to others (e.g. children), the effects of pump mechanics as a potential means to influence dosing, and differences in sunscreen application based on marketing message (e.g. specially formulated for the face as opposed to traditional sunscreen).

Additionally, previous research by de la Fuente has found a difference in grip strength between children and adults (Javier & Fuente, 2004). It is possible that this difference in grip strength affects the ability to dispense product from a squeeze bottle. Thus, further research that compares the differences between how adults and children apply sunscreen to themselves from different package types based on the target market would better inform the packaging decision making process.

Limitations

The primary limitations of this study were the distribution of ages within the sample and the method of estimating surface area. The range of ages sampled at the two study locations were different from each other, with MSU's participants ranging from 20 to 35 years old and Cal Poly's participants ranging from 19 to 23 years old. In Sociology, a cohort effect is influenced by both age and the time period (Keyes, Utz, Robinson, & Li, 2010), thus it is possible that there were factors that influenced the sunscreen application behaviors of the different sample populations that were not controlled for, despite only sampling from the millennial generation.

A second limitation was the method used to estimate surface area of application. A rudimentary method was selected for ease of data collection at multiple locations, but because the method of measuring with a tape measure is

subject to human error, arms and legs are not perfect truncated cones, and variability across limbs, even on the same body, the surface area estimates are not perfect. Thus, we are limited in the amount of inferences that can be made.

APPENDICES

APPENDIX A

Approved Forms

Research Participant Information and Consent Form

Title: Effect of Packaging and Labeling Interventions on Sunscreen Application

Principal Investigator:
Dr. Laura Bix, School of Packaging, Michigan State University 517-355-4556

Secondary investigator:
Alyssa Harben, Grad. Student, Michigan State University, 530-210-3864

To participate in this research you must:

- be between 18- 36 years old
- have no known history of skin condition (e.g. eczema, latex allergy, etc.)
- Be a user of sunscreen

Purpose of the research:
You are being asked to participate in a research study, which investigates the link between packaging and labeling and the application of sunscreen. This experiment will take no more than 30 minutes.

What you will do:
First, we will ask you to fill out some basic demographic information (age, gender, etc.) and we will take measurements of your arm and lower leg so that we can calculate the surface area later.
Then, you will be asked to apply sunscreen to each of your arms and each of your lower legs. We will ask you to roll up any t-shirt sleeves so they are not in the way of application. We will ask you to use each of the four packages once, for a total of four (4) different applications. You will be given hand wipes to clean your hands in between trials.
After you have applied the four different sunscreen package-label options, you will be asked to fill out a secondary survey. This survey will include information about your health history, risk perception, and risk awareness. We will then analyze the amount of sunscreen applied by weighing the package.

Benefit
Although there is no direct benefit to you for participating in this research, it is our hope that the data gathered could be used to understand the interface between people and sunscreen packaging in order to create designs that will facilitate proper application.

Risk
You will be asked to apply sunscreen in SPF 30. The sunscreen being used is Rocky Mountain Sunscreen Kids Broad Spectrum SPF 30. It is free of PABA, gluten, peanut oil and anything else that regularly irritates sensitive skin. That said, as with any lotion or cream, it may cause irritation in small segments of the population. To

minimize possible staining or other damage to clothing, participants are asked to wear shorts and either a tank top or t-shirt to participate in the study.

Privacy & confidentiality
All information about subjects will be tied to a subject number and you will not be identifiable by name (even to the research team). Information collected during this study will be stored in a password-protected computer in spaces controlled by the Principle Investigator in the School of Packaging . Research records will be accessible only to authorized researchers and members of MSU HRPP (Human Research Protection Program) at MSU. Occasionally, publications ask for raw data sets associated with published work. In the event that these are requested, they would be furnished to the journal (de-identified). Records will be kept for a minimum of three years after the closing date of the project.

Your rights to participate
Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You may change your mind at any time and withdraw. You may choose not to answer specific questions or to stop participating at any time.

Costs and Compensation
There is no cost for being in this study. In exchange for your participation, you may choose $10 cash OR SONA credit if you are enrolled in a participating class in the College of CAS. Participants who consent to take part in this study, for SONA credit, will be awarded SONA credits through http://msucas.sona-systems.com. In the SONA system, 1 hour of research participation is worth 1 SONA credit and this credit is pro-rated in 15-minute increments. It is up to individual course instructors to determine how many points this converts to in their classes (this should be specified in the syllabus for each course).

The duration of this study is approximately 30 minutes. Hence, participants who complete this study will receive .5 SONA credits.

Participation in this study is voluntary. You may withdraw at any time without penalty. This means that no SONA credits will be deducted from your account, nor will withdrawal have any effect on your relationship with any of your instructors. Participants who withdraw partway through the study will be awarded credit based on the portion of the study they complete (1/2 completion = .25 SONA credit). Students who view the materials but do not participate in any part of the research will receive 0 SONA credit.

The right to get help if injured
If you are injured as a result of your participation in this research project, Michigan State University will assist you in obtaining emergency care, if necessary, for your research related injuries. If you have insurance for medical care, your insurance carrier will be billed in the ordinary manner. As with any medical insurance, any costs that are not covered or in excess of what are paid by your insurance, including deductibles, will be your responsibility. The University's policy is not to provide financial compensation for lost wages, disability, pain or discomfort, unless required by law to do so. This does not mean that you are giving up any legal rights you may have. You may contact *Dr. Laura Bix*, MSU, 517-355-4556, ext. 153 or Alyssa Harben 530-210-3864 with any questions or to report an injury.

Contact Information
If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researcher, Dr. Laura Bix, Laura Bix 517-355-4556; 153 Packaging Building East Lansing MI 48824 bixlaura@msu.edu.

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@ora.msu.edu or regular mail at Olds Hall, 408 West Circle Drive #207, MSU, East Lansing, MI 48824.

Documentation of Informed Consent
Your signature below means that you voluntarily agree to participate in this research study.

_____ _____
Signature Date

You will be given a copy of this form to keep.

Demographic & Health History Questionnaire: The Effect of Package Dispenser and Label on Sunscreen Application

Subject #_____ Date_____

Location of Study Cal Poly MSU

Handedness Right Left
Ambidextrous

Laterality Right-Right Right- Left Left-Right Left-Left

Arm Measurements: Wrist: _____Upper Arm: _____Length: _____

Leg Measurements: Ankle: _____Below Knee: _____Length: _____

Trial	Treatment (AA, AB, BA, BB)	Application Area (1,2,3,4)	Initial Weight	Final Weight	Difference
1					
2					
3					
4					

If you are uncomfortable answering any of the following questions, feel free to leave the response field blank.

1. Please record which two sunscreens you applied from the options of the board:

_____ _____

2. Do you have children?

YES NO

3. Do you have any personal experience with severe (second or third degree) sunburns?

YES NO

4. Please list if you or anyone you know has a history of skin cancer? If not you please state their relation.

5. How frequently do you apply sunscreen (a product with greater than 15 SPF)?

Less than once a month	1 to 3 times per month	1 time per week	Between 2-6 times a	Everyday

6. When you go outside for more than 1 hour on a warm, sunny day, how often do you wear sunscreen?

1	2	3	4	5
Always		Sometimes		Never

7. How likely do you think it is that you will develop skin cancer in the future?

1	2	3	4	5
Very low		Moderate Chance		Very High

7. Compared to the average person your age, would you say that you are:

1	2	3
More likely to get skin cancer	About as likely to get skin cancer	Less likely to get skin cancer

9. How often do you worry about getting skin cancer?

1	2	3	4
Rarely/Never	Occasionally	Often	All of the time

10. Gender:_____

11. Age:_____

For Question 12 please use the back of your hand.

12. Skin Tone using the provided Pantone Booklet:_____

APPENDIX B

Sunscreen Labels Used in Study

The labels included in this section were the other options for the question testing label recall. These labels were designed to look similar but have different messaging that is commonly used on sunscreen products to test whether or not the participants could recall the messaging from the sunscreen they applied.

Figure 9. Incorrect Option for Survey Response #1

Figure 10. Incorrect Option for Survey Response #2

Figure 11. Incorrect Option for Survey Response #3

Figure 12. Incorrect Option for Survey Response #4

APPENDIX C

Test Plan

"The four products that you are applying are all different, please inspect them carefully prior to applying them as you would if were to spend the entire day outside on a very clear, sunny day."

Key: **P**= pump bottle **S**=Squeeze Bottle **IA**=Label in increase amount **DA**=Label to decrease amount **LA**=Left Arm **LL**= Left Leg **RA**=right arm **RL**= Right Leg

Subject # Within Block	Package Order	Application Area Order
1	PIA, PDA, SIA, SDA	LA, RA, RL, LL
2	PDA, SIA, PIA, SDA	RA, LA, RL, LL
3	SDA, SIA, PIA, PDA	LA, RA, LL, RL
4	SIA, PDA, SDA, PIA	RA, LL, LA RL,
5	PIA, SDA, SIA, PDA	LL, RA, RL, LA
6	PDA, PIA, SIA, SDA	RA, LL, RL, LA
7	PIA, SIA, PDA, SDA	RL, RA, LL, LA
8	PDA, SIA, SDA, PIA	RA, RL, LA, LL
9	SIA, PIA, PDA, SDA	LL, LA, RL, RA
10	PDA, PIA, SDA, SIA	RA, LA, LL, RL
11	SDA, PIA, PDA, SIA	LL, LA, RA, RL
12	SIA, SDA, PDA, PIA	LA, LL, RA, RL
13	PDA, SDA, PIA, SIA	LL, RA, LA, RL
14	SDA, SIA, PDA, PIA	RL, LA, LL, RA
15	PDA, SDA, SIA, PDA	LL, RL, RA, LA
16	PIA, PDA, SDA, SIA	RL, LL, LA, RA
17	SDA, PDA, PIA, SIA	LA, RL, LL, RA
18	SIA, PIA, SDA, PDA	RL, LL, RA, LA
19	SDA, PIA, SIA, PDA	LA, LL, RL, RA
20	PIA, SDA, PDA, SIA	RL, LA, RA, LL
21	SIA, SDA, PIA, PDA	RA, RL, LL, LA
22	PIA, SIA, SDA, PDA	LA, RL, RA, LL
23	SDA, PDA, SIA, PIA	LL, RL, LA, RA
24	SIA, PDA, PIA, SDA	RL, RA, LA, LL

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