THE EFFECTS OF DIRECT TO CONSUMER ADVERTISING ON HEALTHCARE UTILIZATION AMONG MEDICAID CHILDREN WITH ASTHMA

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A DISSERTATION

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ABSTRACT

National guidelines recommend treatment of asthma with preventive long term medication, but adherence remains low, resulting in high healthcare utilization among those affected by the chronic disease. The increase in DTCA since the easing of restrictions by the FDA in 1997 has prompted much debate on the effects of the DTCA, with critics arguing that it is harmful while proponents see many benefits such as increased medication adherence.

This study examines the impact of DTCA on healthcare utilization and asthma medication use by combining Medicaid administrative data and a national advertising data set on asthma medication from 1999 to 2002. Univariate and multivariate regression analysis were performed to analyze the data. The principal findings of the study showed that DTCA significantly increased the new cases of asthma diagnosis. Healthcare utilization and asthma medication use among Medicaid children was impacted by DTCA. However, there was a differential impact of DTCA on healthcare utilization for Whites and Blacks.

Keywords: asthma, Medicaid children, direct to consumer advertising, asthma medication
DEDICATION

In loving memory of my mother, Leila R. Turner who inspired me to pursue my dreams and made the ultimate sacrifice for education and my sister, Carmen E. Kentish who paved the way. To my husband, Carl and our children, Charis and Malachi, who made one of the greatest sacrifices in allowing me to pursue my dream.
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CHAPTER 1
INTRODUCTION
An Overview of Asthma

Asthma is a chronic lung disease that causes inflammation and narrowing of the airways. This disease affects more than 300 million people worldwide (Masoli, Fabian, Holt, & Beasley, 2004). With increasing urbanization of the world’s population, the number of people affected by the disease is expected to grow to more than 400 million by 2025 (Masoli et al., 2004). Approximately 38.4 million people in the United States have been diagnosed with asthma at some point in their lifetime (O. J. Akinbami, Moorman, & Liu, 2011). Currently, 24.6 million Americans, or 8.2% of the population, have asthma (O. J. Akinbami et al., 2011).

The prevalence of asthma is higher among African Americans, women, children, and those from low income families (Bloom, Cohen, & Freeman, 2011). African American women were 30 percent more likely to be stricken with the disease than non-Hispanic white women from the years 2001 to 2003 (Moorman, Rudd, & Johnson, 2007). In 2006 African Americans were found to be three times more likely than non-Hispanic whites to die from causes related to asthma (Heron et al., 2009). Health care utilization is higher amongst these groups, particularly among African Americans who had asthma-related emergency department visits 4.5 times more often than whites in 2004 (Moorman et al., 2007).

Children have a higher rate of asthma than adults, and prevalence among children has been increasing. Specifically, according to the 2009 National Health Survey, approximately 7.1 million children (9.6% of children in the US) are estimated to have

1
asthma (Bloom et al., 2011). This compares with 6.5 million (8.9% of children) in 2005 (L. Akinbami, 2006).

Mortality, morbidity, and health service utilization related to asthma is higher among minority children. There were approximately 4,000 asthma U.S. related deaths in 2006. Of those, 131 occurred in children under 15 (CDC, 2009). Even when symptoms are not severe enough to require hospitalizations or visits to emergency departments, there may be adverse effects that significantly alter the quality of life. Between 2003 and 2005, the asthma death rate of African American children was seven times that of non-Hispanic white children (L. Akinbami, 2006). A total of 198,000 children were hospitalized for asthma related conditions in 2004 which equates to 27 hospitalizations per 100,000 children with asthma (L. Akinbami, 2006). The hospitalization rate was 250% higher for minority children compared to non-Hispanic white children and the death rate from asthma was 500% higher among minority children compared with non-Hispanic white children (L. Akinbami, 2006).

Asthma is the leading cause of emergency department visits amongst children, particularly, the youngest and those from minority groups (US Department of Health and Human Services, OHHS, 2008). Additionally, the number of emergency department visits among African American children is 260% more than the number for non-Hispanic white children (L. Akinbami, 2006). In 2006 it was estimated that 10.6 million doctor visits, 1.1 million non-emergency hospital outpatient visits, 1.6 million emergency department visits, and 440,000 hospitalizations were attributable to asthma (CDC, 2008). The number of emergency department visits rose to 1.75 million in 2007 from 1.6 million in 2006 and asthma related hospitalizations rose to 456,000 in 2007 from 440,000 in 2006.
Children are more likely to be hospitalized with 189 per 100,000 children compared to 113 per 100,000 adults (Coffey, et al. 2006)

The burden of asthma has far reaching societal and economic impact, particularly among children. The economic cost of asthma is substantial (Global Initiative for Asthma, 2003). The direct medical burden includes hospitalizations, emergency department visits and medication costs. Total expenditures for asthma treatment have been estimated to exceed $30 billion yearly in the United States (CDC, 2009).

Medicaid insurance bears a large burden of the cost. Approximately one half of all hospitalizations for asthma among children are billed to Medicaid (Pleis, Lucas, & Ward, 2009). It is estimated that Medicaid expenditures on asthma may exceed $4 billion dollars per year. Medicaid spending is highest in the Northeastern states. California, Texas, Florida and New York were estimated as having the highest spending with more than $1.5 billion for asthma care for their Medicaid enrollees (Coffey et al., 2006).

The indirect costs of asthma include time lost from school and work (Global Initiative for Asthma, 2003). Over 14 million school days were missed yearly due to asthma in 2007, making it one of the leading causes of school absenteeism (CDC, 2008). Furthermore, quality of life may be impaired due to loss of sleep, and restricted activities and often cause disruption to family routines (OHHS, 2008).
Biology of Asthma

The cause of asthma is unknown. Genetic and environment factors have been suggested as possible reasons for airway inflammation (OHHS, 2008). Asthma tends to run in families and may be inherited, but the evidence is inconclusive. Similarly, asthma in early life is more prevalent among boys, but specific hormones have not been linked to asthma (OHHS, 2008). Major environmental factors such as contacts with allergens, pet dander, dust mites and respiratory infections are thought to affect development and persistence of the disease. Additional factors that may trigger asthma include increased physical activity and strong emotions (http://www.lungusa.org/lung-disease). However, individuals are affected differently by these triggers.

Asthma affects the airways, making it difficult for air to pass in and out of the lungs. The airways are often swollen and inflamed in individuals with the disease making them very sensitive to asthma triggers, which can include the common cold, changes in the weather, dust, smoke, chemicals, or other allergens or irritants. Asthma triggers that are inhaled result in increased mucus in the airways and increased inflammation or swelling. The airways then become more constricted making breathing very difficult. Since children have smaller airways, the disease becomes more serious for them. Wheezing, coughing, chest tightness and trouble breathing in the early morning and during the night may be symptoms of asthma. Symptoms that are worse than usual may be referred to as an asthma attack (http://www.lungusa.org/lung-disease).

Asthma is not only common, but complex, as the symptoms and the patterns of the disease are variable. It is characterized by recurring symptoms, airway obstruction,
inflammation and hyper responsiveness (OHHS, 2008). The severity of asthma and the treatment of such are determined by the characteristics of asthma (NHLBI, 2007).

Diagnosis and Classification of Asthma

Several measures exist to diagnose asthma such as spirometry and peak expiratory flow, with the spirometry being the preferred method when measuring limitation of airflow to the lungs. Diagnosis is often based on the symptoms and medical history of the patient. While suspicion of asthma may be more likely with symptoms such as wheezing, reaction of asthma triggers, and history of cough, chest tightness and other asthmatic symptoms, diagnosis may not be confirmed until it is performed by measurements of lung functions (Global Initiative of Asthma, 2010).

Asthma is classified into four categories according to level of severity: (1) mild intermittent, (2) mild persistent, (3) moderate persistent and (4) severe persistent. Mild intermittent asthma is characterized by asthma symptoms less than two times a week and night time symptoms less than two times per month. Mild persistent indicates having asthma symptoms less than two times per week, but less than one time a day. Additionally, activity may be affected by asthma exacerbation. Moderate persistent asthma implies daily symptoms, exacerbations which may be more than two times per week and may last for days that will affect daily activities. Severe persistent asthma is defined as continual symptoms with frequent night time symptoms, limited physical activities and frequent exacerbation (NHLBI, 2007).
Asthma Treatment

Like the disease, treatment of asthma is complex. There are four components of care required to control asthma. They include 1) assessing and monitoring asthma severity and asthma control 2) patient/doctor partnership 3) reducing risk exposure and 4) medications (NHLBI, 2007).

Assessing and Monitoring Asthma Severity and Asthma Control

It is important to first assess the severity and intensity of the disease. Patients are to be assessed in order to determine treatment regimen and adherence to treatment. Additionally it is important to determine the level of asthma control among patients and consistently monitor patients to maintain control and establish the lowest dose of treatment in order to manage asthma (NHLBI, 2007).

Patient/Doctor Partnership

To control asthma, the patient or care provider should have a working relationship with the physician. Patients should be educated on the variety of methods to control asthma, including how to avoid triggers, taking correct dosage of medication, and the difference between types of medications. Working with the physician, the patients should have a written personal asthma action plan which includes what the regular treatment should be, an assessment of the level of asthma control, how to increase treatment if and when needed, when to call the doctor, and determine when there is an actual emergency and what actions are to be taken during that time (NHLBI, 2007; Global Initiative for asthma, 2010).
Identification and Reduction to Risk Exposures

A number of factors may cause asthma symptoms. Common asthma triggers include environmental tobacco smoke, dust mites, outdoor air pollution, cockroach allergen, pets, and mold. Other triggers may include the common cold, strenuous physical exercise, medicines; inclement weather such as thunderstorms, high humidity, or freezing temperatures, certain types of foods and/or food additives, certain chemicals or other allergens or irritants and “strong emotional states.” Some triggers such as air pollution and weather changes are uncontrollable, however others may be avoided. Individuals are affected by different triggers and it recommended that patients be tested for factors that trigger asthma attacks. Patients may need medications to control their asthma symptoms. A number of strategies, however, are recommended to avoid asthma triggers. Avoidance of tobacco smoke and certain types of foods may reduce symptoms. The asthma management plan includes taking certain precautions to reduce exposures to triggers such as house dust mites, outdoor pollen and other environment factors (Global Initiative for asthma, 2010).

Medications

The fourth component, medications, is based on the symptoms of asthma. A variety of asthma medications are available to control asthma symptoms. There are two main categories of medications: (1) long-term and (2) quick-relief or rescue medications. Long-term medications include: inhaled corticosteroids [fluticson (Flovent), budesonide (Pulmicort), triamcinolone (Azmacort), flunisolide (Aerobid), beclomethasone (Qvar), mornetasone (Asmanex) and ciclesonide (Alvesco); leukotriene
**modifiers** [montelukast (Singulair), zafirlukast (Accolate) and zileuton (Zyflo)];

**combination inhalers** [Advair (fluticasone and salmeterol), Symbicort (budesonide and formoterol) and Dulera (mometasone and formoterol); and **theophylline**. Long-term medications are taken over a period of time to maintain control of persistent asthma. The second category, quick-relief medications are also called short-acting bronchodilators. They include **albuterol, pirbuterol and levalbuterol**. The most frequently used quick relief medication is albuterol. Short acting bronchodilators may work quickly, however they do not work at maintaining control of the symptoms over a long period (www.mayoclinic.com).

Inhaled corticosteroids have been advocated as the cornerstone medication for persistent asthma (NHLBI, 2007). Regular adherence of inhaled corticosteroid has been shown to decrease emergency department visits (Suissa, Ernst, Benayoun, Baltzan, & Cai, 2000), Benayoun, Baltzan, & Cai, 2000); Carmago et al., 2007; Piecoro et al., 2001). However, adherence to asthma medication is poor, particularly among children in state Medicaid plans (Camargo et al., 2007).

Several studies have examined adherence of inhaled corticosteroids (ICS) and utilization of emergency department visits and hospitalizations (Butz et al., 2006; Piecoro et al., 2001). Adherence of asthma medication has been attributed to a number of factors which include education, and knowledge of the risks and side effects of the drugs (NHLBI, 1997 & 2007). Other factors may include forgetfulness, and stigmatization (Wells, 2008). Morbidity and mortality of asthma patients can be prevented with increased patient education and medical management (NHLBI, 1997; Carmargo et al., 2007).
An Overview of Direct to Consumer Advertising

Direct to Consumer Advertising (DTCA) is defined as any type of prescription drug advertising that is geared towards the consumer or patient, rather than towards health care providers. There are three main categories of direct to consumer advertisements: (1) help seeking, (2) reminder and (3) product claims (Morgan, 2007; Pines, 1999). Help seeking advertisements provide sufficient information to assist consumer in identifying certain types of diseases and encourage physician visits. However, the product name is not mentioned (Morgan, 2007; Pines, 1999). This type of advertisement is permitted in the United States and Canada (Morgan, 2007). According to Morgan (2007) reminder advertisement in which the name of the product is mentioned, but there are no claims as to what the product does, is also allowed in both countries with some minor exceptions in Canada (Morgan, 2007). While the “medicinal” purposes of the drug are not mentioned (Pines, 1999), the manufacturer and the name of the product serve as a reminder to consumers. In product-claim or product-specific advertisement, which is not allowed in Canada, the name of the product, manufacturer and the type of disease is mentioned (Morgan, 2007; Pines, 1999).

Until the early 1990s, almost all advertising for prescription medications was aimed at physicians who would make judgments about what to prescribe and when; and most advertisements directed toward consumers were in print (Calfee, 2002; Morgan, 2007; Pines, 1999). This changed in August of 1997 when the Food and Drug Administration (FDA) eased the restrictions placed on DTCA of prescription drugs, allowing broadcast product-claim advertisements (Calfee, 2002; Pines, 1999). The FDA guidelines made it easier for pharmaceutical companies to provide product-claim
advertisements. The information about major side effects and contraindications didn’t have to all appear in the television advertisements. Instead, the FDA guidelines allowed advertisers to include such information by referring consumers to a toll-free phone number to obtain additional information that could either be mailed, faxed, or read to the consumer; a reference to a print advertisement that contained a short summary of the risks of the advertised drug; a website with more information about the drug and where consumers could obtain the package insert; or refer consumers to a physician, pharmacist or other health professional to obtain more information (Morgan, 2007; Pines, 1999).

Currently, the United States and New Zealand are the only developed countries that allow product-claim DTCA of prescriptions (Calfee, 2002). As a result of the policy changes by the FDA in August 1997, there has been an exponential growth in DTCA of prescription drugs. DTCA spending accelerated from 790 million in 1996 (Morgan, 2007) to $2.7 billion in 2001 (IMS Health, 2002). In 2005, pharmaceutical companies spent approximately $4.24 billion on DTCA (Morgan, 2007).

Two Conflicting Views of DTCA

The increase in DTCA of prescription drugs has prompted much debate on its effects. There remain conflicting views on the effects of DTCA with supporting studies for both arguments. Proponents of DTCA argue that it is good for consumers who seek autonomy and desire to have access to information concerning their medical care. Critics, on the other hand, argue that it can be potentially harmful to consumers.

Support for DTCA comes from a number of studies. According to Adeoye and colleagues, DTCA allows patients to inform themselves of the various options available
providing more patient empowerment and ownership of the decision making in healthcare (Adeoye et al., 2007). The symptoms and treatments for certain medical conditions that are presented in the advertisements may help to raise awareness of those conditions among the affected minority population (Mastin, Andsager, Choi, & Lee, 2007).

Two studies by the National Medical Association (NMA) in 2001 and 2006 found that DTCA educates patients regarding disease states. The studies also showed that when patients request specific medication, they are more likely to be compliant because they feel that they have helped make a decision (Allison-Otten, Ruffin & Allison, 2003; Morris, Gadson, & Burroughs, 2007). In a similar study of physicians, Murray and colleagues (2003) reported that DTCA of prescription drugs may also serve as a compliance tool coupled with health care provider intervention (Murray, Lo, Pollack, Donelan & Lee, 2003).

DTCA is believed to influence the relationship between the patient and the physician. Proponents of direct to consumer advertising see a positive effect on the physician-patient relationship in that it may enrich the relationship. DTCA prompts patients to talk with their doctor about medications that have been advertised and seek their opinion thus improving communication between physicians and patients (Allison-Otten et al. 2002; Calfee 2002; Allison-Otten et al., 2003; Morris et al., 2007; Kaiser Foundation, 2001; Friedman & Gould, 2007). Ultimately, physicians will be able to provide better treatment as a result of DTCA.

Opponents of DTCA present arguments that it produces more harm than good. Several studies have found that DTCA may decrease the quality of healthcare since it
may impair the relationship between the patient and the physician (Allison-Ottesy et al., 2003 & Mintzes, 2002). Since DTCA increases the likelihood that a drug advertised may be requested and granted by the physician (Mintzes, 2002; Datti & Carter 2006; Mintzes et al., 2003), there is concern that this may put pressure on physicians to comply with patients’ requests (Allison-Ottey et al., 2003). DTCA advertising may further impair the physician patient relationship when doctors feel uncomfortable about the choice of treatment sought by patients (Mintzes, 2002). It is also possible that requests may lead to conflict in the relationship as patients may second-guess the diagnosis and thus create tension between a doctor and a patient (Morris et al. 2007).

Opponents of DTCA fear that even though it may give patients information about a particular drug, the patients may not know if a particular drug is good for them. According to studies by Lexchin and Mintzes (2002) and Donohue et al. (2007) many DTCAs omit important safety information and may often exaggerate the product’s benefits. Drugs such as Oraflex, Baycol and Vioxx that had significant levels of advertising were later withdrawn for safety reasons (Lexchin and Mintzes, 2002). Side effects of the drugs advertised are often hidden in the advertisement with a small amount of the advertisements encouraging patients to seek more information (Wilkes et al., 2000).

Another concern is that most of the drugs advertised are new, providing insufficient background on side effects or effectiveness. For example, advertising campaigns began for Singulair and Advair [used as long-term control for asthma] within a year after FDA approval of the drugs in 1999 (Donohue et al., 2007). New drugs,
which represent the majority of the drugs that are advertised, may prove to be harmful for the consumers as compared to already established drugs (Mintzes, 2002).

**DTCA and Minorities**

One of the main aims of DTCA is to create a perceived need for a particular drug among consumers. However, the symptoms and treatments for certain medical conditions that are presented in the advertisements may help to raise awareness of those conditions among racial minority groups (Mastin et al., 2007). This awareness may be high among minorities as they tend to have more exposure to DTCA in general compared to whites, with blacks being more exposed to DTCA than Hispanics (Avery et al., 2008). The impact on health outcomes may be unclear. Studies have found that despite the higher exposure amongst minorities, they are less likely to receive the prescription requested (Parnes et al., 2009; Datti et al., 2006).
Research Questions

This study addresses the following questions:

*Research Question 1*

Does DTCA increase the diagnosis of new cases asthma cases?

DTCA is believed to increase awareness of a medical condition and drive patients to see their doctors. Results from this study will assist in determining the role DTCA plays in the informing and diagnosis of new asthma cases.

*Research Question 2*

Does DTCA increase utilization of asthma medication among children on Medicaid?

Adherence to medication is important in the treatment and control of asthma (Szefler et al., 2010). DTCA is believed to increase visits to doctors and communication between patient and doctor, and may increase medication adherence. This study will help to determine the effectiveness of DTCA on asthma medication use.

*Research Question 3*

Is DTCA associated with a reduction in asthma-related emergency department visits and hospitalizations for Medicaid children with asthma?

Results from this study will determine the effects of DTCA of asthma medication health utilization. It may help explain the role of information obtained through advertising on health outcomes during the study period.
Purpose and Significance of Study

This study examines the effectiveness of DTCA on adherence to asthma medication among children under the age of 18 who are Medicaid recipients. DTCA is believed to bring about awareness and educate consumers about drugs and health conditions that may aid in patient outcomes. While there have been conflicting results of the effects of DTCA, many empirical studies have shown that DTCA has led patients to seek care, request medication and adhere to their medication (Murray et al., 2004; Allison-Ottey et al., 2003). However, to date the effects of DTCA on asthma medication adherence, hospital utilization, in particular on the Medicaid population have not been studied.

This study is important for allocation of Medicaid funds for asthma treatment, guidance of health care organizations and other government agencies to reduce the burden of asthma and also improvement of patient based outcomes. There is a higher prevalence rate of asthma among the Medicaid population, more so than beneficiaries of commercial insurers, military health systems, employee sponsored commercial insurers and the Department of Veteran Affairs health systems (Gibson et al., 2009). Medicaid spends an enormous amount on asthma. National Medicaid expenditure on asthma is estimated to be $4 billion dollars, most of which is from hospitalization and emergency department visits which may be avoided through proper management of the disease (Coffey et al., 2006). From a patient-based outcome perspective, this study could be significant in the encouragement of educational interventions for asthma patients by providers. This may ensure better understanding of the medical condition, and available drugs thereby leading to improved patient outcomes.
CHAPTER 2
REVIEW OF LITERATURE

Asthma Medication and Adherence

While there is no cure for asthma, there have been improvements in treatment over the years. The severity and frequency of asthma attacks can be controlled with appropriate monitoring and use of medications. Additionally, external environment factors that may lead to asthma can be eliminated or decreased (NHLBI, 2008).

The National Asthma Education and Prevention Program (NAEPP) published guidelines that serve as a strategy to diagnose and manage asthma. These require cooperative efforts among patients, families and providers (NHLBI, 2008). Included in the guidelines is the recommended daily use of inhaled corticosteroid to treat and prevent asthma exacerbation for patients who have persistent asthma; thus, reducing asthma-related emergency department visits and hospitalizations (NHLBI, 2008).

Adherence is defined as the extent to which a patient complies with the medication treatment or advice provided by a physician or health care provider (Rachelefsky, 2007). Nonadherence may include failing to fill a prescription, inappropriate dosage, skipping treatments or pills, or simply not taking the medication (Griffith, 1990). To control asthma symptoms and prevent attacks, the controller medications need to be used daily (NHLBI, 2008). Not only do some patients not follow the recommended daily dosage, they may use less than the amount prescribed, take the wrong medication, or simply not take their medication during periods where there are no visible asthma symptoms (Piecoro et al., 2001). Nonadherence to the prescribed
treatment contributes significantly to poor health outcomes in asthma patients (Gillisen, 2007).

Nonadherence continues to be problematic in asthma patients as corroborated by studies reporting low asthma medication adherence (David, 2004; Piecoro et al., 2001; Conn et al., 2005; Butz et al., 2006) despite evidence that adherence to the NAEPP guidelines of the use of long-acting beta agonists or inhaled corticosteroids is associated with decreased hospitalizations (Camargo et al., 2007). Piecoro and colleagues found that less than 40 percent of asthma patients received a prescription for rescue medicine, which is recommended for all asthma patients with persistent asthma. In the same study, adherence to daily inhaled steroids was less than 10 percent (Pecoro et al., 2001). This evidence of poor adherence is further supported by Bender (2002). He found that adherence rate for asthma medication is less than 50 percent (Bender, 2002).

Adherence and Children with Asthma

Non-adherence is more problematic in children, leading to higher health care utilization. Hospitalization and emergency department visits for asthma exacerbation are particularly high among children despite many programs in place to reduce the burden of the disease (NHLB, 2008). Children are more likely to be admitted to a hospital for asthma than are adults (27.5 vs. 12.7 per 10,000). Failure to comply with the recommended inhaled corticosteroid may lead to exacerbation of the disease and the need for hospitalization (Milgrom et al., 1996). Milgrom and colleagues (1996) found that the median compliance with inhaled corticosteroids was a mere 13.7 percent for those who experienced an asthma attack requiring hospitalization or steroid to control their asthma.
compared to a compliance rate of 68 percent of for those who didn’t experience adverse effects (Milgrom et al., 1996).

Adherence is poor among Medicaid children, in particular for minorities who are less likely to have or use daily anti-inflammatory medication (Camargo et al., 2007; Conn et al., 2005; David, 2004, Finkelstein et al., 2002). Camargo and colleagues studied 10,976 children enrolled in Florida Medicaid with a hospitalization or emergency department visit for asthma from January 1999 to June 2001. They measured adherence by the medication possession ratio (MPR). There was a significantly low adherence, an average MPR of .16 for asthma controller medication. This low adherence amongst this group is linked to poor outcomes as shown in the following studies. Bratton and colleagues reported longer stays in pediatric intensive care unit and longer hospital stays among Medicaid children with asthma (Bratton et al., 2002). This low adherence is further confirmed by Finkelstein and colleagues (2000). In a comparison study with Medicaid and non-Medicaid recipients and their adherence to medication, Finkelstein and colleagues (2000) found that Medicaid recipients had higher hospitalization rates and emergency visits than non-Medicaid recipients (Finkelstein et al., 2000).

Factors Affecting Adherence to Asthma Medication

Asthma management is complex (NHLBI, 2008). The NAEPP guidelines recommend, in addition to assessment of asthma control and patient concerns, physicians’ assessment of the medication technique being utilized, and review of the written asthma action plan at every patient visit (NHLBI, 2008). However, there are numerous factors affecting nonadherence that further complicate management. Whether
the patient intentionally or unintentionally does not adhere to the medication, the outcome can be negative (Gillissen, 2007). Factors that affect adherence can be categorized as treatment related, patient related and clinician related (Rachelefsky, 2007).

**Treatment-related Nonadherence**

Factors related to treatment technique may be a key contributor to patient nonadherence (Rachelefsky, 2007). Treatment related barriers to adherence may include patient’s inability to determine the benefits of the medication or treatment, hence resulting in premature discontinuation of the therapy. Additionally, others may discontinue long treatment because they are no longer experiencing symptoms and feel they no longer need the medication (Rachelefsky, 2007). The complexity of the treatment regimen is another barrier to adherence (Farber et al., 2003). Proper use of inhalation technique is important for patients to receive the appropriate dosage. Parents often find the giving of daily medications a hassle (Yoos et al., 2003).

Other treatment related factors include side effects of the medication. Ivanova and colleagues (2008) studied the association between adverse effects and adherence to ICS therapy and found that the unpleasant taste of the asthma affected adherence (Ivanova et al., 2008). Other studies further confirm the impact of side effects on adherence (Yoos et al., 2003 & Ponieman et al., 2008). Concerns of being addicted to the drugs or that they were ineffective also led to nonadherence (Ponieman et al., 2008; Yoos et al., 2003; Conn et al., 2005). Only one study (Butz et al., 2006) showed conflicting results. They found that parental concerns about side effects was not associated with the number of prescription drugs filled, although children less than 6 years old had a significantly lower number of inhaled corticosteroid prescriptions.
Patient-related

Parental belief and attitude about asthma may be significant contributors to non-adherence (Raschelefsky, 2007). Parents of children with asthma may intentionally fail to comply with treatment guidelines due to misunderstanding of the disease. In some instances they may use the medicine as a last resort in treating asthma (Yoos et al., 2003). However, they are not likely to see immediate results since corticosteroids do not relieve symptoms (NHLBI, 2008). Patients with mild asthma are more likely to be non adherent. When symptoms are not visible, there is the belief that no treatment is necessary (Raschelefsky, 2007). A study by Ponieman et al. (2009) found that 88% of the participants reported the importance of using an inhaled corticosteroid when they were experiencing symptoms (Ponieman et al., 2009) contrary to the NAEPP guidelines (NHLBI, 2008). On the other hand, those who have severe asthma may not be adherent to long-term medication because of lack of faith that there won’t be improvement in health condition (Raschelefsky, 2007).

Physician/Clinician-related

Physicians play an important role in the asthma management plan (NHLBI, 2008). Adherence to the NHLBI guidelines is important in the improvement of patient outcomes (Wisnivesky et al., 2008). However, lack of confidence in the health care provider and infrequent appointments for follow up may severely affect the treatment regimen leading to nonadherence. While some of these barriers may be contributed to the patient, the physicians may also contribute to nonadherence through not explaining treatment, not being interested in the patient’s welfare, or taking time to answer questions (Raschelefsky, 2007). Physicians may contribute to nonadherence by not authorizing
refills or giving appropriate prescription (David, 2004; Camargo et al., 2007). Camargo and colleagues (2007) found that after 30 days of an emergency department visit or being hospitalized for an asthma exacerbation, many patients did not receive asthma medication and of those who received an asthma medication, “rescue medicine” was most common (Camargo et al., 2007).

Socioeconomic factors play a role in barrier to adherence. Butz et al. (2006) studied the use of these drugs in 180 children from lower socio-economic groups in two inner cities over a 12 month period and found that one out of five children had either no medication or only “rescue” medicine (short-acting beta agonists) at the end of 12 month follow up (Butz et al., 2006). In a study done on Florida Medicaid, it was found that approximately 11% of children had preventive medication half of the time during the study (David, 2004). Other studies reported similar results (Celano et al., 2010; Piecoro et al., 2001).

Efforts to Improve Asthma Adherence

Numerous programs and efforts have been made to improve adherence of asthma medication and thereby reduce the morbidity and mortality rate associated with exacerbations of the disease. The use of electronic health records, educational programs, school based programs and internet based home monitoring are just some of the initiatives undertaken (Bell et al., 2010; Chan et al., 2007; Charles et al., 2007). Charles and colleagues (2007) found that audiovisual reminders increase adherence of inhaled corticosteroids (Charles et al., 2007). In a comparison study of internet based home monitoring and office monitoring, it was found that there were similar results in
following therapy and in health outcomes. Both groups had a decrease in number of hospitalizations (Chan et al., 2007) indicating that monitoring of patients whether internet based home monitoring or office based is effective in improving patient adherence.

Most of the intervention studies to increase adherence include an educational component. One recent study, however, included an interactive computer-based multimedia presentation of the direct to consumer advertising of Singulair (Clerisme-Beaty et al., 2011), a long-term medication to control asthma symptoms. In this study the group that was exposed to an enhanced presentation which included the direct to consumer advertising had a significantly higher rate of adherence than other groups that didn’t receive an enhanced presentation. Individuals who were shown the enhanced presentation were four times as likely to adhere to their medication than those who weren’t shown the direct to consumer advertisement and received a placebo medicine (odds ratio, 4.0; 95% CI, 1.1-14.3)(Clerisme-Beaty et al., 2011).

Direct to Consumer Advertising (DTCA) and Adherence

Evidence show that DTCA may educate consumers, increase visits to doctors, and encourage discussion about medication (Calfee, 2002; Allison-Ottey et al., 2003; Morris et al., 2007). Additionally, the confidence to talk about health conditions promotes better doctor-patient relationship and encourages patients to follow advice and instruction of the physicians (Murray et al., 2003; Kaiser Foundation, 2001).

Few empirical studies have shown a link between DTCA and adherence. Hansen and colleagues (2010) reported that patients who received advertised antidepressants
were more likely to be adherent (Hansen et al., 2010). Another study by Donohue and colleagues (2004) reported that there was an increase in the initiation of treatment therapy for depression during periods of high spending on DTCA and a small increase in the number of patients who received appropriate treatment of antidepressant medication (Donohue et al., 2004).

Studies by Bradford and colleagues confirm the impact of DTCA prescribing behavior. DTCA may increase prescribing rate among a class of drugs. Bradford and colleagues (2006) examined the effect of DTCA on prescribing behavior for osteoarthritis patients. The particular drugs examined were Vioxx and Celebrex which at the time were the most popular anti-inflammatory drugs (Bradford et al., 2006). They found that Vioxx ads had a significant positive effect on the prescribing rates of Vioxx and a marginal effect on Celebrex (Bradford et al., 2006). In another study, Bradford and colleagues, using a sample of 18,235 patients diagnosed with osteoarthritis, studied how DTCA affects the delay between diagnosis and treatment with prescription drugs for patients who were suffering from a chronic disease. In this study, the data on advertising for Vioxx and Celebrex were utilized. The results for the two drugs were mixed. With an increase in DTCA for Vioxx, there was a shorter time between diagnosis of the disease and use of the drug. However, with Celebrex, there was a longer time period between the diagnosis and the use of the drug. Further analysis of result of the delayed adoption rate for Celebrex showed that DTCA helps to provide information to assist physicians in matching therapy with the patients (Bradford et al., 2010). For patients who may be poor candidates for treatments, there is a delay in adopting treatment, indicating that DTCA may be providing information that is useful to physicians and patients in providing
therapy (Bradford et al., 2007). The effect of DTCA on the timing of treatment is also confirmed in another study by Bradford & Kleit (2008). They found that with more advertising there is a greater likelihood of adopting treatment (Bradford & Kleit, 2008).

Summary

Numerous studies have confirmed low adherence of inhaled corticosteroids, the recommended treatment for persistent asthma and also the utilization of emergency department visits and hospitalizations (Butz et al., 2006; Piecoro et al., 2001). Barriers to adherence are extensive, and include factors such as, misunderstanding of the disease, treatment techniques, and lack of physician adherence to the guidelines (Ponieman et al., 2008; Ivanova et al., 2008; Camargo et al., 2007; Conn et al., 2005; David, 2004; Yoos et al., 2003). Adherence is particularly low among the Medicaid population (Butz et al., 2006, Piecoro et al., 2001; Finkelstein et al., 2002). Several intervention studies on improving adherence amongst have been done, with a most recent study including an enhanced presentation of an oral asthma control medication (Clerisme-Beaty et al., 2011). The findings indicated that showing of the direct to consumer advertising of the oral asthma control medication increased adherence (Clerisme-Beaty et al., 2011).

Misunderstanding and concerns about side effects of medication are factors affecting adherence of asthma medication (Farber et al., 2003; Butz et al., 2006). DTCA which provides education of medication, including the benefits and side effects of the drugs (Frosch et al., 2010; Murray et al., 2004; Mastin et al., 2007; Donohue, 2006) and also remind patients to take their prescription, may increase adherence (Allison-Otley et al., 2003).
Adherence of asthma medication is low among Minorities and as a result they are more likely to have higher rate of hospitalizations and emergency department visits (Camargo et al., 2007; Conn et al., 2005; David, 2004; Finkelstein et al., 2002). They are also more impacted by DTCA (Kaiser Foundation, 2001). With a more positive attitude towards direct to consumer advertising than Whites, Blacks are more likely to request prescription drugs from their physicians (Lee & Begley, 2010; Datti & Carter, 2006). Hence, they may be likely to benefit from DTCA. With minorities making up more than 50% of the children in the United States who are on state Medicaid, there is potential evidence that DTCA may potentially contribute to improved adherence among the Medicaid population (Kaiser Foundation, 2001).

The literature on direct to consumer advertising and medication adherence is scant. There are few empirical studies that examine the effects of DTCA on depression medication (Hansen et al., 2010; Donohue et al., 2004). It is unknown how DTCA of asthma medication may affect adherence. Additionally, as of this study, no studies have been done on the impact of DTCA on requests for asthma medication and asthma-related emergency department visits or hospitalizations in the Medicaid population, particularly among children with asthma.

Theoretical/Conceptual Framework

The burden of asthma is significant and there are many initiatives that are in place that seek to lessen the consequences of the disease, including the direct and indirect costs associated with increased hospitalizations and emergency department visits. While increased hospitalizations and emergency department visits are associated with low
adherence, there are other factors that are associated with health care utilization of asthma patients.

The Andersen model of health care utilization is a framework that aids in the understanding of all the factors that determine health care use (Andersen, 1995). The model posits that population characteristics along with environmental factors affect personal health choices and ultimately healthcare utilization. There are three main categories of the model, external environment, health services systems factors, and individual factors. As shown in Figure 1, the model posits that individual factors (predisposing factors, enabling resources and needs) work along with the external environment (societal factors) and the healthcare system to affect personal health choices and ultimately health care utilization (Andersen, 1995).
Figure 1: The Andersen Model of Healthcare Utilization

Health services systems factors – this is characterized by the resources such as labor and capital that is devoted to healthcare, how the organization uses its resources to provide medication service, and access.

Societal factors – these are factors in the environment, social and cultural that might affect health care use.

Individual factors – these include predisposing factors, enabling factors, and need. The predisposing factors are demographics variables such as age, gender, and race and the beliefs and attitudes of individuals. The enabling resources are income, parental education, and residence. The need component include the level of illness that brings about health service use.
The Andersen model of health care utilization may be used as a framework to address how DTCA affects prescription use. According to the model, individual factors work along with the external environment and the healthcare system to affect personal health choices and ultimately health care utilization (Andersen, 1995). The external environment which includes social and cultural factors such as direct to consumer advertising may affect health care use through influence on beliefs and attitudes of individuals. Predisposing factors such as race/ethnicity, gender and age affects exposure, and attitudes about DTCA. Enabling factors which may include income, residence and education may also affect the exposure, attitudes and overall influence of DTCA. Together, enabling and predisposing factors may affect adherence of medication and ultimately health care utilization through changed attitudes and beliefs. According to Yang and colleagues (2010) DTCA provides information that may change beliefs and attitudes about medical conditions, and treatment therapy (Yang et al., 2010). Need is the condition of the disease that may lead to patients seeking care. DTCA may bring about awareness of the severity of an illness and thus prompt patients to receive care.

There are a few empirical studies that show a link between direct to consumer advertisement and adherence. Studies by Hansen and colleagues and Donohue and colleagues reported a link between depressant medication advertised and adherence (Hansen et al. 2010; Donohue et al., 2004). Additional support of the link between DTCA and adherence comes from studies by Bradford and colleagues (Bradford et al., 2006; Bradford et al., 2007; Bradford & Kleit, 2008).
Conceptual Model of Andersen Health Care Model of Utilization for DTCA

As studies have shown, DTCA provides information to consumers, and is likely to change attitudes about medications and medical condition (Calfee, 2002; Allison-Otten et al., 2003; Morris et al., 2007). This has impacted prescribing behavior and adherence with drug therapy (Bradford & Kleit, 2008; Bradford et al., 2010; Donohue et al., 2004) and may lead to improved patient health outcome and reduce health care utilization.

A conceptual model shown in Figure 2 was created to depict the relationship between individual characteristics, DTCA, adherence and health care utilization. The individual characteristics: predisposing factors, enabling factors and need influence adherence of medication. In turn, adherence influences the outcome of hospitalization and emergency department visits. DTCA also influences adherence which in turn influences health care utilization. Additionally, health care utilization is influenced directly by individual characteristics.

In this conceptual model of the effects of DTCA on medication use, we hypothesize that DTCA, which would be considered an environmental factor, along with individual characteristics (enabling factors, predisposing factors and needs), affects attitudes leading to adherence of asthma medication and ultimately improved health outcomes in the form of lower emergency department visits and hospitalizations.
Figure 2: Conceptual framework for DTCA and Medication Use

Predisposing Factors
(race/ethnicity, gender, age)

Enabling Factors
(Residence)

Need
(Asthma condition)

Asthma Diagnosis

DTCA (mass media advertising)

Asthma Controller Medication use

Rescue Medication use

Asthma-Related Hospitalizations

Asthma-Related Emergency Department Visits
Hypotheses

As studies have shown, DTCA provides information to consumers, and is likely to change attitudes about medications and medical condition (Calfee, 2002; Allison-Ottey et al., 2003; Morris et al., 2007). There is some evidence that DTCA impacts prescribing behavior and timing of treatment (Bradford & Kleit, 2006, Bradford et al., 2007) and adherence with drug therapy (Donohue et al., 2004; Hansen, 2010) and may lead to improved patient health outcome and reduce health care utilization. Hence, this study examines the following hypotheses:

**Hypothesis 1: An increase in DTCA is associated with an increase in the proportion of children diagnosed with asthma.**

If DTCA increases awareness of the medical condition and treatment, it may drive patients to seek care. An increase in the proportion of children diagnosed with asthma corresponding to higher DTCA expenditures would support this hypothesis.

**Hypothesis 2: An increase in DTCA is associated with an increase in utilization of asthma medications.**

DTCA is intended to persuade and remind consumers about particular medications. An increase in prescribing of asthma medication during periods of DTCA of asthma drugs would support this hypothesis.
Hypothesis 3: An increase in DTCA is associated with a decrease in asthma-related emergency department (ED) visits.

As DTCA affects prescribing behavior and thus increased utilization of asthma medication, this may affect asthma-related emergency department visits. A decline in the number of emergency department visits for children with asthma in cases where prescribed asthma medications are filled would support this hypothesis.

Hypothesis 4: An increase in DTCA is associated with a decrease in asthma-related hospitalizations.

As DTCA affects prescribing behavior and thus increased utilization of asthma medication, this may affect asthma-related hospitalizations. A decline in the number of asthma-related hospitalizations for children with asthma in cases where prescribed asthma medications are filled would support this hypothesis.

Hypothesis 5: An increase in DTCA is associated with a decrease in asthma-related ED visits through increase in use of asthma controller medication.

DTCA may ultimately lead to improved health outcome and thus require less asthma-related ED visits. Increased use of asthma controller medication with decreases in the number of asthma-related ED visits for asthma exacerbations would support this hypothesis.
Hypothesis 6: An increase in DTCA is associated with a decrease in asthma-related hospitalizations through increase in use of asthma controller medication.

DTCA may ultimately lead to improved health outcomes. Increased use of asthma controller medication with decreases in the number asthma-related hospitalizations for asthma exacerbation would support this hypothesis.
CHAPTER 3

METHODOLOGY SECTION/RESEARCH DESIGN

Data Collection

This study includes children between the ages of 5 and 18 who had an asthma diagnosis and were Medicaid recipients between the years 1999 and 2002. Two data sources, Medicaid Analytic Extract (MAX) database and an advertising database obtained from TNS Media Intelligence are merged for use in this study using county identifiers. The MAX dataset provides information used for billing, reimbursement, and healthcare utilization. From the MAX dataset, information was obtained on demographics, the number and type of asthma medication prescriptions filled, health services utilization, and diagnoses. The use of these data was approved by the UAB Institutional Review Board and by the Centers for Medicare and Medicaid Services Privacy Board.

Specifically, Medicaid files which indicated a diagnosis for asthma were used in this study. They include the denominator file which provides a summary of children with an asthma claims; county files which provides information on the asthma diagnosis in all counties; asthma claims file which provides information on claims for health related asthma physician visits hospitalizations, emergency department visits; and prescription files which includes information on prescription claims for both short and long term asthma medication. The long term prescription drugs included in the MAX dataset were Serevent, Singulair, Advair, Accolate, Flovent and Qvar. The short term (rescue) medication was albuterol.
The advertising dataset used was a national report of monthly and yearly network sales of newspaper, cable television, magazine and television advertisements of asthma medication from the years 1999 to 2002. However, for this study only spot television advertisement was used which provided information at the county level. The data included advertising sales for long-term asthma medication reported in thousands of dollars and the number of times the ads appeared in the major metropolitan cities, considered the top local media markets in the United States.

The advertised asthma drugs included Advair (Fluticasone and Salmeterol), Flovent (Fluticasone), Serevent (Salmeterol), and Singulair (Montelukast). Advair is considered a combination drug as it contains Flovent, a corticosteroid which is used to reduce swelling and inflammation of the airways and Serevent, a long acting bronchodilator that reduces airway constriction. Advair was approved in 1999 by the FDA and is recommended for children ages four and older. Fluticasone (Flovent), another corticosteroid approved in 2000, is prescribed individually as part of asthma management program to children ages four and older. Serevent was approved in 1997 by the FDA for children ages 12 and older. It is a long acting beta agonist and is used for a short period of time when inhaled corticosteroids are not adequately controlling asthma symptoms. It is recommended that the drug be prescribed with another medication, not as a single medication. Approved by the FDA in 1998, Singulair is one of three leukotriene modifiers used to treat children 12 months and older with mild persistent asthma. It is available in the form of a tablet or oral granules and works to reduce asthma symptoms.
The highest spending was for Advair, followed by Singulair. Flovent and Serevent followed in that order. However, DTCA spending was aggregated across all four drugs. Variables representing 16 quarters over the four year study period were created. As a measure of DTCA spending, the aggregated DTCA spending was summed across quarters by counties. DTCA spending per MSA was used to create 4 quartiles to measure the effects of DTCA spending at different levels.

Samples

Two samples were used for analysis. The first sample consisted of data from 486 counties in 44 states (including DC) with advertising data for the period of 1999-2002, and it is used to test hypothesis 1. This sample includes county level data of the number of Medicaid children between the ages of 5 and 18 with an asthma diagnosis, as well as the number of Medicaid kids with a new asthma diagnosis in each quarter. The second sample consisted of Medicaid children between the ages of 5 and 18 who had an asthma diagnosis at any time during the study period 1999 to 2002, and it is used to test hypotheses 2-6. Children not residing in counties with DTCA advertising were excluded from the sample. Asthma diagnosis was defined based on three of four HEDIS criteria for persistent asthma: 1) At least 1 ED visit with asthma as the principal diagnosis, or 2) At least 1 hospital admission with asthma as the principal diagnosis, or 3) At least 4 ambulatory visits with asthma as the principal diagnosis and at least 2 asthma medication (Berger, W. et al., 2004). In order to reduce potential bias, the HEDIS medication use criterion (at least 4 asthma medication dispensing events) was not used in this study.
However, for hypothesis 1, the four criteria were used to determine the number of children with persistent asthma by county.

Operationalization of Variables

**Dependent Variables**

The dependent variables in the study are asthma diagnosis, asthma medication use, asthma-related emergency department visits, and asthma-related hospitalizations. Asthma diagnosis is defined as the number of new cases of asthma diagnosed in each quarter during the study period. Asthma medication use is defined as both short term rescue medication (albuterol) and long-term asthma medication to prevent asthma attacks. It is measured by filled claims for prescription asthma medication. Asthma-related emergency department visits (ED visits) is defined as the number of visits to the emergency department for asthma-related illnesses among children who have asthma. Asthma-related hospitalization is measured by the number of asthma-related hospitalizations that occurred for asthma-related conditions among the number of children with asthma.

Asthma controller medication (long-term medication), considered a mediating variable, is defined as the use in a given quarter of long-term asthma medication prescribed to control persistent asthma. Utilization of medication is affected by the independent variables, but also affects asthma-related hospitalizations and asthma-related emergency department visits.
**Independent Variables**

The independent variable of interest is DTCA. This is defined as expenditures on spot television or local advertising for asthma controller medication that is directed to the patient. It is quantified as DTCA spending per quarter by county. A squared term for DTCA spending was also created to examine the nonlinear effects of DTCA. Covariates variables race, age, and gender, predisposing factors according to the Andersen model (1995) were controlled for in the fixed effects models where the data were structured as repeated observations for each child in each quarter. The models were also stratified by race. Race is classified as white and black and based on the administrative data sources. Age is a continuous variable and is classified as age at base line.

**Method of Analysis**

For hypothesis 1, the unit of analysis used to determine the association between the incidence of asthma and DTCA is the county in which the children in the sample resided. To determine the effects of DTCA over a period of time, DTCA was lagged over four quarters. A fixed effect model was used with robust standard errors to account for observations clustered within counties.

For hypotheses 2-6, the unit of analysis used in determining medication and healthcare utilization is Medicaid patients per quarter. The STATA command, xtset was used to declare the data panel data (STATA 10). The panel variable is the Medicaid children’s identification number and the time variable is quarter. This was a balanced panel dataset containing observations on multiple individuals who had measures in every
quarter during the study period. The individuals are observed over 16 quarters in the 4 year study period, 1999 to 2002. All analysis was done using version 10 of STATA.

The models were estimated using xtlogit with a Generalized Estimating Equation Model (GEE) population-averaged model. This effectively controlled for time-invariant variables. Odds ratios were included and marginal effects were then obtained. In the population average model for this panel data analysis, the regression coefficients are a function of the population rather than the individuals (Zeger, S., Liang, K & Albert, P, 1988). The marginal effects of the parameters of the model are then reported to determine the marginal impact that DTCA has on healthcare utilization.

Stratified models were estimated based on race to capture the effects of race on healthcare utilization. The race variable was classified as black and white since the data did not support analysis of other races. Each model estimates the effects of overall DTCA spending and DTCA spending at the 3rd quartile and higher. Quartiles were created based on DTCA spending per quarter per MSA level. The research questions and hypotheses are listed below:

Research Question 1: Does DTCA increase the diagnosis of new asthma cases?

**Hypothesis 1: An increase in DTCA is associated with an increase in the proportion of children diagnosed with asthma.**

A fixed effects linear regression model was used to address this question. The dependent variable, asthma diagnosis is defined as the proportion of new cases of asthma in each county. It is a continuous variable, calculated by taking the proportion of the
number of children with a new asthma diagnosis over the number of Medicaid children in each county. The main predictor variable is DTCA. A squared term for DTCA spending was also created to examine the nonlinear effects of DTCA. DTCA was lagged over three years to examine effects of DTCA over time.

Research Question 2: Does DTCA increase utilization of asthma medication among children on Medicaid?

**Hypothesis 2: An increase in DTCA is associated with an increase in utilization of asthma medications.**

A population-average model was used to estimate the effects of DTCA on the probability of asthma medication use. The dependent variable, asthma medication use per quarter, is a dichotomous variable with values of 0 and 1. Asthma medication use was assigned a value of 1 and 0 otherwise. Separate variables were created for controller medication and for rescue medication. Asthma controller medication use per quarter and rescue medication use per quarter are dichotomous variables with a value of 1 and 0 otherwise. The predictor variable was DTCA which has both a linear value and a squared term. DTCA is a continuous variable and is defined as DTCA spending per quarter by county. A squared term for DTCA spending was also created to examine the nonlinear effects of DTCA. The models are stratified by Black and White. The models estimate the effects of overall DTCA spending and at the 3rd quartile and higher of DTCA spending.
**Research Question 3**

Is DTCA associated with a reduction in asthma-related emergency department visits and hospitalizations for Medicaid children with asthma?

**Hypothesis 3: An increase in DTCA is associated with a decrease in asthma-related emergency department (ED) visits.**

A population-average model was used to estimate the effects of DTCA on the probability of asthma-related ED visits. Asthma-related ED visits is a binary variable with values of 0 and 1. An asthma emergency department visit per quarter was assigned a value of 1 and 0 otherwise. To estimate the coefficients for the predictor variables, asthma-related ED visits will be used as the dependent measure. The predictor variable is quarterly DTCA summed by county and is a continuous variable. A squared term for DTCA is also used. The models are stratified by race.

**Hypothesis 4: An increase in DTCA is associated with a decrease in asthma-related hospitalizations.**

A population-average model was used to estimate the effects of DTCA on the probability of asthma-related hospitalizations. Asthma-related hospitalization use per quarter is a dichotomous variable with values of 0 and 1. An asthma-related hospitalization in any quarter during the study period per individual is assigned a value of 1 and 0 otherwise. Asthma-related hospitalizations will be used as the dependent measure. The predictor variable is quarterly DTCA summed by county and is a continuous variable. A squared term for DTCA is also used. The models are stratified by race.
Hypothesis 5: An increase in DTCA is associated with a decrease in asthma-related ED visits through increase in use of asthma controller medication.

Hypothesis 6: An increase in DTCA is associated with a decrease in asthma-related hospitalizations through increase in use of asthma controller medication.

In this study it is hypothesized that asthma controller medication will have a mediating effect between DTCA and asthma-related emergency department visits and hospitalizations. Asthma-related emergency department visits and hospitalizations are affected by asthma controller medication use. High usage of asthma medication may have a positive effect on reduced asthma-related hospitalization and emergency department visits. Two separate models were estimated for each variable, asthma-related hospitalization and emergency department visits.

A mediating variable is one that causes or influences a relationship between the predictor variable and the outcome variable. Mediating variables explain how or why an effect occurs (Baron and Kenney, 1986). In this study, asthma medication use is proposed to have a mediating effect between DTCA and utilization of health services (asthma-related emergency department visits and hospitalizations). Hence, asthma-related emergency department visits and hospitalizations are influenced by asthma medication use. High adherence may have a positive effect on reduced asthma-related hospitalization and emergency department visits.

The mediation between DTCA and asthma-related emergency department is depicted in Figure 3 and the path model of the mediation between DTCA and asthma-related hospitalization is shown in Figure 4. The path diagram in Figure 3 assumes that
there is an indirect relationship or effect of the independent variable, DTCA on the outcome variable, asthma-related ED visits as shown in (c). The path labeled (a) indicates that there is a direct relationship between DTCA and asthma controller medication use. The path labeled (b) indicates that there is direct relationship between asthma controller medication and asthma-related ED visits.

**Figure 3: Mediating Effect between DTCA and Asthma-Related ED Visits**

To test the mediation effect of DTCA on asthma-related ED visits as shown in Figure 3, a series of longitudinal logistic regression models with population average effect were estimated. According to Barron and Kenny (1986), there are four steps in testing mediation.

1) The first step is to test for a relationship between DTCA and asthma-related ED visits to determine path (c). The dependent variable asthma-related ED visits per quarter is a dichotomous variable with values of 0 and 1. An asthma-related ED visits in any
quarter during the study period per individual is assigned a value of 1 and 0 otherwise. The independent variable, DTCA is a continuous variable.

2) The second step is to test for a relationship between DTCA and asthma controller medication to determine path (a). In this study, asthma controller medication use is regressed on the independent variable, DTCA as shown in this simple model: \( Y = b_0 + b_1X_1 \), where \( Y \) represents asthma controller medication and \( X_1 \) represents DTCA. In this case the mediator is treated as a dependent variable. The dependent variable, asthma controller medication per quarter is a dichotomous variable with values of 0 and 1. The predictor variable is DTCA summed over quarters and counties and is a continuous variable. A squared term for DTCA is also used.

3) The third step is test for a relationship between asthma controller medication and asthma-related ED visits. The dependent variable, asthma-related ED visits per quarter is a dichotomous variable with values of 0 and 1. An asthma-related ED visit in any quarter during the study period is assigned a value of 1 and 0 otherwise. The predictor variable DTCA is quarterly expenditures per county and is a continuous variable. A squared term for DTCA is also used.

4) The fourth step is to perform a multiple regression where both DTCA and asthma controller medication are used to determine asthma-related ED visits. Paths (a) and (b) are used to predict path (c). The dependent variable asthma-related ED visits is dichotomous. Asthma-related ED visits in any quarter is assigned a value of 1 and 0 otherwise. The independent variables are DTCA and asthma controller medication use.

To determine mediation, Baron and Kenny (1986) suggest that all conditions from step 1 to three must be significant 1) the independent variable must affect the mediator.
In this case DTCA must affect asthma controller medication use 2) the independent variable must affect the dependent variable. That is, DTCA must show some effect on health care utilization (emergency department visits) and 3) the mediator must affect the dependent variable. In this study, asthma controller medication use must affect health care utilization in order to establish mediation.

According to Barron and Kenny (1986) if significance is found then the next step is to proceed to step four. If asthma controller medication is significant after controlling for DTCA, then some form of mediation is established. If DTCA is found to be insignificant after controlling for the mediation variable (asthma controller medication) then there is full mediation. Partial mediation is also established when DTCA is found to be significant.

Similar to the path diagram in Figure 3, Figure 4 assumes that there is an indirect relationship or effect of the independent variable, DTCA on the outcome variable asthma-related hospitalizations as shown in path (c). The path labeled (a) indicates that there is a direct relationship between DTCA and the mediator variable, asthma controller medication use. The path labeled (b) indicates that there is a direct relationship between asthma controller medication and asthma-related hospitalizations.
To test the mediation effect of DTCA on asthma-related hospitalizations as shown in Figure 4, a series of longitudinal logistic regression models with population average effect were estimated. The same steps were followed as in hypothesis 5. The variables are asthma controller medication, DTCA and asthma-related hospitalizations. Asthma controller medication per quarter (mediating variable) is dichotomous with values of 0 and 1. The predictor variable is quarterly DTCA by county and is a continuous variable. A squared term for DTCA is also used. The dependent variable, asthma-related hospitalizations per quarter is a dichotomous variable with values of 0 and 1.
CHAPTER 4

RESULTS

Descriptive Statistics

Sample Characteristics

The first sample consisted of 44 states including the District of Columbia and 496 counties in which there were children with an asthma diagnosis. Montana, Wyoming, North Dakota, South Dakota, Vermont, Idaho and Alaska were excluded from the sample because they had no DTCA of asthma medication during the study period. California had the highest number of asthma diagnosis during the study period. Utah had the least amount. Asthma diagnosis ranged from 20 to 799,039 per county. The average diagnosis per county was 8,880. The total number of new diagnosis during the study period was 462,509. There were no new diagnoses in some counties.

The sample characteristics of the second dataset are summarized in Table 1. The sample size included 180,584 children between the ages of 5 and 18 with a mean age of 9. Males (56.5%) accounted for a larger proportion of the sample compared to females. The study included a higher percentage of whites (42.7%) compared to blacks (29.9%). The largest percentage of children in the sample resided in the South (33.4%). Northeastern region accounted for 30.7% of the sample, followed by the Western region with 20.5%. The smallest percentage of the sample resided in the Midwest (15.4%).

Healthcare and medication utilization is also depicted in Table 1. Prescription drug use which includes use of controller medication and rescue medication was 35.5%. Only 28% of the sample used controller medication. Asthma-related hospitalization rate was 6.4% and asthma-related ED visits of 20.2%.
DTCA spending for the asthma drugs, Advair, Singulair, Flovent and Serevent during the study period, 1999 to 2002 is also summarized in Table 1. There was no DTCA in some counties in some quarters. The maximum spending per quarter by county was 187.8 thousand dollars. The average spending per quarter per county was 2.9 thousand dollars.

Table 1: Sample Characteristics

<table>
<thead>
<tr>
<th>Variables</th>
<th>Mean/Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sample (N = 180,584)</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Demographics</strong></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>42.7%</td>
</tr>
<tr>
<td>Black</td>
<td>29.9%</td>
</tr>
<tr>
<td>Other</td>
<td>27.4%</td>
</tr>
<tr>
<td>Male</td>
<td>56.5%</td>
</tr>
<tr>
<td>Age (Years)</td>
<td>9.1</td>
</tr>
<tr>
<td><strong>Region</strong></td>
<td></td>
</tr>
<tr>
<td>Midwest</td>
<td>15.4%</td>
</tr>
<tr>
<td>Northeast</td>
<td>30.7%</td>
</tr>
<tr>
<td>South</td>
<td>33.4%</td>
</tr>
<tr>
<td>West</td>
<td>20.3%</td>
</tr>
<tr>
<td><strong>Healthcare and Medication Utilization</strong></td>
<td></td>
</tr>
<tr>
<td>Prescription drugs</td>
<td>35.5%</td>
</tr>
<tr>
<td>Controller drugs</td>
<td>28.7%</td>
</tr>
<tr>
<td>Asthma-Related Hospitalizations</td>
<td>6.4%</td>
</tr>
<tr>
<td>Asthma-Related Emergency room Visits</td>
<td>20.2%</td>
</tr>
<tr>
<td><strong>DTCA Spending</strong></td>
<td></td>
</tr>
<tr>
<td>Average Quarterly Advertising Expenditures*</td>
<td>2.9</td>
</tr>
<tr>
<td>Average MSA Advertising Expenditures*</td>
<td>22.2</td>
</tr>
</tbody>
</table>

*Advertising Expenditures are in thousands of dollars by county of residence per quarter
Multivariate Analysis

Hypothesis 1: An increase in DTCA is associated with an increase in the proportion of children diagnosed with asthma.

Table 2 summarizes the results from the analysis of the effects of DTCA spending on asthma diagnosis. There is a statistically significant effect of DTCA spending on the proportion of newly diagnosed cases of asthma ($p = 0.001$). As DTCA spending increased the proportion of new cases of asthma increased slightly. However, the effects of the advertising decreased at higher levels of spending. At DTCA squared there was a decrease in the incidence of asthma ($p = 0.001$). Thus there was a positive effect with decreasing returns to the scale of DTCA on rates of new asthma diagnosis. Similar results occur at the 3rd quartile and higher of DTCA spending. When DTCA was lagged, there was no significant effect on asthma diagnosis.

**Table 2: Multiple Regression Estimates of the Relationship between the Proportion of New Asthma Diagnosis and DTCA**

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Coefficient</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average Quarterly Advertising Expenditures</td>
<td>0.39636911</td>
<td>0.001</td>
</tr>
<tr>
<td>Average Quarterly Advertising Expenditures squared</td>
<td>-.3249503</td>
<td>0.001</td>
</tr>
<tr>
<td>Average Quarterly Advertising Expenditures lag1</td>
<td>-4.14e-07</td>
<td>0.92</td>
</tr>
<tr>
<td>Average Quarterly Advertising Expenditures lag2</td>
<td>3.73e-06</td>
<td>0.19</td>
</tr>
<tr>
<td>Average Quarterly Advertising Expenditures lag3</td>
<td>-3.39e-06</td>
<td>0.44</td>
</tr>
</tbody>
</table>
**Hypothesis 2**: An increase in DTCA is associated with an increase in utilization of asthma medications.

Table 3 shows parameter estimates of DTCA on use of either albuterol (rescue medication) or controller asthma medication use among children on Medicaid, and stratified by white and black children. Included in the model are average quarterly advertising expenditures and average quarterly advertising expenditures squared. As the average quarterly advertising expenditure increased, the use of prescription drugs among Medicaid children increased (p < 0.0001). The marginal effect of each million dollar of advertising spent is an increase in the use of asthma medication by 1 in 10,000. The effects of average quarterly DTCA spending squared was also significant (p < 0.0001). The marginal effect of DTCA squared on asthma prescription medication was negative 1 in 10 million per million-squared dollars. The interaction effects were not significant, indicating that DTCA had the same effect on black and white children.

**Table 3: Logistic Regression Estimates of the Relationship between Asthma Medication Use and DTCA by Race**

<table>
<thead>
<tr>
<th>Dependent Variable: Use of Any Asthma Medication</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Independent Variables</strong></td>
</tr>
<tr>
<td></td>
</tr>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
</tr>
<tr>
<td>Expenditures Squared</td>
</tr>
<tr>
<td>Black*DTCA</td>
</tr>
<tr>
<td>Black*DTCA^2</td>
</tr>
</tbody>
</table>

**DTCA – Direct to consumer advertising**

**Black*DTCA - Interaction of DTCA with black race indicator**
Table 4 shows parameter estimates of DTCA on use of controller asthma medication among children on Medicaid, and stratified among white and black children. Included in the model are average quarterly advertising expenditures and average quarterly advertising expenditures squared. As the average quarterly advertising expenditure increased, the use of prescription drugs among Medicaid children increased (p < 0.0001). The marginal effect of each million dollar of advertising spent was an increase in the use of asthma medication by 5 in 100,000. The effects of average quarterly DTCA spending squared was also significant (p = 0.007). The marginal effect of DTCA squared on asthma prescription medication was negative. The interaction effects of race and DTCA were not significant. A similar model (not shown) with DTCA spending at the 3rd quartile and higher, yielded similar results.

Table 4: Logistic Regression Estimates of the Relationship between Asthma Controller Medication Use and DTCA by Race

<table>
<thead>
<tr>
<th>Dependent Variable: Use of Asthma Controller Medication</th>
<th>All Children N = 180,584</th>
<th>White Children N = 79,445</th>
<th>Black Children N = 58,941</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent Variables</td>
<td>Marginal Effects p - Value</td>
<td>Marginal Effects p - Value</td>
<td>Marginal Effects p - Value</td>
</tr>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>0.00005 0.0001</td>
<td>0.000065 0.0001</td>
<td>0.00015 0.0001</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-.00000003 0.007</td>
<td>-.00000068 0.001</td>
<td>-.000001 0.0001</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>0.00004 0.150</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Black*DTCA²</td>
<td>-.00000003 0.205</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator
Hypothesis 3: An increase in DTCA is associated with a decrease in asthma-related emergency department (ED) visits.

Table 5 summarizes the findings of the regression model of DTCA on asthma-related ED visits for all Medicaid children. The variables are DTCA spending per quarter and DTCA spending squared. Advertising spending on asthma medication drugs had a statistically significant effect on asthma-related ED visits for all Medicaid children (p =0.03) and among black children (p = 0.001). Asthma-related ED visits decreased as DTCA spending increases among all Medicaid children and among black children. The marginal effects of DTCA spending on asthma-related ED visits among those two groups are relatively small. However, the marginal effect of DTCA on asthma-related ED visits among blacks is higher than among all Medicaid children. Asthma-related ED visits increased with DTCA spending squared, but not significantly (p=0.08).

Advertising spending on asthma medication drugs was not statistically significant among white Medicaid children (p =0.75). Asthma-related ED visits increased with DTCA spending squared, but not significantly (p =0.58). The interaction effects of black and DTCA were significant, consistent with previous studies showing that there is a greater effect of DTCA on minorities.
Table 5: Logistic Regression Estimates of the Relationship between Asthma-Related ED Visits and DTCA by Race

Dependent Variable: Asthma-Related ED Visits

| Independent Variables | All Children  
| N = 180,584 | White Children  
| N = 79,445 | Black Children  
| N = 58,941 |
|----------------------|----------------|----------------|----------------|
| Marginal Effects     | p - Value     | Marginal Effects | p - Value | Marginal Effects | p - Value |
| Quarterly DTCA       |                |                |                |
| Expenditures ($ million) | -.0000248 | 0.03 | -.000000495 | 0.757 | -.0000956 | 0.001 |
| Expenditures Squared | .000000204 | 0.08 | .000000992 | 0.587 | .000000764 | 0.005 |
| Black*DTCA           | -.000072 | 0.01 | -- | -- | -- | -- |
| Black*DTCA^2         | -.000000568 | 0.05 | -- | -- | -- | -- |

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator

Similar models were examined with DTCA at quartile 3 and above for all Medicaid children, and also whites and blacks. The results are shown in Table 6. The findings show that DTCA spending per quarter had a statistically significant effect on asthma-related ED visits among all Medicaid children compared to previous findings at all levels of DTCA spending. The marginal effect was negative, and there was a stronger effect of DTCA among all Medicaid children compared to whites or blacks. At DTCA squared the marginal effect was positive and significant, consistent with previous findings at all levels of DTCA spending. Among white children, however, the effects of DTCA squared remained insignificant (p = 0.09). The interaction variables of black and DTCA indicate that there is a stronger effect of DTCA on blacks.
Table 6: Logistic Regression Estimates of the Relationship between Asthma-Related ED Visits and DTCA by Race at the 3rd Quartile and above

Dependent Variable: Asthma-Related ED Visits

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>All Children (N = 89,465)</th>
<th></th>
<th>White Children (N = 37,768)</th>
<th></th>
<th>Black Children (N = 32,218)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Marginal Effects</td>
<td>p - Value</td>
<td>Marginal Effects</td>
<td>p - Value</td>
<td>Marginal Effects</td>
</tr>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>-.000047</td>
<td>0.0001</td>
<td>-.000035</td>
<td>0.05</td>
<td>-.0001183</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>.000000365</td>
<td>0.003</td>
<td>.00000032</td>
<td>0.09</td>
<td>.00000093</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>-.0000802</td>
<td>0.009</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>Black*DTCA^2</td>
<td>.000000636</td>
<td>0.034</td>
<td>--</td>
<td>--</td>
<td>--</td>
</tr>
</tbody>
</table>

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator

Hypothesis 4: An increase in DTCA is associated with a decrease in asthma-related hospitalizations.

Three models were used to estimate the effects of all levels of DTCA spending on asthma related hospitalizations among the study group. The first model included all Medicaid children, the second model includes white children on Medicaid and the third model included black children on Medicaid. Results are summarized in Table 7. Both DTCA spending per quarter and DTCA spend squared per quarter had a significant impact on asthma-related hospitalization. Asthma-related hospitalization increased as DTCA spending increased among all children and white children (p <0.0001). However, it had no significant effect on black children. The marginal effect was positive at DTCA spending but negative at DTCA squared. There was a significant decrease in asthma-
related hospitalization at DTCA spending squared among Medicaid children and white Medicaid children during the study period (p < 0.0001), but not among black children.

Table 7: Logistic Regression Estimates of the Relationship between Asthma-Related Hospitalizations and DTCA by Race

Dependent Variable: Asthma-Related Hospitalizations

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>All Children N = 180,584</th>
<th>White Children N = 79,445</th>
<th>Black Children N = 58,941</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>Marginal Effects</td>
<td>p - Value</td>
<td>Marginal Effects</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-0.000000359</td>
<td>0.001</td>
<td>-0.000000479</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>-0.0000685</td>
<td>0.001</td>
<td>--</td>
</tr>
<tr>
<td>Black*DTCA^2</td>
<td>-0.000000554</td>
<td>0.003</td>
<td>--</td>
</tr>
</tbody>
</table>

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator

Separate models estimated the effects of DTCA spending at the 3rd quartile and similar results were found as shown in Table 8. Both DTCA spending per quarter and DTCA squared per quarter had no significant effect on asthma-related hospitalizations among blacks, but was significant among all Medicaid children and white Medicaid children.
Table 8: Logistic Regression Estimates of the Relationship between Asthma-Related Hospitalizations and DTCA spending at the 3rd Quartile and above

Dependent Variable: Asthma-Related Hospitalizations

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>All Children N = 89,465</th>
<th>White Children N = 37,768</th>
<th>Black Children N = 32,218</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Marginal Effects</td>
<td>p - Value</td>
<td>Marginal Effects</td>
</tr>
<tr>
<td>Quarterly DTCA</td>
<td>.0000364</td>
<td>0.0001</td>
<td>.0000411</td>
</tr>
<tr>
<td>Expenditures ($ million)</td>
<td>- .000000382</td>
<td>0.0001</td>
<td>-.0000000500</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>- .00000663</td>
<td>0.0001</td>
<td>--</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>.00000536</td>
<td>0.004</td>
<td>--</td>
</tr>
</tbody>
</table>

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator

Hypothesis 5: An increase in DTCA is associated with a decrease in asthma-related ED visits through increase in use of asthma controller medication.

Several models were used to estimate the mediation effect of controller medication between asthma-related ED visits and DTCA. The first set of models show estimates of all Medicaid children in the study sample. The second set reflects stratification by race for hospitalization and DTCA among whites and for controller medication and hospitalization. The third set of models show estimates among blacks.

Tables 9a, 9b and 9c summarize the 1st three steps in testing for mediation according to Baron and Kenny (1986). Table 9d shows the fourth and final step in establishing mediation.
Table 9a shows the results in step 1 in establishing mediation which is to determine path (c), that there is an indirect relationship between asthma-related ED visits and DTCA spending (Baron and Kenny 1986). Table 9a shows that DTCA increased spending was associated with a decrease in asthma-related ED visits among all Medicaid children in the study sample (p = 0.03). However, at DTCA square the effects of asthma-related ED visits increased but not significantly (p = 0.08). The marginal effect of each million dollar of advertising spent is a decrease in the use of asthma medication by 2.48 in one 100,000, a relatively small, but significant effect (p = 0.03). The marginal effect of DTCA squared on asthma prescription medication was not significant. Therefore, in general we find that DTCA affected asthma-related ED visits. The interaction variables were significant indicating that there is a negative relationship between DTCA and asthma-related ED visits among blacks.

Table 9a: Logistic Regression Estimates of the Relationship between Asthma-Related ED Visits and all levels of DTCA

<table>
<thead>
<tr>
<th>Dependent Variable: Asthma-Related ED Visits</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Children</td>
</tr>
<tr>
<td>N = 180,584</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA</td>
<td>-0.0000248</td>
<td>0.03</td>
</tr>
<tr>
<td>Expenditures ($ million)</td>
<td>0.00000204</td>
<td>0.08</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>-0.000072</td>
<td>0.01</td>
</tr>
<tr>
<td>Black*DTCA^2</td>
<td>-0.000000568</td>
<td>0.05</td>
</tr>
</tbody>
</table>

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator
Table 9b summarizes the parameter estimates in the 2nd step in the mediation model testing path (a), that there is a direct relationship between use of asthma controller medication and DTCA spending among all Medicaid children in the study period. DTCA spending significantly impacted asthma controller medication use \((p < 0.0001)\) at both average DTCA spending per quarter and DTCA spending squared. Asthma controller medication use increased at DTCA spending per quarter, but decreased at DTCA squared. The marginal effect of DTCA spending on asthma controller medication was much less at DTCA squared than at average DTCA spending. The interaction terms were insignificant indicating that the effect of DTCA on asthma controller medication was not significantly different among blacks.

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>All Children N = 64,110</th>
</tr>
</thead>
<tbody>
<tr>
<td>Expenditures ($ million)</td>
<td>Marginal Effects</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-0.00000003</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>0.00004</td>
</tr>
<tr>
<td>Black*DTCA^2</td>
<td>-0.00000003</td>
</tr>
</tbody>
</table>

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator

The 3rd step in the mediation model is depicted in Table 9c. This tests the relationship between asthma-related ED visits and asthma controller medication to
establish path (b). As the use of asthma controller medication increased asthma-related ED visits increased but not significantly (p = 0.83). However, the use of asthma rescue medication had a significant impact on asthma-related ED visits (p = 0.04). As the use of asthma rescue medication increased asthma-related ED visits also increased.

Table 9c: Logistic Regression Estimates of the Relationship between Asthma-Related ED Visits and Asthma Controller Medication

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>All Children N = 64,110</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controller Medication</td>
<td></td>
<td>.0011381</td>
<td>0.81</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td></td>
<td>.011796</td>
<td>0.04</td>
</tr>
</tbody>
</table>

According to Baron and Kenny (1986), the first three steps must be significant to proceed to step four. All three of the models in steps 1 to 3 had significant results. The parameter estimates for the fourth step are presented in Table 9d. Table 9d summarizes the mediation effect of asthma controller medication between DTCA and asthma-related ED visits. The effects of controller medication on asthma-related ED was not significant when we controlled for DTCA (p = 0.83). However, asthma rescue medication was statistically significant (p = 0.05). There was a small positive marginal effect of less than 1% of an increase in the use of asthma rescue medication on asthma-related ED visits. DTCA and DTCA square remained significant as in previous models. At average quarterly DTCA spending, asthma-related ED visits decrease. The marginal effect was negative and significant (p = 0.04). At DTCA square asthma-related ED visits increased,
but at a decreasing rate, as seen in previous findings \( (p = 0.02) \). According to Baron and Kenny (1986), there is partial mediation as DTCA spending remained significant after including all the other variables in the model.

**Table 9d. Logistic Regression Estimates of Mediating Effect of Asthma Controller Medication between DTCA and Asthma-Related ED Visits**

Dependent Variable: Asthma-Related ED Visits

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Children N = 64,110</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Asthma Controller Medication</td>
<td>.0010143</td>
<td>0.83</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>.0117661</td>
<td>0.05</td>
</tr>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>-.0003089</td>
<td>0.04</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>.00000357</td>
<td>0.02</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>.0000391</td>
<td>0.91</td>
</tr>
<tr>
<td>Black*DTCA(^2)</td>
<td>-.000000961</td>
<td>0.79</td>
</tr>
</tbody>
</table>

**DTCA – Direct to consumer advertising**

**Black*DTCA - Interaction of DTCA with black race indicator**

The following models depict the steps in establishing mediation effect of asthma controller medication between DTCA and asthma-related ED visits among whites. Tables 10a through 10c show the first three steps in establishing mediation. Step 4 is depicted in Table 10d. Table 10a summarizes the first step 1 in establishing mediation, establishing the effects of DTCA spending on asthma-related ED visits among whites. There was no significant effect at average quarterly DTCA spending and DTCA squared.
Table 10a: Logistic Regression Estimates of the Relationship between Asthma-Related ED Visits and all levels of DTCA (Stratified – White)

Dependent Variable: Asthma-Related ED Visits

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA Expenditures</td>
<td>-.000000495</td>
<td>0.757</td>
</tr>
<tr>
<td>($ million)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>.000000992</td>
<td>0.587</td>
</tr>
<tr>
<td>N = 79,445</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 10b summarizes the parameter estimates in the 2nd step of the mediating model testing path (a), that there is a direct relationship between DTCA and asthma controller medication, the mediating variable (Baron and Kenny 1986). The results show that there was a significant effect of DTCA on asthma controller medication use at all levels of DTCA spending among white children in this study. At average quarterly DTCA spending, the marginal effect of increased use of asthma controller medication was less than 1% per quarter by county of residence (p < 0.001). However at DTCA squared, the effect of DTCA spending decreased, resulting in a decreased use of asthma controller medication (p = 0.001).
### Table 10b: Logistic Regression Estimates of the Relationship between Asthma Controller Medication and DTCA (Stratified – White)

**Dependent Variable: Asthma Controller Medication**

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>0.0000648</td>
<td>0.0001</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-.000000680</td>
<td>0.001</td>
</tr>
</tbody>
</table>

The third step in the mediating model is depicted in Table 10c. This is testing the relationship between asthma controller medication and asthma-related ED visits to establish path (b) according to Baron and Kenny (1986). The findings show that an increase in use asthma controller medication among white children on Medicaid increased of asthma-related ED visits but not significantly (p = 0.92). Similar results were found for rescue medication use among white Medicaid children with asthma during the study period.

### Table 10c: Logistic Regression Estimates of the Relationship between Asthma-Related ED Visits and Asthma Controller Medication (Stratified – White)

**Dependent Variable: Asthma-Related ED Visits**

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controller Medication</td>
<td>.0006972</td>
<td>0.92</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>.0105278</td>
<td>0.21</td>
</tr>
</tbody>
</table>
According to Baron and Kenny (1986), the first three steps must be significant to proceed to step four. Only two of the three models in steps 1 to 3 have significant results therefore, there is failure to establish mediation and moving to the fourth step is unnecessary. However, the parameter estimates for the fourth step are presented in Table 10d. The model included DTCA quarterly expenditures, DTCA squared, asthma controller medication and rescue medication. The dependent variable is asthma-related ED visits. The variables were all insignificant. Hence, a mediation effect between asthma medication case and asthma-related ED visits among white children on Medicaid during the study period cannot be established.

**Table 10d. Logistic Regression Estimates of the Mediating Effect of Asthma Controller Medication between DTCA and Asthma-Related ED Visits (Stratified – White)**

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Controller Medication</td>
<td>.0006776</td>
<td>0.92</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>.0105247</td>
<td>0.18</td>
</tr>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>-.0000738</td>
<td>0.71</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>.00000180</td>
<td>0.43</td>
</tr>
</tbody>
</table>

The next set of models represents the mediation effect of asthma controller medication between asthma-related ED visits and DTCA among black children on Medicaid during the study period. Tables 11a, 11b and 11c summarize the 1st three steps in testing for mediation between asthma controller medication and asthma-related ED
visits. Table 11a shows the results in step 1 in establishing mediation which is to determine path (c), that there is an indirect relationship between asthma-related ED visits and DTCA spending (Baron and Kenny 1986).

Table 11a summarizes the findings of the regression model of DTCA on asthma-related ED visits among black Medicaid children. The variables are DTCA spending per quarter and DTCA spending squared. Similar results were found as in the model that included all Medicaid children. Advertising spending on asthma medication drugs had a marginal effect on asthma-related ED visits of less than 1% (p = 0.001). At DTCA squared asthma-related ED visits, marginal effect was negative but much smaller (p = 0.005) indicating the decreasing effect of DTCA.

Table 11a: Logistic Regression Estimates of the Relationship between Asthma-Related ED Visits and DTCA (Stratified – Black)

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA Expenditures</td>
<td>-.0000956</td>
<td>0.001</td>
</tr>
<tr>
<td>($ million)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>.00000764</td>
<td>0.005</td>
</tr>
</tbody>
</table>

Table 11b summarizes the parameter estimates in the 2nd step of the Mediating model which is testing path (a) that there is a direct relationship between DTCA and asthma controller medication, the mediating variable (Baron and Kenny). The results show that there was a significant effect of DTCA on asthma controller medication use at
both levels of spending. Average quarterly DTCA spending was statistically significant (p< 0.0001). However at DTCA squared, the marginal effect of DTCA spending decreased (p<0.0001).

Table 11b: Logistic Regression Estimates of the Relationship between Asthma Controller Medication and DTCA (Stratified – Black)

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA Expenditures</td>
<td>.0001489</td>
<td>0.0001</td>
</tr>
<tr>
<td>($ million)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-.000000114</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

The third step in the mediating model is depicted in Table 11c. This is testing the relationship between asthma controller medication and asthma-related ED visits to establish path (b). The findings show that an increase in use asthma controller medication among black children on Medicaid had a negative marginal effect on asthma-related ED visits but it was not significant (p = 0.37). Rescue medication use had a positive, but insignificant marginal effect (p = 0.84).
Table 11c: Logistic Regression Estimates of the Relationship between Asthma-Related ED Visits and Asthma Controller Medication (Stratified – Black)

Dependent Variable: Asthma-Related ED Visits

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controller Medication</td>
<td>-.0080343</td>
<td>0.37</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>.0017249</td>
<td>0.84</td>
</tr>
</tbody>
</table>

N = 19,813

Only two of the models in the first three steps of testing the mediation effect of asthma controller medication among blacks show significant results. Therefore, one can conclude that there was failure to establish mediation. However, the parameter estimates for the fourth step are presented in Table 11d. The model included DTCA quarterly expenditures, DTCA spending squared, asthma controller medication and rescue medication. The dependent variable is asthma-related ED visits. The predictor variables had no significant impact on asthma-related ED visits. Therefore, there was no mediation effect between controller medication and asthma-related ED visits among black children on Medicaid during the study period.
Table 11d. Logistic Regression Estimates of the Mediating Effect of Asthma Controller Medication between DTCA and Asthma-Related ED Visits (Stratified – Black)

Dependent Variable: Asthma-Related ED Visits

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Controller Medication</td>
<td>-.0080658</td>
<td>0.35</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>.0017062</td>
<td>0.84</td>
</tr>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>-.00035271</td>
<td>0.32</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>.00000321</td>
<td>0.35</td>
</tr>
</tbody>
</table>

Hypothesis 6: An increase in DTCA is associated with a decrease in asthma-related hospitalizations through increase in use of asthma controller medication.

Several models were used to estimate the mediation effects of controller medication between asthma-related hospitalizations and DTCA. The first set of models estimated the effects among all races. The second set represents effects among whites and the third set of models show estimates among blacks.

Tables 12a, 12b and 12c summarize the 1st three steps in testing for mediation according to Baron and Kenny (1986). Table 12a shows the results in step 1 in establishing mediation to determine a path (c), that there is an indirect relationship between asthma related hospitalization and DTCA spending (Baron and Kenny 1986). Table 12a shows increased asthma-related hospitalizations at lower levels of DTCA spending. However it decreased at higher levels of spending at DTCA squared (p < 0.0001) among all racial groups. The interaction variables were significant which indicates that there is no significant difference between the effects on Blacks and Whites.
Table 12a: Logistic Regression Estimates of the Relationship between Asthma-Related Hospitalizations and all levels of DTCA spending

Dependent Variable: Asthma-Related Hospitalizations

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>( p ) - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>0.000033</td>
<td>0.0001</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-.000000359</td>
<td>0.0001</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>-0.0000685</td>
<td>0.0001</td>
</tr>
<tr>
<td>Black*DTCA(^2)</td>
<td>-.000000554</td>
<td>0.003</td>
</tr>
</tbody>
</table>

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator

Table 12b summarizes the parameter estimates of asthma controller medication and DTCA spending among all Medicaid children in the study period. DTCA spending significantly impacted asthma controller medication use (\( p < 0.0001 \)) at both average DTCA spending per quarter and DTCA spending squared. Asthma controller medication use increased at DTCA spending per quarter, but decreased at DTCA squared. The marginal effect of DTCA spending on asthma controller medication was much less at DTCA squared than at average DTCA spending. The interaction terms were insignificant indicating that the effect was not significantly different among minorities.
Table 12b: Logistic Regression Estimates of the Relationship between Asthma Controller Medication and all levels of DTCA spending

Dependent Variable: Asthma Controller Medication

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>0.00005</td>
<td>0.0001</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-0.0000003</td>
<td>0.0001</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>0.00004</td>
<td>0.15</td>
</tr>
<tr>
<td>Black*DTCA^2</td>
<td>-0.0000003</td>
<td>0.20</td>
</tr>
</tbody>
</table>

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator

Table 12c summarizes the effects of asthma controller medication on asthma-related hospitalizations. The marginal effect of asthma controller medication on asthma-related hospitalizations was negative and not statistically significant (p = 0.18).

However, there was a small negative marginal effect on asthma-related hospitalizations (p < 0.0001).

Table 12c: Logistic Regression Estimates of the Relationship Between Asthma-Related Hospitalizations and Asthma Controller Medication

Dependent Variable: Asthma-Related Hospitalizations

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controller Medication</td>
<td>-0.0042627</td>
<td>0.18</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>-0.0119748</td>
<td>0.0001</td>
</tr>
</tbody>
</table>
The models in the first three steps of testing the mediation effect of asthma controller medication among all racial groups showed significant results. The parameter estimates for the fourth step are presented in Table 12d. The predictor variables are DTCA quarterly expenditures, DTCA squared, asthma controller medication and rescue medication. The dependent variable is asthma-related hospitalizations. While asthma controller medication was not statistically significant, rescue medication was, establishing partial medication effect of asthma medication between DTCA and asthma-related hospitalizations. Additionally, quarterly DTCA spending remained significant, also establishing partial mediation effect of asthma controller medication among all children during the study period.

Table 12d: Logistic Regression Estimates of the Mediating Effect of Asthma Controller Medication between DTCA and Asthma-Related Hospitalizations

<table>
<thead>
<tr>
<th>Dependent Variable: Asthma-Related Hospitalizations</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Controller Medication</td>
<td>-.0043871</td>
<td>0.14</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>-.0119587</td>
<td>0.0001</td>
</tr>
<tr>
<td>Quarterly DTCA Expenditures</td>
<td>-.0002354</td>
<td>0.03</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>.00000205</td>
<td>0.07</td>
</tr>
<tr>
<td>Black*DTCA</td>
<td>-.0004088</td>
<td>0.21</td>
</tr>
<tr>
<td>Black*DTCA$^2$</td>
<td>.00000155</td>
<td>0.66</td>
</tr>
</tbody>
</table>

DTCA – Direct to consumer advertising
Black*DTCA - Interaction of DTCA with black race indicator
Table 13a summarizes the parameter estimates of asthma controller medication and asthma-related hospitalizations among white Medicaid children in the study period, the first step in testing the mediation effects of asthma controller medication. DTCA spending significantly impacted asthma-related hospitalizations at average DTCA spending and DTCA spending squared. The marginal effects of average DTCA spending increased at DTCA spending per quarter, but decreased at DTCA squared. The marginal effect of average DTCA spending was positive and significant (p<.0001). At DTCA squared the marginal effects of were negative but less than 1% per million dollars of DTCA spending.

Table 13a: Logistic Regression Estimates of the Relationship between Asthma-Related Hospitalizations and all levels of DTCA spending (Stratified – White)

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>.0000386</td>
<td>0.0001</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-.000000479</td>
<td>0.0001</td>
</tr>
</tbody>
</table>

Table 13b summarizes the parameter estimates in the 2\textsuperscript{nd} step of the Mediating model according to Baron and Kenny (1986) in testing path (a) that there is a direct relationship between DTCA and asthma controller medication. The results show that there was a significant effect of DTCA on asthma controller medication use at both levels of spending. DTCA spending increased the use of asthma controller medication (p <
However, at DTCA squared there was a decreased marginal effect of DTCA per million dollar spent ($p = 0.001$).

Table 13b: Logistic Regression Estimates of the Relationship between Asthma Controller Medication and DTCA (Stratified – White)

Dependent Variable: Asthma Controller Medication

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>0.0000648</td>
<td>0.0001</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-.000000680</td>
<td>0.001</td>
</tr>
</tbody>
</table>

The third step in the mediating model is depicted in Table 13c. This is testing the relationship between asthma controller medication and asthma-related hospitalization to establish path (b) according to Baron and Kenny (1986). The findings show that an increase in use asthma controller medication among white children on Medicaid decreased asthma-related hospitalizations but the effect was not statistically significant ($p = 0.86$). Use of rescue medication, however, was likely to affect asthma-related hospitalizations among white Medicaid children. The marginal effect was negative and minimal, but significant ($p = 0.002$).
Table 13c: Logistic Regression Estimates of the Relationship between Asthma-Related Hospitalizations and Asthma Controller Medication (Stratified – White)

Dependent Variable: Asthma-Related Hospitalizations

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Controller Medication</td>
<td>-0.0007947</td>
<td>0.863</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>-0.0107104</td>
<td>0.002</td>
</tr>
</tbody>
</table>

The first three steps must be significant were significant. The parameter estimates for the fourth step are presented in Table 13d. The model included DTCA quarterly expenditures, DTCA squared, asthma controller medication and rescue medication.

DTCA quarterly expenditures was marginally significant at $p = 0.06$. Controller medication was insignificant ($p = 0.85$). Statistical significance was found for rescue medication. The marginal effect of rescue medication use on asthma-related hospitalizations was less than 1 in 100 ($p = 0.01$). This establishes partial mediation between asthma rescue medication and asthma-related hospitalizations among white children on Medicaid during the study period.
Table 13d: Logistic Regression Estimates of the Mediating Effect of Asthma Controller Medication between DTCA and Asthma-Related Hospitalizations (Stratified – White)

Dependent Variable: Asthma-Related Hospitalizations

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Controller Medication</td>
<td>-.000856</td>
<td>0.85</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>-.010698</td>
<td>0.01</td>
</tr>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
<td>-.0002886</td>
<td>0.06</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>.00000276</td>
<td>0.11</td>
</tr>
</tbody>
</table>

The next set of models represents the mediation effect of asthma controller medication between asthma-related hospitalizations and DTCA among black children on Medicaid during the study period. Tables 14a, 14b and 14c summarize the 1st three steps in testing for mediation between asthma controller medication and asthma-related hospitalizations. Table 14a shows the results in step 1 in establishing mediation which is to determine path (c), that there is an indirect relationship between asthma-related hospitalizations and DTCA spending (Baron and Kenny 1986). Table 14a shows that both DTCA spending per quarter and DTCA spending squared per quarter had no effect on asthma-related hospitalizations among black children on Medicaid during the study period.
Table 14a: Logistic Regression Estimates of the Relationship between Asthma-Related Hospitalizations and all levels of DTCA spending (Stratified – Black)

Dependent Variable: Asthma-Related Hospitalizations

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expenditures ($)</td>
<td>-0.000026</td>
<td>0.142</td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>0.00006117</td>
<td>0.484</td>
</tr>
</tbody>
</table>

Table 14b summarizes the parameter estimates in the 2nd step of the mediation model to test path (a) that there is a direct relationship between DTCA and asthma controller medication, the mediating variable. The results show that there was a significant effect of DTCA on asthma controller medication use at both levels of spending. As DTCA spending increased, use of asthma controller medication increased (p < 0.0001). However at DTCA squared, the effect of DTCA spending decreased, resulting in a decreased use of asthma controller medication among black children on Medicaid during the study period (p < 0.0001).

Table 14b: Logistic Regression Estimates of the Relationship between Asthma Controller Medication and DTCA (Stratified – Black)

Dependent Variable: Asthma Controller Medication

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>N = 58,941</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Quarterly DTCA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Expenditures ($)</td>
<td>0.001489</td>
<td>0.0001</td>
<td></td>
</tr>
<tr>
<td>Expenditures Squared</td>
<td>-0.0000114</td>
<td>0.0001</td>
<td></td>
</tr>
</tbody>
</table>
The third step in the Mediating model is depicted in Table 14c. This is testing the relationship between asthma controller medication and asthma-related hospitalization to establish path (b). The findings show that increased asthma controller medication use among black children on Medicaid decreased asthma-related hospitalizations but it was not significant ($p = 0.20$). However, rescue medication use impacted asthma-related hospitalizations among black children. The marginal effect was negative and less than 1%, but significant ($p < 0.0001$).

**Table 14c: Logistic Regression Estimates of the Relationship between Asthma-Related Hospitalizations and Asthma Controller Medication (Stratified – Black)**

<table>
<thead>
<tr>
<th>Dependent Variable: Asthma-Related Hospitalizations</th>
<th>N = 19,813</th>
<th>Marginal Effects</th>
<th>$p$ - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Controller Medication</td>
<td>-.0077312</td>
<td>0.200</td>
<td></td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>-.0148296</td>
<td>0.0001</td>
<td></td>
</tr>
</tbody>
</table>

There was significance in all three models. The parameter estimates for the fourth step are presented in Table 14d. The model included DTCA quarterly expenditures, DTCA squared, asthma controller medication and rescue medication. Asthma-related hospitalization is the dependent variable. DTCA quarterly expenditure was not statistically significant. However, at DTCA squared there was a significant impact on asthma related hospitalizations ($p = 0.03$). Controller medication was insignificant. However, rescue medication was significant. The use of rescue medication decreased asthma-related hospitalizations ($p < 0.0001$). This establishes partial mediation between
asthma medication, particularly rescue medication and asthma-related hospitalizations among black children on Medicaid during the study period.

Table 14d: Logistic Regression Estimates of the Relationship between Controller Medication and Asthma-Related Hospitalizations (Stratified – Black)

Dependent Variable: Asthma-Related Hospitalizations

<table>
<thead>
<tr>
<th>Independent Variables</th>
<th>Marginal Effects</th>
<th>p - Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asthma Controller Medication</td>
<td>-0.0079768</td>
<td>0.13</td>
</tr>
<tr>
<td>Rescue Medication</td>
<td>-0.0147966</td>
<td>0.001</td>
</tr>
<tr>
<td>Quarterly DTCA Expenditures ($ million)</td>
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<td>0.03</td>
</tr>
<tr>
<td>DTCA Expenditures Squared</td>
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<td>0.26</td>
</tr>
</tbody>
</table>
CHAPTER 5

DISCUSSION

Introduction

Asthma is a chronic disease affecting millions of children in the United States resulting in increased use of health care. While there is no cure for the disease, there are recommended guidelines to decrease the impact of the disease. However, there is low adherence to the guidelines, particularly among Medicaid children, the focus of this study.

Direct to consumer advertising is controversial with critics arguing that it may be harmful as consumers may pressure doctors to prescribe medications that may not be appropriate which could impair the physician-patient relationship. Opponents on the other hand argue that DTCA is beneficial; it provides information to patients that help them make better decisions about their healthcare and it may lead to adherence of medication.

The primary goal of this study was to examine the association between DTCA and asthma-related emergency department visits and hospitalizations of Medicaid children. The study further sought to determine the impact of DTCA on asthma medication use. The findings support these hypotheses.
Findings

**Hypothesis 1: An increase in DTCA is associated with an increase in the proportion of children with an asthma diagnosis.**

The findings from this study indicate that DTCA has a significant impact on new cases of asthma diagnosis, implicating a possible increase in awareness of the disease as a result of DTCA advertising. Significance of the DTCA on the increase in the proportion of new cases of asthma diagnosis is supported by Mastin and colleagues findings, that DTCA may increase awareness of a particular disease (Mastin, et. al 2007). Additional findings from of the insignificance of the DTCA lagged over three quarters, provide evidence of decreased effect of DTCA over time indicating that there may be reduced recall of the asthma medication advertising over long periods of time.

**Hypothesis 2: An increase in DTCA is associated with an increase in utilization of asthma medications.**

The findings of the study support this hypothesis. At larger amounts of DTCA spending, there is an increase in use of asthma medication among all Medicaid children. Of interest is the use of controller medication, particularly, inhaled corticosteroid which is the cornerstone treatment for asthma (NHLBI). In this study, the controller drugs were examined as a class of drugs which included some inhaled corticosteroids. The overall findings on the class of controller drugs in the study is supported by previous findings on the effect of DTCA on increasing prescribing rate among a class of drugs rather than individual drugs (Bradford et al., 2006). Additionally, evidence of the impact of DTCA on controller medication is supported by studies that link DTCA and adherence
to antidepressant drugs (Hansen et al., 2010 & Donohue et al., 2004). The findings show a greater impact of DTCA on asthma medication use up to a certain level. However at higher spending the effect begins to decrease. Previous studies by Bradford and colleagues support this finding (Bradford et al, 2006; Bradford et al., 2008).

**Hypothesis 3: An increase in DTCA is associated with a decrease in asthma-related emergency department (ED) visits.**

The findings from this study support this hypothesis. DTCA has a significant effect on asthma-related emergency room visits among black children on Medicaid at all levels of DTCA spending during the study period. The marginal effect of DTCA on asthma-related ED visits among whites occurs only at higher levels of spending. The overall findings are supported by previous studies that asthma-related ED visits among minority children are higher than other groups is consistent with previous findings (Finkelstein et al. 2000).

**Hypothesis 4: An increase in DTCA is associated with a decrease in asthma-related hospitalizations.**

Finding from this study supports this hypothesis amongst white children on Medicaid during the study period. The overall findings may provide support for the importance of DTCA in decreasing healthcare utilization as previous studies show that hospitalizations rates are higher among Medicaid sample (Finkelstein et al., 2000).
**Hypothesis 5:** An increase in DTCA is associated with a decrease in asthma-related ED visits through increase in use of asthma controller medication.

The finding of this study partially supports this hypothesis. There is a mediation effect among rescue medication between DTCA and asthma-related emergency department visits among blacks or whites. Asthma controller medication has no mediation effect. Partial mediation suggests that there are other factors that impact asthma-related hospitalizations. The findings are supported by previous studies that found that asthma controller medication decreases emergency room visits (Suissa, Ernst, Benayoun, Baltzan, & Cai, 2000; Carmago et al., 2007; Piecoro et al., 2001; Butz et al., 2006 & Piecoro et al., 2001), but there are low levels of adherence among Medicaid children (Camargo et al., 2007; Conn et al., 2005; David, 2004, Finkelstein et al., 2002).

**Hypothesis 6:** An increase in DTCA is associated with a decrease in asthma-related hospitalizations through increase in use of asthma controller medication.

The findings provide partial support for a mediation effect rescue medication on hospitalization for both blacks and whites. Partial mediation suggests that there are other factors that may affect hospitalizations. The decrease in the use of hospitalizations as the use of rescue medications increase is not supported by previous studies which link decreased hospitalization use to asthma controller medication (Butz et al., 2006; Piecoro et al., 2001).
Study Limitations

This study has several strengths. The use of Medicaid data provides a large national sample that is representative of asthmatic children and a rich set of information on asthma and health care utilization among children. It combines DTCA with Medicaid sample of children to provide the first study of this kind that examines the effects of DTCA on health care use among this group. However, there are several limitations. The MAX dataset should be considered based on accuracy related to coding, missing information and other factors.

Another limitation is the time period of the study, from 1999 to 2002. This time period was chosen due to availability of Medicaid data that matched with the available DTCA data. Additionally, there were advertisements in select markets in each state and information is only provided on the dollar amount spent. The effects of DTCA may have been confounded by the use of advertising geared toward the physicians, known as detailing.

Policy Implications

From a patient-based outcome perspective, this study could be significant in the encouragement of educational interventions for asthma patients by providers. There are clear associations between DTCA and healthcare utilization and medication use. With DTCA playing a greater role in educational interventions, patients may gain better understanding of medical conditions, treatment options and may increase use of asthma medication.
The findings from this study may also be important for allocation of Medicaid funds for asthma treatment, guidance of organizations and other agencies to reduce the burden of asthma and decrease in health-disparities.

Conclusion and Future Research

This study examined the impact of direct to consumer advertising on health care utilization of asthmatic children and medication adherence. The results show that DTCA has an impact on asthma diagnosis, health care and medication use. DTCA, though controversial, plays a significant role in health care utilization.

While there was no report on who actually saw the ad, the findings were clear that there may be some benefits to DTCA. Studies have shown that minorities are more likely to be exposed to advertisements and are more likely affected. The scope of this study did not include the assessment of appropriate combination of drugs assigned to each individual. There was no evidence adherence to the National guidelines for proper asthma management. Future study could look at appropriate treatment and disparities in prescription medication. Additionally, future study could examine the impact of DTCA on a similar sample during more recent years to determine if the increased trend in DTCA spending continued to play a role in healthcare utilization.

The increasing burden of asthma requires creative measures to combat the associated health, economic and social costs. Affected individuals need to be aware of treatment options and be better educated about the disease. DTCA provides a gateway to disseminate information that could assist in improved health outcome and should be carefully considered in health policy issues.
REFERENCES


Centers for Disease Control and Prevention. You can control your asthma. A guide to understand asthma and its triggers. http://www.cdc.gov/asthma


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US Department of Health and Human Services, National Health Interview Survey (2008).


APPENDIX A

INSTITUTIONAL REVIEW BOARD APPROVAL

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00009560 and it expires on September 29, 2013. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator: MCROY, LUCETA C.
Co-Investigator(s):
Protocol Number: E101101002
Protocol Title: The Effects of Direct to Consumer Advertising on Healthcare Utilization of State Medicaid Children with Asthma

The above project was reviewed on 4/1/11. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This project qualifies as an exemption as defined in 45CF46.101, paragraph _

This project received EXEMPT review.
IRB Approval Date: 4/1/11
Date IRB Approval Issued: 4/18/11

Sheila Moore, CIP
Director, Office of the Institutional Review Board for Human Use (IRB)

Investigators please note:
IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

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