

CAREGIVERS' PERCEPTIONS AND COMPREHENSION OF DOSAGE  
ADMINISTRATION DIRECTIONS FOR OVER-THE-COUNTER COUGH AND COLD  
MEDICATIONS IN CHILDREN 2 TO 12 YEARS OF AGE

by

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(Under the Direction of Paul J. Brooks)

ABSTRACT

Recently, over-the-counter cough and cold medication usage in children has received increased attention by the medical community, parents/caregivers and the Food and Drug Administration. Concerns regarding the efficacy and safety of these medications in the pediatric population are increasing. Prior studies indicate that further caregiver education regarding the use of OTC cough and cold medications in children is needed to further reduce serious adverse events. This pilot study seeks to identify caregiver perceptions of current manufacturer's labels and comprehension of the Directions section. Results indicate that parents are dissatisfied with the current dosing and administration instructions of children's OTC cough and cold products. Specifically caregivers desire educational handouts from their medical team and prefer that the FDA require weight-based dosing, in addition to age, classifications on manufacturer's labels.

INDEX WORDS: Pediatric, OTC, Nonprescription Drugs, Cough, Education, Parent, Caregiver, FDA, Medication, 21 CFR 341, Safety, Comprehension, Literacy

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B.B.A., University of Georgia, 2003

A Thesis Submitted to the Graduate Faculty of The University of Georgia in Partial  
Fulfillment of the Requirements for the Degree

MASTER OF SCIENCE

ATHENS, GEORGIA

2010

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## DEDICATION

This thesis is dedicated to my son, Brian. Thank you for being my inspiration to further educate other parents on safely medicating their children and hopefully one day, your own. It is also dedicated to my parents, John and Suzanne Bagby, whose sacrifices for me are always appreciated, my sister Elizabeth Shults, to whom I credit my level of patience and finally my husband, Brian Senter, my steadfast support system.

## ACKNOWLEDGEMENTS

I would like to thank Joseph and Brandi Sailors for their invaluable assistance and support. I would also like to thank Johnna Hodges for her continuous support and guidance during my enrollment in the University of Georgia's Pharmaceutical and Biomedical Regulatory Affairs program. I would like to thank Dr. Brooks, my advisor, for his patience, advice and constructive criticism during my research. I want to also thank Dr. Mullis and Dr. Termini for finding the time in their busy schedules to offer their advice and expertise in their individual fields as my advisory committee. I would like to especially thank Dr. Termini for assisting me in realizing my thesis topic.

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## **CHAPTER 1**

### **INTRODUCTION**

#### **1.1 Over-the-Counter Medication Usage in Children**

Over-the-counter (OTC) medications are an established and profitable market in the United States. According to the Consumer Healthcare Products Association (CHPA) website, a non-profit membership organization representing OTC manufacturers and distributors, "U.S. retail sales of over-the-counter (OTC) medicines in 2008 (excluding Wal-Mart) were \$16.8 billion."<sup>1</sup> Pediatric specific OTC cough and cold medications are a large submarket and according to Linda Suydam, President of CHPA, "3.8 billion units..." of pediatric OTC cough and cold products were "...sold in the United States [in] 2006."<sup>2</sup> Efficacy in adults has been proven through numerous studies.<sup>2</sup> Yet safety and efficacy data for OTC cough and cold use in children is extremely limited and a cause for concern.<sup>2</sup> Caregivers intending to alleviate their children from the familiar symptoms associated with the 'common' cold, frequently give the incorrect dose due to a variety of factors and their children becoming increasingly exposed to the adverse risks of these medications.

Recently, in response to the Food and Drug Administration's (FDA) scrutiny of available safety and efficacy data for children in OTC cough and cold medications, many OTC drug manufacturers relabeled their products to add proper warnings for use and removed dosage administration for pediatric populations ages 4 and under.<sup>3</sup> This was a voluntary label modification and these actions were taken to reduce erroneous

dosing in small children.<sup>3</sup> While these actions were well received by consumers, the medical community and the FDA, there are still unresolved issues that need to be addressed such as providing caregiver education on OTC cough and cold products, gauging the level of caregiver comprehension of the dosing administration instructions and collecting caregiver opinions regarding the FDA labeling format to advocate revisions if necessary. Further parent/caregiver education regarding OTC labeling, specifically targeting the Directions section, must be conducted to ensure the reduction and possible elimination of pediatric misdosing.

## 1.2 Background of Over-the-Counter Cough and Cold Medications

The FDA's monograph for cough and cold products, i.e. Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drugs or 21 CFR 341, was placed as an advanced notice of proposed rulemaking in the September 1976 *Federal Register*.<sup>4</sup> The FDA identified compounds that were found to be "...generally recognized as safe and effective..."<sup>4</sup> Figure 1.1 lists some of the compounds and marketed uses of some of the available OTC cough and cold medications for children.<sup>5</sup> In that same *Federal Register* notice, dosages were outlined by age groups. At that time, age based dosing model was determined by the FDA's 1972 Cough/Cold Advisory Review Panel to be the "most convenient and easily understood [method]" as it has a "wide margin of safety stemming from adverse events reported" and "time and extent of use," while recognizing that it "may be the least reliable" method against the weight based model.<sup>6</sup> Weight based dosing versus age based dosing was recently discussed at the FDA's October 2007 Nonprescription Drug Advisory Committee (NDAC) and the Pediatrics Advisory Committee (PAC) meeting.<sup>7</sup>

Ingredients and Marketing of Some of the Available Pediatric Cough and Cold Products.*		
Ingredients	Brand Name	Marketed Use
Antihistamine	Pediacare	Nighttime cough
	Triaminic	Cough and runny nose
Antitussive	Robitussin	Long-acting cough
Decongestant	Dimetapp	Decongestant
Antihistamine and antitussive	Robitussin	Long-acting cough and cold
	Tylenol Plus	Cough and runny nose
Antihistamine and decongestant	Dimetapp	Cold and allergy
	Pediacare	Nighttime multisymptom cold
	Triaminic	Nighttime cough and cold
Antitussive and decongestant	Dimetapp	Decongestant plus cough
	Pediacare	Multisymptom cold
	Triaminic	Daytime cough and cold
Decongestant and expectorant	Dimetapp	Cold and chest congestion
	Triaminic	Chest and nasal congestion
Antihistamine, antitussive, and decongestant	Dimetapp	Cold and chest congestion
	Tylenol Plus	Flu
	Tylenol Plus	Multisymptom cold
Antitussive, decongestant, and expectorant	Robitussin	Cough and cold

\* The antihistamines include brompheniramine, chlorpheniramine, and diphenhydramine; the antitussive is dextromethorphan, the decongestant is phenylephrine, and the expectorant is guaifensin. All formulas of Tylenol Plus also contain acetaminophen.

Figure 1.1 - OTC Compounds by Brand and Use<sup>5</sup>

*Note.* From “Over the Counter but No Longer under the Radar - Pediatric Cough and Cold Medications,” by JM Sharfstein et. al., 2007, *The New England Journal of Medicine*, 357, p. 2322. Copyright 2007 by The Publishing Division of the Massachusetts Medical Society. Reprinted with permission.

### 1.3 Challenges to Current Pediatric OTC Dosing

The established OTC monograph, 21 CFR 341: Cough, Cold Allergy, Bronchodilator, Antiasthmatic Drug Products for Over-the-Counter Human Use, presents some unique challenges. These challenges were presented at the FDA's October 2007 NDAC and the PAC meeting by a group of sixteen physicians in support of their FDA submitted Citizen's Petition 2007P-0074 which requested, among other revisions, that Part 341's labeling be revised to state that "over-the-counter antitussive, expectorant, nasal decongestant, antihistamine, and combination cough and cold products state that these products have not been found to be safe and effective in children under 6 years of age for treatment of cough and cold."<sup>8</sup> The physicians and FDA also discussed their concerns of OTC cough and cold products available in the current marketplace for children 2 to under 12 years of age with respect to overdose. During that same meeting in regard to the pediatricians concerns and in support of the questioned medications, the CHPA presented initiatives to modify current labeling for children less than two years of age, provide educational programs regarding labeling compliance and future research study plans for pharmacokinetic data and efficacy data.<sup>2,9</sup>

One of the challenges for the current OTC monograph/delivery system presented at this meeting was labeling.<sup>10</sup> The labeling of OTC products is also known as the Drug Facts box.<sup>11</sup> The FDA proposed revisions to the labeling of OTCs in 1997 in order to simplify the provided information for consumers. Those revisions were made public in an advanced notice of proposed rulemaking in the *Federal Register*.<sup>12</sup> In the final rule published in 1999 in the *Federal Register*, OTC manufacturers had to comply with the

new labeling requirements, i.e. the Drug Facts box, by May 2002 so that they would have adequate time to sell existing inventory.<sup>13</sup> The revised labeling format of the Drug Facts box is depicted in Figure 1.2.<sup>14,15</sup> The revisions were intended to assist the consumer in comprehension and understanding of the provided information in terms of uses, warnings, contraindications and dosage information.<sup>13</sup> However, despite these initiatives by the FDA, caregivers still found children's OTC cough and cold products labeling unclear and confusing.<sup>10</sup>

<b>Drug Facts</b>	
<b>Active ingredient (in each tablet)</b>	<b>Purpose</b>
Chlorpheniramine maleate 4 mg.....	Antihistamine
<b>Uses</b>	
temporarily relieves these symptoms due to hay fever and other upper respiratory allergies: ■ sneezing ■ runny nose ■ itchy, watery eyes ■ itchy nose or throat	
<b>Warnings</b>	
Ask a doctor before use if you have	
<ul style="list-style-type: none"> <li>■ glaucoma</li> <li>■ a breathing problem such as emphysema or chronic bronchitis</li> <li>■ difficulty in urination due to enlargement of the prostate gland</li> </ul>	
Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>■ you may get drowsy</li> <li>■ avoid alcoholic drinks</li> <li>■ alcohol, sedatives, and tranquilizers may increase drowsiness</li> <li>■ be careful when driving a motor vehicle or operating machinery</li> <li>■ excitability may occur, especially in children</li> </ul>	
If pregnant or breastfeeding, 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.	
<b>Directions</b>	
Do not exceed 6 doses in 24 hours	
<ul style="list-style-type: none"> <li>■ Adults and children 12 years of age and older ~ one tablet every 4 to 6 hours</li> <li>■ Children 6 to under 12 years of age ~ ½ tablet every 4 to 6 hours</li> <li>■ Children under 6 years ~ ask a doctor</li> </ul>	
<b>Other information</b>	
<ul style="list-style-type: none"> <li>■ Store at controlled room temperature 2°-30°C (30°-86°F)</li> <li>■ Protect from excessive moisture</li> </ul>	
<b>Inactive ingredients</b>	
D&C Yellow 10, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch	
<b>Questions?</b> Call toll-free 1-800-XXX-XXXX	

Figure 1.2 - OTC Drug Facts box<sup>14,15</sup>  
 Note: FDA, Silver Spring, MD. Public Domain.  
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Specifically, the primary packaging of several children's OTC cough and cold products on the market in 2007 were too similar in color, proprietary name and product claims/presentation.<sup>10</sup> The packaging stated for use in 'infants' as well as may contain a picture of an 'infant', but to comply with the FDA's OTC labeling requirements, dosages for children under two are designated as "ask a doctor."<sup>10,16</sup> Usage of the term 'infant' and the image of an 'infant' sent a "mixed message" to the caregiver, which could have resulted in medication errors. In anticipation of the labeling concerns by NDAC and PAC, these products were voluntarily withdrawn by the CHPA prior to the October 2007 FDA joint meeting of the NDAC and the PAC.<sup>17</sup> A list of these withdrawn 'infant' medications are presented in Figure 1.3.<sup>18</sup>



Figure 1.3 - Infant Medicines Voluntarily Withdrawn<sup>17</sup>

Note. From www.OTCsafety.org. Copyright 2007 by CHPA. Reprinted with permission.

Medication errors that were inadvertently caused by product mislabeling are a direct violation of the OTC monograph and the Food, Drug and Cosmetic Act.



Companies have stretched the limit by marketing products labeled for ‘babies’ and ‘infants’ as aforementioned. 21 CFR 341 does not indicate labeling for children under age two or in some cases, under 6 years of age in its public component.<sup>19</sup> However, it does contain labeling for children ages two to six years of age in its Professional Labeling section, 21 CFR 341.90. Unlike the other sections of 21 CFR 341, the information presented in 21 CFR 341.90 is for medical professionals only and may not be disseminated to the general public. Therefore, adequate safety and efficacy information is not available to caregivers for children less than two years of age.

Dose duplication was a second challenge identified at the 2007 meeting in regards to pediatric medication errors.<sup>10</sup> Frequently, more and more product names and packaging are phonetically identical to other marketed products. Outer packaging and marketing plans are also similar in this product market.<sup>10</sup> One example of this challenge is when caregivers scan the primary packaging for specific symptom relief claims and select two products to alleviate the different symptoms. Inadvertently, the child is given two doses of the same active ingredient and the caregiver unknowingly overdoses their ward. The caregiver was attentive to symptom relief instead of product formulation. This problem, among others, was presented by Jincy John, PharmD in his article published in the June 2005 edition of the *Journal of Pharmacy Practice*.<sup>20</sup> John states that number one reason for therapeutic error was the “[child] inadvertently took/given medication twice.”<sup>20</sup>

Improper dosing was another primary area of concern.<sup>10</sup> In its 2006 Annual Report of the National Poison Data System, the American Association of Poison Control Centers (AAPCC) reports that “...of the 2,403,539 human exposure calls...” received

that year, 50.9% occurred in children 6 years and younger and 38.0% of that included children under 3 years of age.<sup>21</sup> A little more than half of the emergency calls fielded by the AAPCC were for children under 6 years. More specifically, AAPCC indicates that 10.2% (244,511) of the aforementioned total human exposure calls were a result of therapeutic errors.<sup>21</sup>

Sometimes the calibrated markings on the provided dosing devices that were packaged with the medications are unclear.<sup>10</sup> Caregivers could not determine the correct marking for the required measurement. Additionally the enclosed measuring device sometimes does not have an exact measurement for all provided dosages located on the Drug Facts box, either on the outer carton or on the actual bottle of medication.<sup>10</sup> This phenomenon occurs primarily with medicinal cups; it can also occur with syringes. Repeatedly, caregivers measure a volume of liquid between two calibrated, marked measurements ultimately 'guessing' on the correct amount. This type of dosing practice seldom provides the therapeutic dose.<sup>22</sup> It may underdose or overdose the child, not relieving the presenting cold symptoms or unintentionally adding side effects to the initial symptoms.

Finally, the most alarming challenge presented at the meeting was uneducated caregivers.<sup>10</sup> In a study published in July 1997 in the *Archives of Pediatrics & Adolescent Medicine*, caregivers were asked to determine the correct dose of an OTC product for their child. The study found that while 82% of the caregivers were high school graduates, "...only 30% of the caregivers were able to demonstrate both an accurately measured and correct dose for their child."<sup>23</sup> These caregivers are frequently confused with the difference between teaspoons and tablespoons. With a

wide margin for error in selecting the appropriate measurement, caregivers often medicate their child by mistake.

#### 1.4 Purpose of Research

Relevant literature proposes that the largest contributing factor to label confusion is a “knowledge deficit” of an uneducated caregiver.”<sup>10</sup> Broadly, the term “knowledge deficit” refers to a defined learning need. An uneducated caregiver may be characterized as illiterate, one who disregards the labeling, or does not sufficiently understand or interpret the terminology on the OTC label.<sup>10</sup>

The aforementioned literature suggests that identifying knowledge deficits and providing caregiver education are the most important interventions for assuring proper use and understanding of dosing directions for pediatric patients. However, more data is needed to help determine how caregivers interpret and apply product label information. It is the hypothesis of this study that the recent FDA position for industry voluntary label modification for pediatric populations is not sufficient to ensure the reduction and possible elimination of pediatric misdosing.

This pilot research will explore caregivers’ perceptions and comprehension of dosage administration directions for pediatric populations that was printed on manufacturing labels. Qualitative data will be collected from caregivers from different socioeconomic backgrounds to determine their interpretation of common products’ labeling instructions for pediatric patients. Additionally, the data will be analyzed to detect potential knowledge deficits and comprehension level variability among the defined groups of caregivers. Caregiver opinions also will be collected with regards to aspects for more effective labeling instructions through the predetermined regulatory

format. These findings will be collated and used to identify divergent and convergent themes with previously published work, regarding enhancement of product labeling guidelines for pediatric patients.

#### 1.5 Potential Outcomes of this Research

The intent of this research is to add to the body of knowledge of deficits in caregiver education for pediatric populations. Specifically, the outcomes of this study should inform the medical community of the identified target populations in which label confusion is still apparent and at what education levels of which the targeted population is comprised. By identifying these populations, the medical communities' educational programs may be specialized to address the specific needs of the caregivers identified in this study, which will more effectively decrease pediatric adverse events.

## **CHAPTER 2**

### **LITERATURE REVIEW**

#### **2.1 Literature Availability**

The review of previous published literature regarding pediatric OTC usage is considerable. However, published literature regarding parents/caregivers understanding and comprehension of OTC pediatric labeling is extremely limited. This review is based on the limited studies presently available to the researcher.

#### **2.2 Published Studies**

Parent/Caregiver education on the proper use and administration of OTC pediatric cough and cold medications is essential for the reduction of adverse reactions and mortality in children. This statement has been confirmed in the presently available research. For example, in a survey of caregivers conducted in pediatric emergency facilities in the mid 1990's, the majority of the caregivers stated that they received their child's dosing information for OTC's from a physician or family member; yet a mere 28% of these caregivers understood that these medications could cause adverse reactions.<sup>23</sup> Further efforts must be made to increase caregiver knowledge regarding these medications.

In January 2008, a mere two months after the joint meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the Pediatric Advisory Committee (PAC) in which safety and efficacy concerns of pediatric OTC cough and cold medications were discussed, the FDA issued a Public Health Advisory

"recommending that [children's OTC cough and cold medications] not be used to treat infants and children under 2 years of age because serious and potentially life-threatening side effects can occur."<sup>24</sup> In response to this Public Health Advisory, Garbutt et. al. surveyed a group of pediatricians and parents to determine their current attitudes in regards to those products and to the advisory.<sup>25</sup> Of the physicians surveyed, 63% chose the following response in regards to parents who request their recommendations on the usage of pediatric OTC cough and cold products: "Do not use OTC cough and cold medicines because they are not effective and they may cause serious and potentially life-threatening side effects."<sup>25</sup> While 46% of physicians thought the Public Health Advisory could be implemented without incident, 48% believed parents would demand treatment with these products anyway and 14% believed "lack of educational materials for parents" would be detrimental to implementation.<sup>25</sup> Of the parents surveyed, 70% believed that the products would assist their child to be more comfortable.<sup>25</sup> Following the advisory, however, only 15% of parents stated that they would continue to administer the products to their children age two and under.<sup>25</sup> For parents of children two to eleven years, 61% stated they would also continue to use them to alleviate their child's symptoms.<sup>25</sup>

Nicole Lokker, et. al. sought to assess the comprehension and understanding of OTC pediatric cold and cough labeling by parents in a research study that was published in *Pediatrics* in 2009.<sup>26</sup> This research evaluated "[parent/]caregiver understanding of the age indication of over-the-counter cold medication labels and identify factors, associated with caregiver understanding."<sup>26</sup> Caregivers with children less than 1 year old were invited to participate in this study by completing surveys

related to their understanding and characterization of pediatric OTC cough and cold labeling. The results indicate that product packaging influenced caregiver decisions. Pictures of infants and the specific "infant" term on the labeling weighed heavily on the caregivers perception.<sup>26</sup> Results also indicate that the age categories supplied on OTC pediatric labeling are complicated for caregivers to understand; caregivers in this instance primarily meaning mothers.<sup>26</sup> Barring that the caregivers recruited in Lokker's study had children less than 1 year old, the conclusions drawn regarding comprehension and understanding of OTC pediatric labeling may be extrapolated to caregivers with children 2 to less than 12 years of age.

Similarly, another study found that errors in dosing were more likely when age or other factors were used to measure the correct dose. Siu Fal Li et. al., conducted a study regarding pediatric misdosing in OTC antipyretics.<sup>27</sup> Results of Li et. al.'s study indicates that more than one fourth of study participants cited package labeling as their source to determine the correct dose. However, only approximately one half of those who chose package labeling accurately measured the correct dose.<sup>27</sup> These results clearly indicate that further education of the labeling for dosage administration in OTC pediatric cough and cold medications is needed.

Another detriment to parent/caregiver understanding of pediatric OTC cough and cold labeling is literacy and label comprehension. In a study by Yin et. al., results indicate that caregivers with low or marginal literacy levels had decreased knowledge regarding dosing factors other than age.<sup>28</sup> Yin et. al.'s data further validates previously published studies on this issue. Prior studies have also identified links between low literacy skills and trouble following directions for the labeled use of medications.<sup>28,29</sup>

OTC pediatric cough and cold dosing errors have been shown to occur due to parent/caregiver lack of understanding which could be attributed to lower literacy skills.

Enhanced caregiver educational programs on understanding OTC pediatric cough and cold labeling, i.e. the components of the Drug Facts box, is currently an unmet need. Veronica Gunn et. al. presents examples of this need in case studies regarding child morbidity from OTC pediatric cough and cold products in a 2001 *Pediatrics* article.<sup>30</sup> In the second case study, the parents were adamant that they only administered their child an OTC antipyretic, but when they provided the physical bottle of the medication, the antipyretic was also combined with an antihistamine and an antitussive, i.e. cough suppressant.<sup>30</sup> The parents were unaware of the other active ingredients in the medication as the identifiers on the medication label were in a smaller font.<sup>30</sup> In the study discussion, Gunn et. al. references prior studies that show "...caregivers reported that they primarily followed dosing guidelines on the medication package."<sup>30</sup> Gunn et. al. state that this practice could potentially lead to errors such as misinterpretation of the labeled dose and frequency of dose. These factors were illustrated in the second case study presented by Gunn et. al.<sup>30</sup> As the child's parents did not carefully examine the label, the child was inadvertently given a cough and cold product instead of a single antipyretic. This also further demonstrates the link between literacy level, label comprehension and further caregiver educational needs.

Educating parents and caregivers is a combined effort for all members of the medical team i.e physician, nurse and/or pharmacist. However, these are not the only three possibilities that parents/caregivers have available to them for information. The internet is becoming a more relied upon source for information as well as other



parents/friends and prior experience with the medications. This has been previously shown in research by Lea S. Eiland, Maria Salazar and Thomas English.<sup>31</sup> In their study, they asked caregiver's to rank seven different sources for their information; 65% of the 62 participants chose physicians first, nurses were second, pharmacists came in third with friends and family in fourth, child care/teachers placed fifth, the media came in sixth and finally in seventh place was the internet.<sup>31</sup>

Educational programs implemented by all types of educators must keep one basic characteristic in mind; the literacy level of the caregiver. In order for the caregiver to improve health behaviors through education, the caregiver must be able to read and comprehend the topics addressed. Sanders et. al. sought to evaluate the literacy level of US caregivers and the reading level of typical pediatric health information and the corresponding relationship between the two.<sup>32</sup> Sanders et. al. discovered that most child health information requires a tenth grade reading level and nearly 1 in 3 young adults scored low on literacy tests.<sup>32</sup> In addition to these outcomes, adults with lower literacy skills "...are 1.2 to 4 times more likely to exhibit negative health behaviors that affect child health."<sup>32</sup> Thus, giving credence to better educational programs for caregivers with literacy levels in mind.

Caregivers are not the only group that needs further education on OTC pediatric use. Ecklund and Ross identified that health care "...providers need further education [regarding incorporating] inquires about OTC medication use into their history taking."<sup>33</sup> In their literature search, Ecklund and Ross acknowledged two previously published works that indicate directions regarding OTC medications given to parents by health care providers often fail to include the benefits versus the risks.<sup>33</sup> When Ecklund and

Ross provided a questionnaire to parents asking them to indicate their usage of OTC medications in their children as well as their thought processes behind medicine decision, the data signified that further education and guidance is needed for caregivers.<sup>33</sup> Data from Ecklund and Ross' study also indicate that if caregivers perceived the OTC medications to be effective, they were more likely to use them. Due to those findings, the authors conclude that precise "...guidelines for the appropriate use of OTC medications should be provided to parents..."<sup>33</sup> Finally, it was determined that vulnerable age groups, such as those with low literacy and younger caregivers should be given individual attention to assist them in self autonomy about using OTC medications in children and when it is necessary to seek out assistance from health care providers.<sup>33</sup>

In summary, available literature suggested that caregivers require more education on the usage of these products; specifically on the benefits as well as the side effects of use. Literature also suggested that parents found the age categories in the dosage administration labeling section confusing and a contributing factor to this confusion was literacy level of the caregiver.

## **CHAPTER 3**

### **METHODOLOGY**

#### **3.1    Research Hypothesis**

It is the hypothesis of this study that the recent FDA position for industry voluntary label modification for pediatric populations is not sufficient to ensure the reduction and possible elimination of pediatric misdosing. This research will explore caregivers' perceptions and comprehension of dosage administration directions for pediatric populations that is printed on manufacturing labels through prior studies and then apply that knowledge through human focus groups.

#### **3.2    First Level of Research**

First, a literature search was performed to identify prior studies conducted on this same topic and were discussed in Chapter 2. A bibliography of the search results was compiled and is presented in Appendix A. From that data, a set of interview questions was compiled and applied to the second level of research involving human subjects.

#### **3.3    Disclosure**

The researcher discloses that she is part of the community in which the study was conducted and has a child in the specified age range as defined in the inclusion criteria. The researcher also discloses that her personal social media site, i.e. Facebook®, was used for recruitment of subjects in addition to the recruitment that was conducted through the partnership between the researcher and a North Georgia

pediatrician's group. This usage of the personal social media site resulted in about half of the focus group participants personally knowing the researcher.

### 3.4 Study Design

An inductive qualitative study was employed for the second level of research by utilizing homogeneous focus groups. Jenny Kitzinger examined the use of focus groups in her study Qualitative Research: Introducing focus groups as published in the 1994 *British Medical Journal*.<sup>34</sup> Kitzinger stated that focus groups "...are a popular method for assessing health education messages and examining public understandings of illness and of health behaviours."<sup>34</sup> Kitzinger also effectively demonstrated the applicability of inductive qualitative study through the usage of focus groups in yet another of her studies, The methodology of Focus Groups: the importance of interaction between research participants, as presented in the 16th volume of the *Sociology of Health & Illness* journal.<sup>35</sup> Kitzinger's study concludes that focus groups "...are ideal for inductive approaches aimed at generating concepts and hypotheses which...may have far more potential for health education research, theory and practice than dominant deductive models."<sup>35</sup> As the purpose of the research was to examine caregivers understanding and comprehension of pediatric OTC cough and cold labeling, a focus group approach was the most ideal method to apply. Group settings can foster open dialogue between participants about topics which they find important.<sup>35</sup> Focus groups can also enable interaction that individual interviews or surveys might hinder by allowing the researcher to observe participant body language, emotions and nonverbal communication.

Inclusion and exclusion criteria for the focus groups were modeled after similar criteria from prior studies. The inclusion/exclusion criteria are presented Table 3.1.

Men and women age 18 and over were chosen as responses were being sought from parents and caregivers and those from children were not desired.

Table 3.1: Focus Group Inclusion/Exclusion Criteria

INCLUSION CRITERIA		EXCLUSION CRITERIA
Focus Group 1	Focus Group 2	Focus Groups 1 & 2
Men and Women	Men and Women	Children
Minimum age of 18	Minimum age of 18	Anyone 17 years or younger
At least 1 child in the current household ages 2 to 12 years of age	At least 1 child in the current household ages 2 to 12 years of age	Households without children ages 2 to 12 years of age
Minimum education level of a Bachelor's degree	Maximum education level of a high school diploma or GED	
Household disposable income of more than \$49080 <sup>38</sup>	Household disposable income of less than \$49080 <sup>38</sup>	Teenagers with children who are dependents in another household
English as a primary language	English as a primary language	English as not the primary language
Willingness to provide informed consent	Willingness to provide informed consent	Unwillingness to provide informed consent

In the state of Georgia, 18 is the legal age of consent for medical treatment and the 21st title of the Code of Federal Regulations part 50.3(o) defines children as "... means persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted."<sup>36,37</sup> As the study was to examine caregivers perceptions of pediatric OTC cough and cold labeling, the caregivers needed to have at least one child in the household that fell inside the labeled age range of 2 to 12 years of age.<sup>19</sup> Since the study was designed to analyze differences in education

levels as a subset, minimum and maximum education levels were established. The economic inclusion criteria was derived from the median household income for the state of Georgia from the 2007 Census dataset.<sup>38</sup> The criteria for English as the primary language was chosen as the study was not designed to include vulnerable participants such as immigrants. Finally willingness to provide consent was desired to preserve the ethic of the study and required by the IRB.

The subject questionnaire was originally developed as the tool that confirmed the subject met the inclusion criteria and placed each subject into the appropriate focus group based upon subject self reporting of education level and income. The subject questionnaire is presented in Appendix B. It was modeled after a similar study as conducted by Simon and Weinkle.<sup>23</sup> Although the tool used in this study was not validated, it followed a similar standard set by Simon and Weinkle's questionnaire. Simon and Weinkle used their study's questionnaire to gain self reported participant information regarding "...general demographic characteristics, recent OTC use and medical history of the patients..."<sup>23</sup> This study's questionnaire, upon application in the focus groups, was used to gather socioeconomic information through self reporting of each participant, which was similar to the application of the tool by Simon and Weinkle.<sup>23</sup> The interview/focus group questions for this study were designed to collect information regarding recent OTC use instead of collecting that data via the subject questionnaire like with Simon and Weinkle's tool.<sup>23</sup> Since this study relied upon the subject to accurately self report, researcher concerns arose regarding truthful reporting. Specifically, the researcher was concerned that the subject may not accurately select the appropriate income choice due to feelings of anxiety and/or vulnerability; moreover,

he or she may refuse to answer the question despite the anonymity of the questionnaire. Because of these concerns and the desire to eliminate potential distress to the subject, the questionnaire evolved into a tool to collect subject socioeconomic data in order to analyze sub-themes such as level of education completed, income level, age and number of children in the household among participants.

The interview/focus group questions were derived after reviewing the available literature on this topic as presented in Chapter 2. They were designed to facilitate group discussion and interaction in a positive environment to cultivate the opinions of the participants. The interview/focus group questions are presented in Appendix C. During the focus groups, participants were asked a series of questions regarding how they obtain information regarding the dosing of their child, their opinions of the OTC cough and cold labeling and what they would recommend for improvement.

Interested parties used the contact information on the recruitment flyer to obtain additional information about the study from the researcher. Informed consent was requested from each subject by signing the official form. Participant informed consent was derived to protect the subject's rights as well as to inform them of the purpose of the research and the benefits/risks associated with participation. Two focus group sessions were scheduled on consecutive weekends in anticipation of subject availability. As the study population included parents and caregivers, weekends, specifically Saturdays, were chosen to try accommodate the schedules of the participants. The estimated time required for the focus group sessions was 60 to 90 minutes. The same methodologies, i.e. informed consent interview questions, light refreshments and subject questionnaires did not differ for either session.

### 3.5 Institutional Review Process

This study was submitted to the University of Georgia's (UGA) Institutional Review Board (IRB) for approval as required by departmental policy, University of Georgia policy, state law, and 45 CFR Part 46.<sup>39,40</sup> The study's research methods, benefits to the participant, i.e. light refreshments during the focus group session, and tools applied to participants were approved by the UGA IRB on November 18, 2009. The tools include a recruitment flyer, participant informed consent, interview/focus group questions and the subject questionnaire. When the study design was revised from two separate focus groups to one collective group, an IRB amendment was submitted on February 25, 2010 to the IRB and the researcher received IRB approval on February 26, 2010.

### 3.6 Subject Recruitment

The researcher partnered with a pediatrician's group in North Georgia to increase the probability of obtaining the desired subject population with 12-15 participants. Recruitment for the study began on January 19th, 2010 and ended on March 5th, 2010. The study was not intended to generalize and extrapolate themes to a specific population; thus a large sample population was not required. Therefore, purposeful sampling was employed to identify "...information rich-cases--those from which one can learn a great deal about issues of central importance to the purpose of the research," thus the term purposeful sampling.<sup>41</sup> The IRB approved recruitment flyer was disseminated to potential subjects on the main campus of the clinic by the medical staff. The recruitment flyer was developed to invite potential subjects to participate in the study. Training on the study was conducted for the medical staff on January 18, 2010.



Recruitment was also conducted on the researcher's social media site, i.e. Facebook®, from which acquaintances meeting the inclusion/exclusion criteria could be identified via networks. Salganik and Heckathorn introduced researchers to a variation of snowball sampling, i.e. respondent-driven sampling, in 34th volume of *Sociological Methodology*.<sup>42</sup> Respondent-driven sampling is built upon "...the friendship network of existing members of the sample."<sup>42</sup> Figure 3.1 illustrates respondent-driven sampling<sup>42</sup> in a social media network.

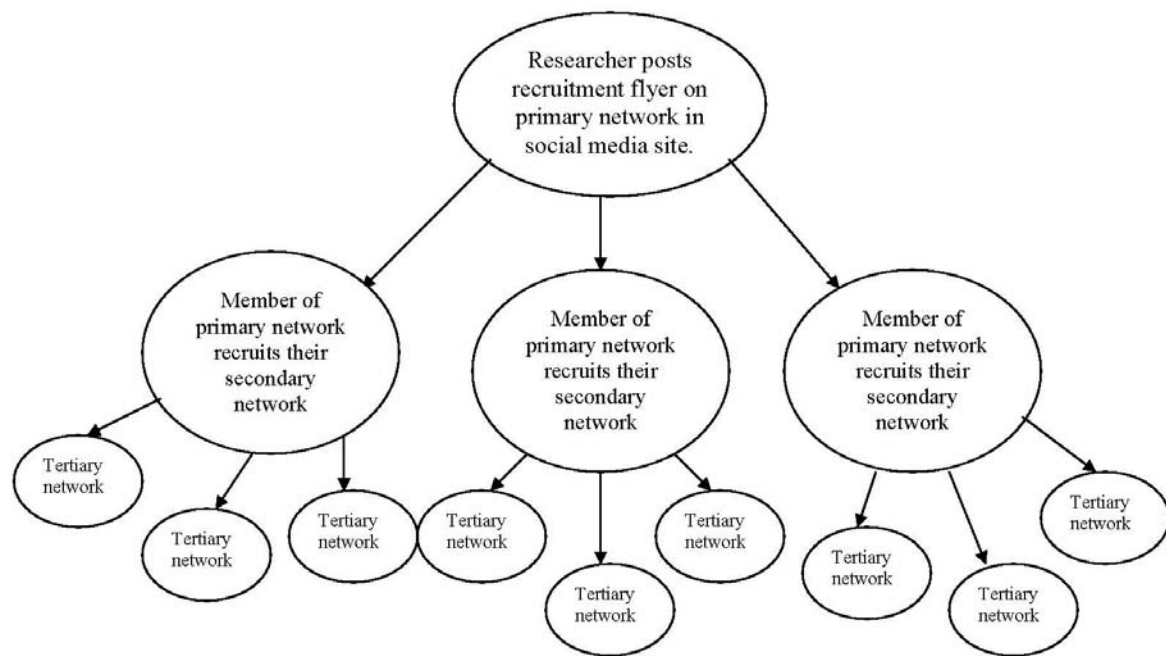


Figure 3.1 - Respondent-Driven Sampling<sup>42</sup> in Social Media Networks

The primary Facebook® network on which subjects were recruited had 280 members as of January 19, 2010. Three of primary network members directed their secondary network members, who were not members of the primary network, to the recruitment flyer. Members of the secondary network became members of the primary network in order to inquire about the study. Subsequently, the members of the secondary network directed their tertiary network members, who were not members of the primary or

secondary network, to the recruitment flyer on the primary network. Members of the tertiary network became members of the primary network in order to inquire about the study. These actions and reactions are examples of respondent-driven sampling.<sup>42</sup>

### 3.7 Data Analysis

The vehicle used to gather data for the study were qualitative focus groups. According to Michael Patton, author of *Qualitative Research & Evaluation Methods*, qualitative data in the form of transcripts are analyzed by the content therein.<sup>41</sup> Exploring text for reoccurring themes and patterns is a specific form of analysis commonly referred to as "content analysis."<sup>41</sup> Phillip Burnard teaches researchers how to analyze data through content analysis in his article included in the 16th volume of the 1996 *Nurse Education Today*.<sup>43</sup> Burnard describes three steps to content analysis: first, the data, i.e. transcripts, are read and categories are identified; next, the data are divided into the identified categories and finally, the data is presented in written form in which the identified categories from step one become the subheadings.<sup>43</sup> Step three would also include "...verbatim sections of the interviews..." which Burnard terms "...illustrations..." that show conclusions directly drawn from the data and not personal opinion.<sup>43</sup> Data from the study was analyzed utilizing Burnards's method. The transcripts from each focus group were reviewed and categories identified. Then the participant's responses were separated into the appropriate category as identified previously. Conclusions were drawn based on the responses given and excerpts from the transcripts were included to emphasize group responses. Finally, participant demographics were presented and analyzed for themes among the closed subset of the patient population.

## CHAPTER 4

### RESULTS

#### 4.1 Focus Group Composition

Focus groups were conducted on consecutive weekends. At the end of each session, subjects were asked to complete the questionnaire anonymously and place them face down on the table for collection. Three subjects participated in the first focus group and ten subjects participated in the second focus group after giving consent. The total participant goal of 12 - 15 was reached with the 13 total participants.

#### 4.2 Exclusions

When the subject questionnaires were analyzed, three out of the 13 total participants did not meet the inclusion criteria. Two of the participants were caregivers but did not have a permanent child in the household; and, the third had a permanent child in the home but the child was not between the ages of two to 12 years of age as set by the study's inclusion criteria. These three participants' data have been excluded from the final results of the study, but were analyzed separately to determine if their responses were similar or different from the 10 participants that did meet the inclusion criteria.

#### 4.3 Included Caregiver Demographics

The caregiver demographic data were analyzed from the self reported questionnaires and are provided in Table 4.1. The participants were primarily female and the mean age of caregivers was 34.3 years with a range of 30 to 46 years. The

mean age of children in the household was 7 with a range of 2 to 12 years of age and 100% of participants gave their consent.

Table 4.1: Included Caregiver Demographics

Characteristic	Mean or Percentage
Mean Caregiver Age, y	34.3
Sex	
Female	90%
Male	10%
Ethnicity	
Caucasian	100%
Primary Language	
English	100%
Education Level Completed	
High school/GED	70%
Undergraduate	30%
Graduate	10%
Marital Status	
Married	70%
Divorced	30%
Income Level	
Less than \$49,080 <sup>38</sup>	30%
More than \$49,080 <sup>38</sup>	70%
Mean age of children in household, y	7

Of the 70% of those who reported the completion of a high school diploma/GED, 30% had an income level of less than \$49,080<sup>38</sup> and a mean total of 1.3 children in the household. Contrastingly, of the 30% of those who reported graduation from college or technical school, 100% had an income level of more than \$49,080<sup>38</sup> and a total of 1 child in the household.

#### 4.4 Included Caregiver Mock Dosing Scenario Results

Focus group participants were asked to read the Directions section in the Drug Facts box for two predetermined medications and provide the correct dose for two predetermined scenarios. The two chosen products were Triaminic® Cough & Sore

Throat and Children's Robitussin® Cough Long-Acting as these products are indicated for four years and above. Those two medications provided the extreme examples for the youngest dosage age group. The first mock scenario was: after reviewing the pertinent labeling from the provided Triaminic® Cough & Sore Throat, what dose would you administer to a 6 year old child? How often would you give this dose? Responses were mixed. One participant from the first focus group and two participants from the second focus group provided the correct answer of two teaspoons every four hours for a six year old child according to the manufacturer's label. Most of the participants in the second focus group answered confidently, but incorrectly, that they would "split the difference and provide one and a half teaspoons" to the child as they believed that two teaspoons would be too much. While those responses were incorrect, they demonstrate that the parents tried to think critically about dosing their child. The caregivers that provided an incorrect dose further stated that they would administer the dose and judge from the child's response to it if they would change the amount on the second dose. Those parents also discussed children who were outliers to the age based dosing model which is discussed further in Section 4.5 below.

The second mock scenario was: after reviewing the pertinent labeling from the provided Children's Robitussin® Cough Long-Acting what dose would you administer to a 4 year old child? How often would you give this dose? One participant from the first focus group and three participants from the second focus group provided the correct answer of one teaspoon every six hours for a four year old child according to the manufacturer's label. Participants stated that they would not administer this product to their child. They stated that the manufacturer's label read "do not use in children under

four." Some of the caregivers were not sure what to administer as a four year old child overlaps into two categories in the Directions section on manufacturers' labeling. One parent pointed out that she called her pediatrician and was given verbal directions on an OTC children's cough and cold product. She went to purchase it at a local drug store and read the label regarding directions. The label contradicted the physician's instructions and was subsequently confused. Inconsistencies between physician instructions and dosage information on the manufacturer's labeling was an identified theme during data analysis and is discussed in detail in Section 4.5 below.

#### 4.5 Data Analysis Among Included Caregivers

During the analysis of the focus groups transcripts, several categories arose and include inconsistencies between physician instructions and dosage information on the manufacturer's labeling, alternate sources of information for dosing directions, educational program improvement for caregivers, Directions section placement and formatting on the manufacturer's labels, and revisions to the Directions section on manufacturer's labels. A sub theme was also identified that included discussion of the dosing devices provided with the OTC children's cough and cold products. Themes that were not part of the study's outcomes were also identified and included off label uses of the medications and alternate therapies.

Inconsistencies between physician instructions and dosage information on the manufacturer's labeling was evident. The group was divided on this category. There was one subgroup with the mindset that their physicians provided directions for the products but their directions were not consistent with the printed label; and, yet another subgroup felt that the medical staff did not explain the directions thoroughly. For

example the participants stated: "mine does but it is usually not lined up with what [the label] tells you to take" and "mine has told me he is too young for it but you can go ahead and use it...." Also another caregiver stated "Benadryl® says don't use under four" to which one of their peers replied "my doctor told me to give [Benadryl®] to my one year old." Caregivers also expressed that they had the utmost trust in their physician/pediatrician and believed that their child's doctor was knowledgeable in available pediatric safety and effectiveness data for OTC cough and cold products. A particular parent stated "I hate to admit this but I do trust the doctor so much that I don't really read the warning label. Like if he tells me what to give...then that is what I give."

Another theme identified was turning to alternate sources of information regarding the labeling. Should the physician fail to adequately explain the directions and dosage information for the children's OTC cough and cold products, caregivers search for alternative sources of labeling information. Several subgroups formed around this theme. One subgroup stated that they would "...rely/read the label" which unearthed additional questions of "how can the label be relied upon if it states 'ask a doctor'?" Another subgroup stated that they would turn to a family member who is in the medical profession. Two examples of this were an aunt who is an "ER nurse" and a step-father who is a "pharmacist". These members also offered that the nurse and the pharmacist relayed the dosage information based on the child's weight instead of age.

Improvement of the methods of education on the use of the children's OTC cough and cold products were identified. For example, caregiver transcription of dosing directions and verbal repetition was suggested. Specifically, the desire to transcribe the directions for these products while the physician explained them and then repeat them

back to the physician to ensure they were understood was evident. In that instance, caregivers expressed desire for autonomy in understanding the directions as given. In contrast to that method, the suggestion of handouts disseminated by the educator, in that instance a medical professional, was made. Particularly, some of the participants felt that handouts with explicit instructions would better assist them to properly dose their child. While handouts were agreed upon by the group, the form of the handout, either written or typed, was not. Some in the group felt that a written handout would not be beneficial; specifically the instructions "...can't be written...because you can't understand their handwriting at all"; "their" referring to physicians. Yet others in the group felt "...like them handing you a written copy in large print would help" with "them" referring to doctors, nurses, pharmacists or other educators. Finally, a third suggestion of clarity and standardization was made to improve education methods on children's OTC cough and cold products.

Directions placement and formatting of the Directions section on the manufacturer's labeling was a repetitious theme during data analysis. More specifically, the "hidden" placement of the Directions section among the other required sections of the monograph was discussed. The other required sections being Active Ingredients, Uses, Warnings, Do Not Use statements and Other Information.<sup>44</sup> The group was again almost evenly divided in this category. The two views of the group were clear. One view expressed the need to move the Directions section to "the top" of the label to determine the required dose "immediately." The caregivers who voiced this view spoke of late night incidences where their child was sick and unable to sleep, the caregiver was tired and they wanted to relieve their child's symptoms immediately. They did not



want to sort through sections of text in the Drug Facts box on the label to locate the Directions section. Contrastingly, the remaining group members felt that the Directions section needs to remain where it is currently. These members noticed that the Warnings section came before the Directions section and felt that placement was appropriate as the parent should "...read....[them] before even considering giving [the child] the medicine." In addition to the placement of the Directions section, the formatting of the Directions section was also discussed. Of the two example products given to the participants to review and comment on, one product had the Directions section in a bulleted list and the other product had the Directions section in an outlined table. The majority of participants preferred the table as opposed to the bulleted list as they felt the table could be easily located due to the border. The Directions section contained in the table was perceived to be more easily understood.

Revisions to the Direction section dosage information was yet another reoccurring theme during the group sessions. The addition of weight to the dose ratio on the OTC cough and cold label that mimics the antipyretic or fever reducing medications such as Children's Tylenol®<sup>45</sup> or Children's Motrin®<sup>46</sup> and the removal of the age ranges was an important request by the group. In fact, it was the most important revision for caregivers with younger children, i.e. less than 7 years. Caregiver's of older children, i.e. older than 7 years, asked "what if some parents did not know their child's weight?" A caregiver interjected "like my daughter, I couldn't tell you how much she weighs right now. She is 12." Those with older children felt that this addition of weight to dose ratio and removal of age would not be an all encompassing solution. A few of the parents with younger children offered a compromise. They

proposed leaving the age ranges on the label and having them coincide with the weight to dose ratio. The group concluded that the compromise was the best solution. During the discussion of adding weight tables to the label, outliers to the current age based dosing model were discussed. A caregiver from the first focus group stated that her child "...was always so skinny, he ever matched up the age and weight." She pondered what amount to give him due to those factors. During the first mock dosing scenario, a caregiver stated that "my six year old is much smaller than most six year olds...I would not give him the six to twelve [dosage] because he is no where near the size of a twelve year old." Another caregiver in the session questioned her statement, "[b]ecause you know his weight?" The first caregiver responded, "I know his stature. Even if I didn't know his weight I can look in his classroom. He is the smallest in his class, so there is no way I would give him two teaspoons." Outliers were discussed again during the second mock dosing scenario. One caregiver asked a parent sitting near her, "So your [child] just turned four so what would you give her?...[she] is tiny." The parent responded "I would give her one teaspoon. She weighs about four pounds less than her three and a half year old." Those statements continue to support the group's aforementioned opinion of adding weight to the current manufacturer's labeling.

While the group agreed that weight needed to be added to the label, some caregivers expressed confusion on the calculation of the dose interval. There was a significant exchange between four of the group participants in regards to this confusion. On one of the example labels provided at the group session, the frequency of dose was labeled as every four hours, not exceeding five doses in a 24 hour period. Several caregivers noticed that the math was incorrect as four hours multiplied by 5 doses (the

maximum dosage frequency in a 24 hour period) equaled 20 hours, not 24 hours. The correct maximum dose frequency in a 24 hour period was six doses. One caregiver stated "...the 24th hour is actually the next day so that would start the next dose range. So you are going to give them two [doses] at the 24 hour period?" Another caregiver provided this statement to clarify the calculation of dose frequency: If you gave it at twelve, four, and eight, then twelve, four and eight, then that is six doses." The caregiver that had asked the question responded "I understand the math part of it. What is noon the next day, does that count with the previous day?"

As a tangent to the previously discussed revisions theme, a sub-theme, devices used to administer the dose, emerged. Various devices were discussed by the group. Some of the participants felt that kitchen utensils were appropriate measuring devices. Comments included "...that is how I was dosed growing up", and "that is what I grew up on." Other devices discussed were droppers and cylindrical spoons. Out of all the devices discussed, the majority agreed that the droppers "really help."

Finally, some miscellaneous themes were identified that were not a part of the study's intended outcomes. Through the group dialogues regarding usage and caregiver opinion of the Directions section of children's OTC cough and cold labeling, caregivers also discussed the following with their peers: off label uses and alternate therapeutic remedies. The off label use of the children's OTC cough and cold products identified was administering the medication to induce drowsiness/sleep. The caregivers admitted that they had given OTC products to their children "...to help [the children] sleep." Four caregivers openly admitted to that use. The caregivers believed that their children needed rest as a remedy to help their symptoms and would give Benadryl® to

obtain that reaction. Yet one of their peers in the group stated that for "...some kids it [has] the opposite..." effect. In response to that statement, a caregiver who had not voiced many opinions, spoke out by stating "...it will jack [their child] off the walls."

Finally, alternative remedies were discussed at length. Honey was a very popular alternative to children's OTC cough and cold medicines. Four participants admitted and discussed the use of honey. In some cases, "...buckwheat honey..." was specified as a relaxation method. Honey in combination with other remedies was also discussed. One caregiver stated that she combined "...warm tea with honey at night." Another caregiver added support to the tea and honey statement by stating "yeah, it coats [the child's] membranes." Those caregivers' statements demonstrated a clear desire to administer remedies to their child to relieve symptoms by taking into account their child's safety.

#### 4.6 Excluded Caregiver Demographics

As aforementioned in Section 4.2 above, when the researcher analyzed the subject questionnaires, three out of the 13 total participants did not meet the inclusion criteria. In lieu of complete exclusion of their data, the researcher chose to analyze them separately to determine if the excluded subjects' data were similar or different from subjects who met the inclusion criteria of this study. This analysis was conducted separately from the included participant data analysis and did not affect the validity of the included participant data.

The excluded caregiver demographic data were analyzed from the self reported questionnaires and are provided in Table 4.2. The participants were primarily female and the mean age of caregivers was 35 years with a range of 26 to 52 years. The

mean age of children in the household was 11 with a range of 3 to 19 years of age and 100% of participants gave their consent. Of the 33% of those who reported the completion of a high school diploma/GED, 100% had an income level of less than \$49,080<sup>38</sup> and a total of 1 child in the household. Contrastingly, of the 67% of those who reported graduation from college or technical school, 33% had an income level of more than \$49,080<sup>38</sup> and a mean total of 1.5 children in the household.

Table 4.2: Excluded Caregiver Demographics

Characteristic	Mean or Percentage
Mean Caregiver Age, y	35
Sex	
Female	67%
Male	33%
Ethnicity	
Caucasian	100%
Primary Language	
English	100%
Education Level Completed	
High school/GED	33%
Undergraduate	67%
Marital Status	
Single	67%
Married	33%
Income Level	
Less than \$49,080 <sup>38</sup>	67%
More than \$49,080 <sup>38</sup>	33%
Mean age of children in household, y	11

#### 4.7 Excluded Caregiver Mock Dosing Scenario Results

The caregivers excluded from the data analysis gave contrasting answers to those caregivers that were included in the predetermined mock dosing scenarios regarding the Triaminic® Cough & Sore Throat and Children's Robitussin® Cough Long-Acting medications. In the first focus group, one participant answered incorrectly

in regards to the first mock dosing scenario with "one teaspoon every four hours." That caregiver was confused as to which category the mock 6 year old child belonged. Other caregivers in the group explained that it was the "Children 6 to under 12 years of age" category. For the second mock dosing scenario, all excluded caregivers provided the correct answer of "one teaspoon every six to eight hours." The caregivers were able to practice dosing administration skills through participation in those scenarios in the group sessions and clearly demonstrated the advantages of caregiver education.

#### 4.8 Data Analysis Among Excluded Caregivers

Interestingly, themes from the excluded participant data were consistent to the themes from the participants who met the inclusion criteria. The themes included inconsistencies between physician instructions and dosage information on the manufacturer's labeling, alternate sources of information for dosing directions, educational program improvement for caregivers and revisions to the Directions section on manufacturer's labels. Medicinal dosing devices were also discussed by the excluded participants.

Inconsistencies between physician instructions and dosage information on the manufacturer's labeling were discussed. One caregiver in the first focus group stated that she "...[does not] request more [information from the physician]..." in regards to OTC labeling directions while in the physician's office. She went on to state "...you don't find that there is a problem...", i.e. confusion with directions from the physician, "...until you read the directions on the bottle." That caregiver also stated that she felt that "...critical reasoning..." was necessary to determine dosage information from the children's OTC cough and cold labeling.

Next, the alternate sources of information for dosing directions theme emerged. A caregiver from the first focus group session felt that other members of the medical profession, i.e. pharmacists, should be better educated on dosing information for children's OTC cough and cold medications. The caregiver offered "I think the pharmacist should be more informed. Because the doctor's time is so limited and then once you figure out that you have a problem, you can't speak to the doctor. So pharmacists need to be equally informed to help you. Because they are readily available." Even though the caregiver did not meet the study's inclusion criteria, her response regarding turning to family members who were pharmacists as alternate sources of information for dosing directions, were similar to other caregivers who had met the inclusion criteria.

As with the aforementioned theme, educational program improvement for caregivers was also identified from the dialogue excluded from data analysis. A caregiver from the second focus group stated that during a recent physician's appointment, her child received three medications and the physician "...threw..." directions "...at [them] at once." She went on to state "[w]e didn't get a hand out on what the steps are. I need a recipe, essentially, to follow." The caregiver also supported the desire to have "...readable print..." as opposed to handwritten directions, which was the same desire expressed from a group of caregivers who met the included criteria. Specifically, the caregiver stated "I need a handout to go back to and say ok this is what I do." Those statements are comparable to the included caregivers.

Yet another theme identified from the excluded data was revisions to the Directions section on manufacturer's labels. Two caregivers from the first focus group

expressed desire for the labels to be revised for the addition of weight. One of those caregivers felt the current label was "...vague..." The two caregivers from the first group stated "[t]here could be a [weight] chart." In contrasting opinion, a caregiver from the second focus group wanted to have the age categories remain on the label as she stated "I don't know how much my kids weigh and I don't have a scale in the house." That caregiver nonverbally agreed with the compromise of adding weight to the label while keeping age on the label as well by nodding her head. Children who parents considered to be outliers were also a part of this discussion regarding revisions to the Directions section. That discussion reinforced the groups desired to include weight on the label. A caregiver from the first focus group stated "...this just goes by ages..." referring to the Triaminic® Cough & Sore Throat. He went on to state "...it doesn't say anything about how big the child, I mean, kids nowadays are ginormous. Just because you have a six year old, he could be the size of a kid three years older than him." The caregiver questioned if that was significant and thought it was. Similarly, another caregiver from the second focus group remarked on the outlier issue, "I have a girlfriend that has a twelve year old and he is a mini man." A third caregiver offered a solution for physicians, "...maybe the doctor could say your child weighs whatever he weighs. [The label's] going to say to give him one teaspoon because he is five years old but because he weighs this amount you can give him up to one and a half." That statement supported the argument to add weight to current children's OTC cough and cold labeling.

Finally, the last theme identified from the excluded data was medicinal dosing devices. A caregiver noticed that sometimes the medicine dispensers provided with



adult OTC products have incorrect markings. He stated how he could see it being a problem for the children's OTC medications. Then the caregiver offered his opinion on a solution, "if there was marketed a child's medicine dispenser that was the correct measurement and you could buy that." Another caregiver agreed that then "you wouldn't have different cups for everything."

## **CHAPTER 5**

### **CONCLUSIONS**

#### **5.1 Convergent Theme Discussion**

The focus group's identified themes raised important points of concern and positive solutions. The data from this study further supports previously published work. Focus group participants state that if the physician does not supply adequate information regarding the directions for children's pediatric OTC cough and cold medications, they will seek alternate sources for the information. Specifically the focus group participants state that they seek information from family members who work in the medical profession, i.e. an ER nurse and a pharmacist. This is consistent with the findings from Eiland, Salazar and English in which nurses were ranked second and pharmacists third as information sources.<sup>31</sup> This is also consistent with findings from Simon and Weinkle's study which reported that from the caregivers surveyed, the majority stated their child's dosing information came from a physician or family member.<sup>23</sup> It is important to note that the participants' responses regarding the sources of information overlap categories as delineated by Eiland, Salazar and English in their study.<sup>31</sup> Participants state that their sources of information were family members, the category ranked fourth in Eiland, Salazar and English's study<sup>31</sup>, as well as members of the medical community. The influences of the overlapping alternate sources of dosing information need further study to determine if they assist in the decrease of incidence of adverse reactions.

In terms of parents/caregivers' comprehension and understanding of the dosage administration directions for OTC cough and cold medications in children two to twelve years of age, caregivers state that the directions are unclear and they become confused as to which age dosing category their child fits. They also state that the dosing intervals are confusing. These findings are consistent with the findings from Lokker et. al.'s study results despite the fact that the participants from Lokker et. al.'s study had children less than two years of age.<sup>26</sup>

During this study's mock dosing scenarios, several caregivers gave a confident incorrect answer to the first scenario of one and one half teaspoons as they felt the labeled amount of two teaspoons was too much for their child. These findings clearly support the prior data from Li et. al.'s study that showed approximately one half of their study participants who chose package labeling as their source of dosing directions accurately measured the correct dose.<sup>27</sup>

## 5.2 Divergent Theme Discussion

The vast majority of the previously published data on parental comprehension and understanding of children's OTC cough and cold products emphasizes reading comprehension, adverse side effects, age versus weight dose determination and measuring skills. The actual formatting of the Directions section is not widely discussed. One sub-theme that emerged in the focus groups was the utilization of a table to convey the Directions section instead of a bulleted list. It is important to note that both of these formats are accepted by the FDA<sup>47</sup> but caregivers clearly prefer the table. Those who wished to move the Directions section to the beginning of the OTC labeling commented that the manufacturer's who utilize the table for the Directions

section made it easier to find dosage information. Unspoken cues, i.e. nodding heads in agreement, intent studying of the two example products, during this discussion further verified participants agreement in regards to the table. Further research on the formatting of the OTC label is needed to better understand how it influences parental comprehension of these products.

While some of the previously published work suggested that further parental education programs on these products are needed, they did not specifically state what to add or improve upon. Caregiver's in this study clearly state what they wish to see in terms of better educational methods on dosing administration. However, parents did not request additional education on potential side effects or adverse events that could occur during use. Simon and Weinkle's data clearly demonstrate that caregiver education on adverse events is needed to reduce dosing errors.<sup>23</sup>

### 5.3 Identified Outcomes

An identified outcome of this study is more consistent directions between the physician and the manufacturer's label. Parents feel that this consistency may be achieved through improved educational programs and labeling requirements which include enhancements to current physician educational programs by providing caregivers printed handouts with their child's dosing directions as a reference. Parents also request, as an enhanced educational measure, parental written transcription of verbal directions followed by verbal repetition of those directions by the parent back to the medical professional to verify accuracy. Another outcome is the addition of weight to the dosing chart requirements on manufacturer labeling. Study participants, both included and excluded, feel that weight is a more accurate measure for the appropriate

dose regarding their children. By combining both age and weight on the manufacturer's label, proper dosing for children two to twelve years of age will occur. Caregivers in this study also feel that formatting the Directions section in a table instead of a bulleted list enables them to easily locate that section on the label.

These outcomes demonstrate that parents/caregivers desire to see revisions to the labeling of current children's OTC cough and cold medications. They feel the Directions as currently labeled are confusing and not easily understood. They express desire to be autonomous in their child's medical care but feel that they are limited in that goal due to the current labeling requirements and lack of information regarding the usage of these products is specific age groups. In order for the manufacturers to change their labeling in accordance with parental wishes, changes must occur in the regulated 21 CFR Part 341 Monograph. The data from this study clearly supports prior data on this topic and provides a vehicle for usage by advocacy groups.

#### 5.4 Study Limitations

There are several limiting factors to this study. While focus groups were the most beneficial data collection method for the study, there are limitations to this method. One limitation is that unlike the one on one interview, participants in focus groups can listen to each other's responses. Those who are introverted might be intimidated by other participants and as a result may not speak out.<sup>41</sup> The usage of focus groups limited the sample size of this study. If other researchers choose to repeat this study, larger sample sizes analyzed through different methodologies would allow extrapolation to larger populations.

The sample size also limited the population as to obtain members of other ethnic groups. The researcher's intent was to examine the different opinions and comprehension of the Directions section of the manufacturer's labeling from a closed sub-set of individuals; not to extrapolate the findings to a larger diverse population. While the researcher partnered with a local North Georgia pediatrician's group to recruit the subjects for the study, the rural area of the community limited the recruitment process. In addition to the limits of the community's geographical area, the study was designed around non-immigrants with English as the primary language. The results collected cannot be extrapolated to immigrants/non-English speakers. As this study was a pilot study for this research, further study for those vulnerable populations and geographical differences is needed.

Published literature demonstrated that literacy level influences caregiver perceptions and understanding of the directions on children's OTC cough and cold medications. This study examined completed education levels and did not determine individual literacy level of participants through a validated tool. Replication of this study using a literacy measuring tool is recommended to determine if study outcomes will be altered.

## APPENDIX A

### BIBLIOGRAPHY COMPILED DURING LITERATURE REVIEW

Bronstein, Alvin C., et. al. "2006 Annual Report of the American Association of Poison Control Centers National Poison Data System (NPDS)". *Clinical Toxicology*. December 2007. 45:8, 815 – 917.

Eiland, Lea S., et. al. "Caregivers' Perspectives When Evaluating Nonprescription Medication Utilization in Children." *Clinical Pediatrics*. July 2008. 47 (6): 578 - 587.

FDA. "Using Over-the-Counter Cough and Cold Products in Children." FDA Consumer Health Information. October 2008.pg. 1-2.

Garbutt, Jane M., et. al. "Physician and Parent Response to the FDA advisory About Use of Over-the-Counter Cough and Cold Medications." *Academic Pediatrics*. 2010/ 10 (1): 64-69.

Gunn, Veronica L., et. al. "Toxicity of Over-the-Counter Cough and Cold Medications." *Pediatrics*. September 2001. 108 (3): e52.

John, Jincy M. "Preventing Medication Errors at Home." *Journal of Pharmacy Practice*. June 2005. 18 (3): 141-144.

Li SF, Lacher B, and EF Crane. "Acetaminophen and ibuprofen dosing by parents." *Pediatric Emergency Care*. December 2000. 16 (6): 394 - 397.

Lokker, Nicole, et. al. "Parental Misinterpretations of Over-the-Counter Pediatric Cough and Cold Medication labels." *Pediatrics*. June 2009. 123 (6): 1464 - 1471.

Madison-Kay, Dianne J. and Frederick S. Mosch. "Liquid Medication Dosing Errors." *The Journal of Family Practice*. August 2000. 49 (8): 741 – 744.

Sharfstein, JM et. al. "Over the counter but no longer under the radar - pediatric cough and cold medications." *The New England Journal of Medicine*. Dec 2007. 357 (23): 2321 - 2324.

Simon, H.K. and D. A. Weinkle. "Over-the-counter medications. Do parents give what they intend to give?" *Archives of Pediatrics & Adolescent Medicine*. July 1997. 151 (7): 654-656.

Williams, M.V., et. al. "Inadequate literacy is a barrier to asthma knowledge and self-care." *Chest*. October 1998. 114 (4): 1008 - 1015.

Yin, Shonna H., et. al. "Association of Low Caregiver Health Literacy With Reported Use of Nonstandardized Dosing Instruments and Lack of Knowledge of Weight-Based Dosing." *Ambulatory Pediatrics*. August 2007. 7 (4): 292 - 298.

## APPENDIX B

### SUBJECT QUESTIONNAIRE

Please select one:

☐ Male ☐ Female

In what year were you born?

19\_\_\_\_\_

In which of the following groups would you most likely place yourself?

- ☐ Caucasian/White
  - ☐ Black/African American
  - ☐ Asian/Pacific Islander
  - ☐ American Indian/Eskimo
  - ☐ Hispanic/Latino
  - ☐ Other (please specify)
- \_\_\_\_\_

Is English your primary language?

☐ Yes ☐ No

What is the highest level of education you have completed?

- ☐ Some high school or less
- ☐ Graduated highschool/GED
- ☐ Some college/technical-  
no degree
- ☐ Graduated college/technical
- ☐ Post graduate  
degree/certificate

Please select your current marital status:

- ☐ Single
- ☐ Married
- ☐ Divorced
- ☐ Separated
- ☐ Widowed

Which of the following categories best describes your total (combined if married) household income last year before taxes?

- ☐ Less than \$49,080
- ☐ More than \$49,080

Do you have children ages 2 to 12 years of age currently living in your household?

☐ Yes ☐ No

If so, please list the ages of each child.

\_\_\_\_\_

Are you willing to give your permission to participate in this focus group by signing a consent form?

☐ Yes ☐ No



## **APPENDIX C**

### **INTERVIEW/FOCUS GROUP QUESTIONS**

Title: Parents'/Caregivers' Opinions and Understanding of Dosage Administration Directions for Over-The-Counter Cough and Cold Medications in Children 2 to 12 Years of Age

#### Focus Group Interview Questions

1. Does your doctor/nurse/pharmacist thoroughly explain the directions section of the labeling of over the counter products?
2. Do you request more information on dosing from your doctor/pharmacist or do they explain it to you without questions from you?
3. What could your doctor/nurse/pharmacist do to better educate you on the usage of over the counter products, especially following the directions as they apply to your child?

Take a moment to review the labeling for Triaminic® Cough & Sore Throat and Robitussin® Children's Cough Long-Acting.

4. What is your opinion of the placement of the directions section on the labeling?
5. After reviewing the pertinent labeling from the provided Triaminic® Cough & Sore Throat, what dose would you administer to a 6 year old child? How often would you give this dose?

(Correct answer: For a 6 year old child, 2 teaspoons. It would be given every 4 hours.)

6. After reviewing the pertinent labeling from the provided Robitussin® Children's Cough Long-Acting what dose would you administer to a 4 year old child? How often would you give this dose?

(Correct answer: For a 4 year old child, 1 teaspoon. It would be given every 6 hours).

7. Are you comfortable with the directions as provided?
8. How could the directions be improved?

## REFERENCES

- 
- <sup>1</sup> CHPA website. "OTC Facts and Figures." Accessed April 6, 2010. Available: [http://www.chpa-info.org/pressroom/OTC\\_FactsFigures.aspx](http://www.chpa-info.org/pressroom/OTC_FactsFigures.aspx)
- <sup>2</sup> Suydam, Linda, et. al. "Safety and Efficacy of Over-the-Counter (OTC) Cough and Cold Medicines for Pediatric Use." PowerPoint presentation. Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the Pediatric Advisory Committee (PAC). Food and Drug Administration. October 2007.
- <sup>3</sup> FDA. "Using Over-the-Counter Cough and Cold Products in Children." FDA Consumer Health Information. October 2008.pg. 1-2
- <sup>4</sup> Office of the Federal Register, National Archives and Records Administration. *Federal Register*. Vol. 41. 156: 38312 – 38424.
- <sup>5</sup> Sharfstein, JM et. al. "Over the counter but no longer under the radar - pediatric cough and cold medications." *The New England Journal of Medicine*. Dec 2007. 357 (23): 2321 - 2324.
- <sup>6</sup> Chang, Marina Y. "Regulatory History of Pediatric Cough/Cold Products." PowerPoint presentation. Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the Pediatric Advisory Committee (PAC). Food and Drug Administration. October 2007.
- <sup>7</sup> Temple, Anthony R. "Pediatric Dosing of OTC Medicines: Application to Cough and Cold Medicines." PowerPoint presentation. Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the Pediatric Advisory Committee (PAC). Food and Drug Administration. October 2007.
- <sup>8</sup> Sharfstein, Joshua M., et. al. "Citizen's Petition." Docket No: 2007P-0074. Accessed April 15, 2010. Available: <http://www.fda.gov/ohrms/dockets/dockets/07p0074/07p-0074-cp00001-01-vol1.pdf>
- <sup>9</sup> CHPA website. "About CHPA." Accessed March 20, 2010. Available: [http://www.chpa-info.org/aboutchpa/about\\_chpa.aspx](http://www.chpa-info.org/aboutchpa/about_chpa.aspx)
- <sup>10</sup> Abate, Richard. "Over-the-counter Cough and Cold Product Medication Errors." PowerPoint presentation. Joint Meeting of the Nonprescription Drugs Advisory Committee (NDAC) and the Pediatric Advisory Committee (PAC). Food and Drug Administration. October 2007.
- <sup>11</sup> US Department of Health and Human Services. "Medicines In My Home: Information for adults using over-the-counter medicines safely." Food and Drug Administration. Publication No. (FDA) 07-1907. Accessed April 13, 2010. Available: <http://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingOver-the-CounterMedicines/UCM201466.pdf>
- <sup>12</sup> US Department of Health and Human Services. "Over-The-Counter Human Drugs; Labeling Requirements." *Federal Register*. March 1999. 64(51): 13254 - 13303.
- <sup>13</sup> Food and Drug Administration. "OTC Drug Facts Label." Accessed April 13, 2010. Available: <http://www.fda.gov/Drugs/ResourcesForYou/Consumers/ucm143551.htm>

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<sup>14</sup> Fitzpatrick, Cindi. "Email to Caitlin Senter, RE: Copyright Permission Request: Medicines In My Home PDF." April 14, 2010.

<sup>15</sup> Termini, Roseann B. *Health Law: Federal Regulation of Drugs, Biologics, Medical Devices, Foods and Dietary Supplements*. 2nd ed. Wynnewood, PA: Forti Publications: 206.

<sup>16</sup> Food and Drug Administration. "New OTC Drug Facts Label." *FDA Consumer Magazine*. July – August 2002. Available: [http://www.fda.gov/FDAC/features/2002/402\\_otc.html](http://www.fda.gov/FDAC/features/2002/402_otc.html)

<sup>17</sup> CHPA. "Makers of OTC Cough and Cold Medicines Announce Voluntary Withdrawal of Oral Infant Medicines." Press Release. October 2007. Available: [http://www.chpa-info.org/10\\_11\\_07\\_OralInfantMedicines.aspx](http://www.chpa-info.org/10_11_07_OralInfantMedicines.aspx)

<sup>18</sup> CHPA. "Infant Cough and Cold Medicines to be Voluntarily Withdrawn." October 2007.

<sup>19</sup> Code of Federal Regulations. Part 341 Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-The-Counter Human Use. Food and Drug Administration. Title 21. Volume 5.

<sup>20</sup> John, Jincy M. "Preventing Medication Errors at Home." *Journal of Pharmacy Practice*. June 2005. 18 (3): 141-144.

<sup>21</sup> Bronstein, Alvin C., et. al. "2006 Annual Report of the American Association of Poison Control Centers National Poison Data System (NPDS)". *Clinical Toxicology*. December 2007. 45:8, 815 – 917.

<sup>22</sup> Madison-Kay, Dianne J. and Frederick S. Mosch. "Liquid Medication Dosing Errors." *The Journal of Family Practice*. August 2000. 49 (8): 741 – 744.

<sup>23</sup> Simon, H.K. and D. A. Weinkle. "Over-the-counter medications. Do parents give what they intend to give?" *Archives of Pediatrics & Adolescent Medicine*. July 1997. 151 (7): 654-656.

<sup>24</sup> Food and Drug Administration. "Public Health Advisory: FDA Recommends that Over-the-Counter (OTC) Cough and Cold Products not be used for Infants and Children under 2 Years of Age." January 2008. Available: <http://www.fda.gov/Drugs/DrugSafety/PublicHealthAdvisories/UCM051137>

<sup>25</sup> Garbutt, Jane M., et. al. "Physician and Parent Response to the FDA advisory About Use of Over-the-Counter Cough and Cold Medications." *Academic Pediatrics*. 2010/ 10 (1): 64-69.

<sup>26</sup> Lokker, Nicole, et. al. "Parental Misinterpretations of Over-the-Counter Pediatric Cough and Cold Medication labels." *Pediatrics*. June 2009. 123 (6): 1464 - 1471.

<sup>27</sup> Li SF, Lacher B, and EF Crane. "Acetaminophen and ibuprofen dosing by parents." *Pediatric Emergency Care*. December 2000. 16 (6): 394 - 397.

<sup>28</sup> Yin, Shonna H., et. al. "Association of Low Caregiver Health Literacy With Reported Use of Nonstandardized Dosing Instruments and Lack of Knowledge of Weight-Based Dosing." *Ambulatory Pediatrics*. August 2007. 7 (4): 292 - 298.

<sup>29</sup> Williams, M.V., et. al. "Inadequate literacy is a barrier to asthma knowledge and self-care." *Chest*. October 1998. 114 (4): 1008 - 1015.

<sup>30</sup> Gunn, Veronica L., et. al. "Toxicity of Over-the-Counter Cough and Cold Medications." *Pediatrics*. September 2001. 108 (3): e52.

- 
- <sup>31</sup> Eiland, Lea S., et. al. "Caregivers' Perspectives When Evaluating Nonprescription Medication Utilization in Children." *Clinical Pediatrics*. July 2008. 47 (6): 578 - 587.
- <sup>32</sup> Sanders, Lee M. et. al. "Literacy and Child Health: A Systematic Review." *Archives of Pediatric Adolescent Medicine*. February 2009. 163 (2): 131-140.
- <sup>33</sup> Ecklund, Connie R. and M. Candice Ross. "Over-the-Counter Medication Use in Preschool Children." *Journal of Pediatric Health Care*. August 2001. 15: 168 - 172.
- <sup>34</sup> Kitzinger, Jenny. "Qualitative Research: Introducing focus groups." *British Medical Journal*. July 1995. 311: 299-302.
- <sup>35</sup> Kitzinger, Jenny. "The methodology of Focus Groups: the importance of interaction between research participants." *Sociology of Health & Illness*. 1994. 16 (1): 103-121.
- <sup>36</sup> [O.C.G.A. TITLE 39](#)
- <sup>37</sup> Code of Federal Regulations. Part 50 Protection of Human Subjects. Food and Drug Administration. Title 21. Volume 5.
- <sup>38</sup> US Census Bureau. State and County QuickFacts: Georgia. Data derived from Population Estimates, Census of Population and Housing, Small Area Income and Poverty Estimates, State and County Housing Unit Estimates, County Business Patterns, Nonemployer Statistics, Economic Census, Survey of Business Owners, Building Permits, Consolidated Federal Funds Report. Accessed: July 2, 2009. Available: <http://quickfacts.census.gov/qfd/states/13000.html>
- <sup>39</sup> University of Georgia. "General FAQ, Question 3." Office of the Vice President of Research at the University of Georgia website. Available: <http://www.ovpr.uga.edu/hso/fags/general>
- <sup>40</sup> Code of Federal Regulations. Part 46 Protection of Human Subjects. United States Department of Health & Human Services: Office for Human Research Protections. Title 45. Available: <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- <sup>41</sup> Patton, Michael Q. *Qualitative Research & Evaluation Methods*. Sage Publications. 3rd. Ed. 2002.
- <sup>42</sup> Salganik, Matthew J. and Douglas D. Heckathorn. "Sampling and Estimation in Hidden Populations Using Respondent-Driven Sampling." *Sociological Methodology*. 2004. 34: 193-239.
- <sup>43</sup> Burnard, Phillip. "Teaching the analysis of textual data: an experimental approach." *Nurse Education Today*. 1996. 16: 279 - 281.
- <sup>44</sup> Code of Federal Regulations. Part 201.66 Format and content requirements for over-the-counter (OTC) drug product labeling. Food and Drug Administration. Title 21. Volume 4.
- <sup>45</sup> McNeil Consumer Healthcare. "Children's Tylenol® Directions." McNEIL-PPC. 2010. Accessed April 22, 2010. Available: [http://www.tylenol.com/product\\_detail.jhtml?id=tylenol/children/prod\\_child.inc&prod=subpchild#](http://www.tylenol.com/product_detail.jhtml?id=tylenol/children/prod_child.inc&prod=subpchild#)
- <sup>46</sup> McNeil Consumer Healthcare. "Children's Motrin® Directions." McNEIL-PPC. 2010. Accessed April 22, 2010. Available: [http://www.motrin.com/page.jhtml?id=motrin/products/1\\_2\\_1.inc&sec=directions](http://www.motrin.com/page.jhtml?id=motrin/products/1_2_1.inc&sec=directions)
- <sup>47</sup> Food and Drug Administration. "Guidance for Industry: Labeling OTC Human Drug Products (Small Entity Compliance Guide)." May 2009. Available: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM150994.pdf>