



The Regulation of Tea and Its Health-Related Claims in the Wake of Developing Scientific Evidence: Food, Drug, or Dietary Supplement?

Citation

The Regulation of Tea and Its Health-Related Claims in the Wake of Developing Scientific Evidence: Food, Drug, or Dietary Supplement? (2004 Third Year Paper)

Link

<http://nrs.harvard.edu/urn-3:HUL.InstRepos:8852111>

Terms of use

This article was downloaded from Harvard University's DASH repository, and is made available under the terms and conditions applicable to Other Posted Material (LAA), as set forth at

<https://harvardwiki.atlassian.net/wiki/external/NGY5NDE4ZjgzNTc5NDQzMGIzZWZhMGFIOWI2M2EwYTg>

Accessibility

<https://accessibility.huit.harvard.edu/digital-accessibility-policy>

Share Your Story

The Harvard community has made this article openly available. Please share how this access benefits you. [Submit a story](#)

THE REGULATION OF TEA AND ITS HEALTH-RELATED CLAIMS

IN THE WAKE OF DEVELOPING SCIENTIFIC EVIDENCE: FOOD, DRUG, OR DIETARY SUPPLEM

Abstract:

This paper examines the place of tea in cultural and regulatory American society. Scientific evidence now abounds about the potential health benefits of tea, and this has put pressure on regulators at the Food and Drug Administration to insure that consumers are well protected. The health claims of tea must be evaluated and screened to avoid consumer fraud. To accomplish this, regulators must first determine what category tea falls under for purposes of the Food, Drug and Cosmetic Act. Unfortunately, this is no easy task given the wide array of potential uses for tea. Therefore, in a modern society where the Internet supplies much of consumers' information, lawmakers and regulators will have to adopt a regulatory scheme that is equipped to handle a diverse and emerging product.

Jean C. Pirina Class of
2004

Harvard Law School

Third Year Writing Requirement

TABLE OF CONTENTS

I. Introduction 3

II. A History of the Importance of Tea in the United States 5

A.

The Origin of T

B. Tea Production and Types of Tea 6

C.

British Influence

D.

Consumption of

E.

Attempts at Int

III. Tea and Health 11

A.

Health and Tea Culture in Asia 11

B.

Current Health

1.

Tea as a
Heart Disease, Stroke, and

2.

Tea as a
Viral, and Fungal

3.

Tea as a
Osteoporosis, and

4.

Herbal

C.

Harmful Effects

IV. The Past and Present Regulation of Teas by The Food And Drug Administration
and The Federal Trade Commission 32

A.

The Tea Importation Act and Its Repeal 32

B.

The Food, Drug, and Cosmetic Act (FDCA) 34

C.

Amendments to the Food, Drug, and Cosmetic Act 38

1.

	The Food and Drug Modernization Act of 1997 (FDAMA)	39
2.	The Nutrition Labeling & Education Act of 1990 (NLEA)	39
3.		
	The Dietary Supplement Health and Education Act of 1994 (DSHEA)	40
4.		
	Health Claims under the Current Law	
	a. Health Claims	45
	b. Nutrient Content Claims	48
	c. Structure/Function Claims	48
D.		
	The Federal Trade Commission's Regulation of Advertising	49
E.		
	FDA Enforcement, Warning Letters, and Publication Advisories	52
F.	Limitations on FTC and FDA's Enforcement Powers	55

V. The Many Faces Of Tea 59

A.		
	Tea as a Food	59
B.	Tea as a Dietary Supplement	59

C.	Herbal Tea and Food Additives	61
D.	Tea as a Cosmetic	61
E.	Tea as a Drug	62
VI.	Application of The Law to Selected Health-Related Claims for Traditional and Herbal Tea	63
VII.	Future Regulation of Teas	69
VIII.	Conclusion	72

I. INTRODUCTION

Tea has always been an important drink for Americans, from the time of British colonization through the present day, and the law has had to deal with the changing role of tea in economic, cultural, medical, and social society. While tea is most often associated with Asia (China and India as consumers since ancient times as well as the largest producers and Japan for its intricate and elegant tea ceremonies) and the United Kingdom (for its cultural place in British society and history as the drink of the social elite), its place in the United States has an interesting history, and an evolving importance to today's population.

Historically, tea in the United States is famous for its role in the Revolutionary War through the Boston Tea Party as a symbol of the colonists' rebellion against British taxation.¹ In this way, tea has been forever woven into our history and taken on almost a mystical characteristic. Beginning in the 18th century and carrying on through the early 20th century, tea was the source of economic conflict around the world and considered important enough to become the focus of lawmakers in many countries around the globe. In fact, the United States passed its federal Tea Importation Act a decade before it passed its first Food and Drug Act.² Tea also continues to be vital to the economies of China, India, Sri Lanka, Kenya, Indonesia, and Argentina, who are among its principal producers and exporters.

Over the past several years, tea has been assuming a new mainstream importance in American society. Tea

¹See Part II.C., *infra*.

²See Part IV.A., *infra*.

and its ingredients have become well known and have been well advertised for their effects on the human body and human health. Alternative medicines, herbal remedies, organic treatments, and natural healing products are everywhere in the marketplace, and tea is no exception. Traditional tea and herbal tea are now associated with preventing and treating many health conditions. Now no longer just a beverage to be consumed for our enjoyment, tea has become the subject of voluminous research around the world, with scientists trying to prove or disprove the potential health benefits of tea. The claims about tea's positive effects on the body's health are as old as the drink itself, but recently the western world has seen an increase in the mainstream market availability of these products and information. As with any new product or claim, the law and regulatory agencies must become involved to protect and inform consumers. Given tea's variety of uses, both traditional and modern, the Food and Drug Administration (FDA) faces the immense challenge of deciding how to regulate tea and monitor the claims made by manufacturers and distributors. Part of this process involves the threshold issue of deciding which category tea falls under in the Food, Drug, and Cosmetic Act (FDCA).³ Tea-related health claims cover the whole spectrum of FDA jurisdiction, and in different situations tea could qualify as a food, a dietary supplement, a drug, and even a cosmetic. This paper examines tea's role in American society and focuses on how the FDA should regulate tea and its new applications to treatments and prevention of diseases, as well as general human health. Part II describes tea's history in the United States and its importance to our culture. Part III summarizes the health claims made about tea and herbal tea and evaluates some of the research. Part IV discusses the statutory and regulatory law governing foods, food additives, dietary supplements, cosmetics, and drugs. Part V analyzes the many different statutory definitions that tea may satisfy under different conditions and the consequences of these categories. Part VI scrutinizes some current advertisements and marketing schemes for various teas and how the current law should apply to them. Finally, Part VII discusses the future of tea regulation and

³21 U.S.C. §331 *et seq.* (2004).

how the FDA should deal with such a versatile product.

II. A HISTORY OF THE IMPORTANCE OF TEA IN THE UNITED STATES

A. The Origin of Tea

Tea is an ancient drink, and it is therefore no surprise that its origin is more of a myth than an historical fact. Legend has it that tea was discovered by Chinese Emperor Shen Nung in 2737 BC when some tea leaves inadvertently floated into his pot of boiling drinking water.⁴ He is believed to have drunk it and proclaimed that it gave “vigor of body, contentment of mind, and determination of purpose.”⁵ However, early tribes of *Homo sapiens* in Southeast Asia more likely first chewed tea leaves much earlier, mimicking nearby monkeys.⁶ Tea was consumed in China and much of Southeast Asia for centuries before it began to be exported to Europe and Africa. Consumption spread throughout the Chinese countryside during the Tang dynasty from 620-907 AD, aided by the publication of Lu Yu’s *The Classic of Tea* in the eighth century.⁷ In 593 AD tea was introduced to Japan where it became a cultural staple by the 1300’s after Shogun Sanetomo credited tea for curing a serious stomach ailment in the early 1200’s.⁸

The Portuguese and Dutch explorers were the first to write about tea and bring some back to Europe

⁴See SIB RANJAN MISRA, TEA INDUSTRY IN INDIA 1 (1986); Marian Segal, Tea: A Story of Serendipity, *available at*: http://www.fda.gov/fdac/features/296_tea.html.

⁵*Id.*

⁶ALAN MACFARLANE & IRIS MACFARLANE, GREEN GOLD: THE EMPIRE OF TEA 41-42 (2003).

⁷*Id.* at 45.

⁸*Id.* at 52-54.

beginning in the mid-1500's.⁹ From there it spread through the social elite to France and, eventually, to England in the 1650's.¹⁰ By 1669 the British East India Company was transporting tea from China to England, and by 1721 it became the monopolist in the trade.¹¹ At this time tea was also being imported into the American colonies from China via England.

B. Tea Production and Types of Tea

All tea is a product of the *Camellia sinensis* plant and is usually divided into three main groups: Green, Oolong, and Black.¹² Herbal Teas are made from a variety of plants and leaves other than *Camellia sinensis*, and although they are referred to as “tea” they are technically only herbal infusions.¹³ The principal difference between the three types of tea is the length of time the leaves undergo fermentation.¹⁴ Green tea is unfermented, oolong partially fermented, and black tea fully fermented.¹⁵ All tea is plucked from the plant

⁹ROY MOXHAM, TEA: ADDICTION, EXPLOITATION AND EMPIRE 16-17 (2003).

¹⁰Even then tea was seen as being related to health, and the first dated reference to tea, in an advertisement in a London newspaper, stated it was “by all Physicians approved.” *Id.* at 17-18.

¹¹The Story of Tea, *available at*: http://www.greentea.com/tw_storyoftea.html.

¹²Additionally a fourth category might be white tea, which is considerably more expensive. Also unfermented, white tea is steamed before it is withered and contains a higher proportion of buds along with the leaves, separating it from green tea. New health claims about white tea have emerged recently. *See, e.g.,* Is White Tea Better Than Other Teas as a Potential Anticarcinogen?, *available at*: <http://lpi.oregonstate.edu/new/whitetea.html>; A Perfect World: Intensely hydrating body cream with white tea, *available at*: http://www.origins.com/templates/products/sp_nonshaded.tpl?CATEGORY_ID=CATEGORY5732&PRODUCT_ID=PROD219.

¹³The FDA allows these herbal products to call themselves “tea” as long as they include the name of the plant before the word “tea” to distinguish themselves from traditional tea or flavored tea. CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., WHAT GUIDANCE DOES FDA HAVE FOR MANUFACTURERS OF TEA? (1997), *available at*: <http://www.cfsan.fda.gov/~dms/qa-ind5o.html>.

¹⁴The Chinese technique for classifying tea is actually much more complicated than this triad. Chinese further classify their tea much like Europeans classify wines: tea is categorized by the variety of the bush, shape and size of the leaf, method of manufacturing, season of plucking, region of production, scale of production, market destination, color, aroma, and taste. *See* DAN M. ETHERINGTON AND KEITH FORSTER, GREEN GOLD: THE POLITICAL ECONOMY OF CHINA'S POST-1949 TEA INDUSTRY 15-16 (1993). Furthermore, in China, western professional tea tasters and buyers in the nineteenth century took a minimum of five to six years to acquire their credentials. *See* ROBERT GARDELLA, HARVESTING MOUNTAINS: FUJIAN AND THE CHINA TEA TRADE, 1757-1937 10 (1994). The complexity of tea classification is further evidenced by the old Fujian saying translated as: “Even though one studies the tea industry until old age, one can never learn all the names of types of tea.” *Id.*

¹⁵Fermentation occurs when chemical compounds called polyphenols are oxidized by an enzyme in the tea plant.

and withered; green tea is steamed after it withers to prevent fermentation, and oolong tea's fermentation is stopped before it reaches the point of black tea. The leaves of all three are then rolled, dried, and packaged.¹⁶

Tea was originally sold mostly in loose form and also as bricks of lower quality tea. In modern times much of this has given way to tea bags, instant tea-flavored powder, and canned or bottled beverages.¹⁷ Although traditionally served hot, the western world has increasingly consumed iced tea as a popular beverage.

C. British Influence on Tea in America and the Boston Tea Party

The American colonists brought their love of tea with them from England and the Netherlands, and for many years it was a popular beverage in the colonies. During the 1700's it increased in popularity but also became more expensive because of the East India Company's monopoly and control of prices.¹⁸ In December 1773, the Boston Tea Party transformed tea from a simple hot beverage of enjoyment to a catalyst for revolution and an enduring symbol of rebellion. Tea was important to the economy of the colonies, especially the ports of Boston, New York, and Philadelphia, and smugglers dominated much of the market.¹⁹ The Tea Act of 1773 imposed a duty on tea imported to the colonies, and England granted the East India Company the rights to import the tea.²⁰ Colonists faced lower quality tea but at a higher price because of this new duty. The colonists began to boycott tea as their gesture of protest for British taxation policies. After several town meetings throughout Massachusetts and weeks of tension in the air, the colonists decided that something must be done to prevent the taxed tea from being unloaded at the colonial docks.²¹ On the night of December 16,

¹⁶ See, e.g., Tea World: Green Tea, available at: <http://www.greentea.com/tw.greentea.html>; Segal, *supra* note 4 for a description of the tea manufacturing processes.

¹⁷ See Segal, *supra* note 4.

¹⁸ See MOXHAM, *supra* note 9 at 24.

¹⁹ See PETER D.G. THOMAS, TEA PARTY TO INDEPENDENCE: THE THIRD PHASE OF THE AMERICAN REVOLUTION 14-15 (1991).

²⁰ See *id.*

²¹ BENJAMIN WOODS LABAREE, THE BOSTON TEA PARTY 132-133 (1964).

1773 patriots dumped over 300 chests of tea from three ships worth over 3000 pounds into Boston Harbor.²²

The story is a familiar one, and the Tea Party is often credited with the honor of triggering the American Revolution.²³

Tea's place in history no doubt has influenced its perception in society, even today. Tea is largely seen as a British drink, and often this is a negative for American consumers.²⁴ However, tea does remain a symbol of American resolve and dedication to independence.

D. Consumption of Tea in the United States

The United States plays an important role in current world tea consumption, although we have changed our pattern of consumption greatly since our tea drinking first began. During colonial America tea was popular with British and Dutch settlers as it was in Europe. However with the strong anti-tea sentiment of the Boston Tea Party and the Revolutionary War, tea drinking in the late eighteenth century and early nineteenth century paled in comparison to its pre-war levels, with imports dropping from about 900,000 lbs pre-war to about 100,000 lbs during the beginning of the 1770's.²⁵ In the early nineteenth century consumption increased but since then has relatively steadily declined in terms of consumption per capita.²⁶ Until quite recently Americans drank mostly green tea, with most of the black tea going to England and the rest of Europe, especially in the nineteenth century.²⁷ Prior to World War II green and black tea shared equal percentages of the U.S. tea market.²⁸ However, with the war came problems with importing from China, which is the major producer of green tea. Therefore, the war left Americans drinking 99% black

²²BENJAMIN WOODS LABAREE, *supra* note 21 at 140-141.

²³*See, e.g.*, The Story of Tea, *supra* note 11. Even this extremely brief account mentions that tea was responsible for American independence.

²⁴*See* MACFARLANE & MACFARLANE, *supra* note 6 at 74.

²⁵*See* DENYS FORREST, THE WORLD TEA TRADE: A SURVEY OF THE PRODUCTION, DISTRIBUTION AND CONSUMPTION OF TEA 164-165 (1985).

²⁶*Id.* Of course in terms of amount of tea imported into the United States, the numbers were consistently rising as the population grew since the early nineteenth century.

²⁷DAVID R. MACGREGOR, THE TEA CLIPPERS: THEIR HISTORY AND DEVELOPMENT 1833-1875 11 (1983).

²⁸Segal, *supra* note 4.

tea from India, and today, black tea continues to dominate U.S. consumption with 95% of the market while green tea now only occupies 4%.²⁹ Argentina is now the top exporter of tea to the United States.³⁰

Today the United States is the second largest importer and fifth largest consumer of tea in the world after China, India, the United Kingdom and Japan, although this calculation does not include consumption of tea bags or iced tea, both of which dominate the U.S. market.³¹ The United States does, however, occupy first place for spending the largest amount of money on tea advertising.³² These positions only make the stance that U.S. lawmakers take with respect to tea all the more important. Americans consume fifty billion cups of tea, 80% of which end up being iced tea with the greatest consumption occurring in the South and Northeast.³³ In 1994, 60% of tea was made from tea bags, 25% from iced tea mixes, 14% from instant tea, and 1% from loose tea.³⁴ The United States is unique for its large consumption of iced tea, a popular soft drink alternative consumed by up to 80% of American households.³⁵ This phenomenon dates back to the creation of iced tea in the United States in 1904.³⁶

While Americans may be in their own category in many ways for the way we consume tea, the United States' place in the world economy for tea is clearly influential. As a major importer and consumer, the structure of its laws and regulations will greatly affect the amount of tea its residents consume and may limit their reasons for consuming it. The FDA has to deal with a potential change from tea drinkers who drank tea for its taste, similarity to soft drinks, or convenience to tea drinkers who may now be drinking tea to supplement their diets, treat diseases, and promote their general health. This will require a much different approach to consumer protection and will be more demanding on the FDA than simply ensuring that the tea is clean

²⁹ *Id.* Much of the green tea consumption occurs on the West Coast where the Japanese population is higher. See FORREST, *supra* note 25 at 168.

³⁰ Segal, *supra* note 4.

³¹ FORREST, *supra* note 25 at 189.

³² *Id.*

³³ Segal, *supra* note 4.

³⁴ *Id.*

³⁵ See FORREST, *supra* note 25 at 167.

³⁶ A tea vendor at the Louisiana State Purchase Exposition in St. Louis, MO poured his tea over ice after the hot temperatures deterred any visitors from buying his hot tea. Segal, *supra* note 4.

and safe to drink.

E. Attempts at International Coordination and Tea Regulation

Tea is a worldwide commodity with vast importance to the economies of several nations.³⁷ It is only natural that these countries try to coordinate and cooperate in regulating tea, for everyone's benefit.³⁸ International coordination has largely failed in the tea industry, with importing and exporting nations finding it difficult to reach an agreement when their interests differ so greatly.

The first attempt at cooperation occurred in the early 1930's with the first International Tea Agreement signed by The Netherlands, India, and Ceylon (now Sri Lanka).³⁹ They agreed to standardize exports and promote tea internationally and this continued until 1955 when prices were quite high and none involved felt further need to regulate themselves.⁴⁰ They allowed the agreement to lapse but the International Tea Committee, which it had created, remained in place in order to collect and disseminate statistical data.⁴¹

In the 1980's the United Kingdom led another movement for international coordination and export quotas,

³⁷Argentina, China, Indonesia, Sri Lanka, and Kenya all export large amounts of tea. ETHERINGTON & FORSTER, *supra* note 14 at 3-4.

³⁸Countries who control supply have the incentive collude, restrict supply, and raise prices. Another good example of this tendency is the formation of OPEC by oil producing countries.

³⁹FORREST, *supra* note 25 at 178.

⁴⁰*Id.* at 179.

⁴¹*Id.*

triggered when the price fell below certain levels, but which would not include green tea in its calculations.⁴² Of course everyone wants to coordinate when times are bad and be on their own when times are good to reap the benefits. With South America and Africa now in the competition for major exporting, the likelihood of an agreement with any kind of power is unlikely. Currently each country must deal with its own tea issues, whether it be an exporter or an importer.

III. TEA AND HEALTH

A. Health and Tea Culture in Asia

From the time it was first discovered or created, the Chinese have believed that tea promotes good health and can prevent and treat diseases.⁴³ Even the legend of the origin of tea involved a health claim.⁴⁴ The Chinese were not alone; the Japanese and Indians studied and used tea as an herbal medicine as soon as they began drinking it.⁴⁵ References to tea and its effects on the body can be traced back centuries to several ancient writings. For example, there is a Chinese Proverb: “Better to be deprived of food for three days than tea for one.”⁴⁶ Because many of the beliefs about tea’s medicinal effects are so ingrained in Asian cultures, it is even

⁴²See *id.* at 180.

⁴³Chinese scholar Kuo P’o described tea as a medicinal beverage in 350 AD. Marian Segal, Tonic in a Teapot, *available at*: http://www.fda.gov/fdac/features/296_tea.html.

⁴⁴See MACFARLANE & MACFARLANE *supra* note 6 at 55.

⁴⁵See *id.* at 256-58; *see also* JOHN BLOFELD, THE CHINESE ART OF TEA 154-5 (1985) (describing traditional health claims for tea by the Chinese); ETHERINGTON & FORSTER, *supra* note 14 at 13-15 (relating the importance of tea to society in China, Japan, and Taiwan).

⁴⁶See The Miracle of Green Tea, *available at*: <http://chinesefood.about.com/library/weekly/aa011400a.htm>.

harder for lawmakers and regulators to develop a reasonable plan of action that takes consumer protection seriously while at the same time being tolerant of the diverse cultures within the American population. When these beliefs run deeper than simply tradition, and are instead tied to ancient cultures and religion, the task is even more arduous. Finally, many lawmakers and regulators may be unaware of the connections between health claims and culture and religion, making it difficult for them to even know that they may be treading on a sensitive and important ground.

In the eighteenth and nineteenth centuries the Chinese medicinal uses of tea caught the eye of several western writers, such as S. Wells Williams and Edward Morse.⁴⁷ During this time especially, and into the early twentieth century until World War II, the West paid close attention to the medical and biological ways of the East.⁴⁸

Most of the scientific research and statistical studies into the validity of tea related health claims began in Asia, specifically Japan, China, and Russia.⁴⁹ From these countries the science of tea and health has spread to Europe and America. It is no surprise that modern science in Asia has taken it upon itself to prove what so many there have believed about tea for thousands of years.

⁴⁷See MACFARLANE & MACFARLANE, *supra* note 6 at 256-263.

⁴⁸*Id.* Not only did westerners observe the health effects of tea itself, but they also noticed the positive effects on human health simply from boiling so much of their water. When the Chinese and Japanese drank boiled tea instead of regular drinking water it greatly impaired the spread of communicable diseases like Cholera.

⁴⁹See, e.g., Melantheria Mitchell, *Tea's Popularity Making Slow but Steady Advances in the U.S.*, ASSOCIATED PRESS NEWSWIRES, May 19, 2003.

B. Current Health Claims and Scientific Evidence⁵⁰

If you believed everything you could read about tea in books, journals, and magazines and on the Internet then you would immediately convert your diet to an all tea liquid diet. Based on its aggregate health claims, tea is literally a cure-all. The sources that claim that tea can improve your health vary from ancient religious and spiritual texts to modern medical journals and everything in between. Of course many of these claims stretch the boundaries of modern science and statistics, and others are based on mere coincidence.⁵¹ Chances are that someone somewhere will claim that tea will help treat or cure any condition that you may have. Tea is claimed to be able to cure external skin problems, internal infections and diseases, whether caught, developed, or inherited, and mental and emotional problems. This wide array of claims makes it difficult to classify tea under a statute like the FDCA.

The following is a summary of the various diseases and ailments that tea is claimed to help to prevent, cure, or treat:

⁵⁰The term “health claim” is defined in the FDCA and is subject to certain requirements. See Part IV.C.4., *infra*. It is used in this Part for its common everyday meaning.

⁵¹*See, e.g.*, Health Benefits of Tea, *available at*: <http://www.no-occident.com/noheal.htm>: “It is of no surprise to a tsaiophilist that the letters “t,e, and a” are found inside of and comprise one half the word health.”

- Cancer
- Heart Disease
- High Blood Pressure
- High Cholesterol
- Anemia
- Stroke
- Tooth Decay
- Constipation
- Upset Stomach
- Indigestion
- Osteoporosis
- Rheumatoid Arthritis
- Alzheimer's Disease
- Food Poisoning
- Toothaches
- Skin Rash
- Acne
- Depression
- Fungal Infections
- Bacterial Infections

- o Headaches
- o Viral Infections
 - o Flu and Respiratory Illness

The following is a list of other supposed general health effects of tea:

- o Accelerates metabolism
- o Lowers Blood Sugar
- o Strengthens Immune System
 - o Reduces Aging
- o Is an Anti-inflammatory
 - o Stimulates Skeletal Functions
- o Aids Weight Loss
 - o Facilitates Muscular Contractions
- o Cleanses the body of alcohol
 - o Increases Bone Density

Tea contains many chemical compounds and ingredients, several of which are believed to affect the human body and health. The most important ingredients in tea in terms of its healthiness are its polyphenols, especially flavonoids like catechins, specifically epigallocatechin gallate (EGCG), because it is a powerful

antioxidant.⁵² Antioxidants like Vitamin C, Vitamin E, and polyphenols are widely believed to help prevent cancer and reduce cholesterol, heart disease, and stroke.⁵³ Green tea contains the highest amount of catechins compared to black and oolong tea because during the fermentation process, which green tea skips, some of the catechins are chemically converted into other compounds.⁵⁴ Therefore, the focus has traditionally been on green tea for medicinal purposes. However, recently the focus has partially shifted to black tea, which contains theaflavins and thearubigens, flavonoids created through fermentation, which may also have healthy properties.⁵⁵ The longer tea leaves are brewed the higher the concentration of flavonoids in the drink.⁵⁶

1.

Tea as a Treatment for Serious Diseases: Cancer, Heart Disease, Stroke, and High Blood Pressure

⁵²See NATIONAL CANCER INSTITUTE, NCI FACT SHEET: TEA AND CANCER PREVENTION (2002), *available at*: <http://www.cancer.gov>; The Miracle of Green Tea, *supra* note 46.

⁵³See Tea and Antioxidant Properties, *available at*: <http://www.teahealth.co.uk/th/facts/3.htm>:

Free radicals are unstable molecules that include the hydrogen atom, nitric oxide (NO) and molecular oxygen (O₂)...In an attempt to stabilize, they attack other molecules in the body potentially leading to cell damage and triggering the formulation of another free radical resulting in a chain reaction. Some scientists believe that this type of free radical action has been implicated in certain chronic and ageing diseases such as cancer, heart disease, stroke, rheumatoid arthritis, cataracts and Alzheimer's disease...Antioxidants are compounds that help to inhibit the many oxidation reactions caused by free radicals thereby preventing or delaying damage to the cells and tissues.

⁵⁴*Id.*

⁵⁵*Id.* Theaflavins and thearubigens are more complex types of flavonoids, while the catechins in green tea are a more simple form of flavonoids; *see also* Black Tea or Green Tea- Which is Healthier?, *available at*: <http://chinesefood.about.com/library/weekly/aa021103a.htm>.

⁵⁶Tea and Antioxidant Properties, *supra* note 53.

Most recent studies on tea have concentrated on whether tea may be effective to prevent or treat many types of cancers.⁵⁷ It goes without saying that cancer is a serious problem around the world, resulting in millions of deaths, and that any treatment or preventative measure would be a huge advance in the medical field. Therefore, it is easy for everyone (patients, patients families, doctors, researchers, scientists, and the general population) to be anxious to follow any leads that may lead toward a cure. However, at the same time, cancer patients and their families are an extremely vulnerable group of people. Those stricken with an illness like cancer are quick to try any treatment that may help them, sometimes regardless of who “prescribed” it, whether it has been shown to be effective, or whether there may be dangerous side effects.⁵⁸

When this kind of group of consumers is involved, the FDA should pay particular attention to the claims of suppliers and strictly scrutinize their literature and advertising. While of course the FDA cannot (and should not try to) protect every consumer all the time, when it is aware that a group who is obviously more vulnerable is being targeted it should act appropriately to closely monitor the situation and quickly react when any new claims are advanced.

Tea and cancer have been the subject of volumes of research all over the world. Some studies have found that people who drink green tea have a lower risk for certain types of cancer. This information is readily available in magazines, journals, and on the Internet.⁵⁹ The following summarizes the results of several statistical studies as reported by various sources:

1)

Chinese men and women who drank green tea experienced a 60% reduction in esophageal cancer;⁶⁰

2)

Men who drank ten cups of green tea a day stayed cancer-free for three years longer than those who drank less than three cups a day;⁶¹

3) Women who had a history of drinking five cups or more of green tea a day had less recurrences of breast cancer and the cancer spread less quickly;⁶²

4) Areas in the Sizuoka Prefecture region of Japan that have higher green tea production have lower rates of cancer, especially gastrointestinal cancers like stomach, esophageal, and liver cancers;⁶³

5) Patients who treated pre-cancerous lesions in the their mouth with tea experienced a 37% regression of the lesion over six months as compared to a 10% regression for patients given the placebo;⁶⁴

6) Polish women who drank black tea daily had a reduced risk of stomach cancer;⁶⁵

7) Postmenopausal women who drank two or more cups of tea a day over an eight year period had a reduced risk of digestive and urinary tract cancers;⁶⁶

8) People who drank green tea had a 48% reduced risk of developing stomach cancer;⁶⁷

9) People who drank one cup of black tea a day had a 50% reduced risk of developing lung cancer.⁶⁸

⁶² See *id.* (citing a Case Western Reserve University study).

⁶³ See Itaro Oguni, Green Tea Prevents Cancer, *available at*: <http://www.daisan.co.jp/health>.

⁶⁴ See Tea and Cancer, *available at*: <http://www.teahealth.co.uk/th/facts/5.htm>; *see also* NATIONAL CANCER INSTITUTE, *supra* note 52 (reporting similar findings).

⁶⁵ See Tea and Cancer, *supra* note 64.

⁶⁶ See *id.*

⁶⁷ See *id.* (citing a 2001 article in the International Journal of Cancer).

⁶⁸ See *id.* (citing a 1998 article in Lung Cancer).

Some studies have found absolutely no correlation, or even a positive correlation, between tea and some cancers.⁶⁹ Nevertheless, the above statistical results reflect some impressive numbers and certainly encourage many people to go out and start drinking tea. Many of these studies no doubt have flaws in their methodology and have failed to control for other variables that affect cancer rates, and this may explain why the results from these kinds of statistical surveys are very inconsistent.

In addition to statistical studies, many researchers have begun animal testing to see if tea or one or more of its components actually result in a reduced risk of cancer in a controlled laboratory environment.⁷⁰ Such studies have found the following:

1)

Mice given green tea extract showed slower growth of tumors and reduced the incidence of cancer to less than 50%;⁷¹

2) Mice given catechins from green tea showed a significantly lower incidence of duodenal cancer;⁷²

3) Rats given white tea showed a significant reduction in pre-cancerous lesions as compared to rats given caffeine alone.⁷³

Obviously from a scientific standpoint, these studies are only the beginning of what researchers would need to actually prove that the components of tea can help fight cancer.⁷⁴ But when the results of these studies are made public in a variety of media, consumers can easily be persuaded to change their behavior and start drinking more tea.

⁷² See *id.*

⁷³ See *Is White Tea Better than Other Teas as a Potential Anti-carcinogen?*, *supra* note 12.

Heart disease and stroke are also serious and deadly conditions affecting millions of people. Tea has been linked to improving circulation through blood vessels, combating high blood pressure, and lowering LDL cholesterol levels in the bloodstream, all of which can lead to a reduced risk of heart disease and stroke.⁷⁵ As with cancer, many researchers have tried to explain the link between tea and heart disease using statistical studies. They have found some of the following:

1)

People who drank more than three cups of tea a day had an 11% lower rate of heart attacks;⁷⁶

2)

People who drank more than four cups of black tea a day showed improved blood vessel function;⁷⁷

3) Regular consumption of black tea can reduce coronary heart disease by 50%;⁷⁸

4) People who drank about nineteen cups of tea per week were less likely to die after a heart attack;⁷⁹

5) Tea flavonoids can help inhibit platelet aggregation;⁸⁰

6) Tea flavonoids can inhibit the oxidation of LDL cholesterol.⁸¹

⁷⁸See Black Tea or Green Tea- Which is Healthier?, *supra* note 55 (citing a Saudi Arabian study).

⁷⁹See Mitchell, *supra* note 49.

⁸⁰See Tea and Antioxidant Properties, *supra* note 53 (citing four separate studies).

⁸¹See *id.* (citing five separate studies); Black Tea or Green Tea- Which is Healthier?, *supra* note 76 (adding that a study in Netherlands found that the reduction in LDL cholesterol led to a reduced risk of stroke).

As with cancer treatment the evidence is still inconclusive and needs to be further examined before any definite claims can be made about tea's cardiovascular value.

Human studies are a completely different arena for the kind of testing that deals with treating cancer, heart disease, stroke, and high blood pressure, and very few studies other than *ex post* statistical analyses have been done.⁸² Any study would probably not be able to use tea exclusively as a treatment when prescription drugs are already the standard treatment unless animal studies showed that tea alone could be extremely effective. Therefore tea would likely be used as a supplement to medication making it harder to determine its true affect on the disease. Moreover, studies addressing these types of diseases must be extremely long in duration in order to be accurate because these diseases develop over time and are influenced by many hereditary and lifestyle factors.

2.

Tea as a Treatment for Infectious Diseases: Bacterial, Viral, and Fungal

Tea has also been studied, more so recently, for its ability to fight various kinds of infections and boost the body's immune system.⁸³ The connection between tea and fighting infection predates any understanding of the science behind the phenomenon. The Chinese would use tea leaves to help fight fungal infections on their feet or as a disinfectant for cuts and lacerations.⁸⁴ Tea is also believed to help fight against bacteria that cause food poisoning because the catechins act to sterilize many of the bacteria that would otherwise reproduce to make one sick.⁸⁵ One study showed that tea drinkers' blood cells responded five times faster to germs than the blood cells of coffee drinkers.⁸⁶ The chemical L-theanine, found in tea, is broken down in the liver into ethylamine which produces gamma-delta T-cells; these T-cells prompt the secretion of interferon to help the body's immune system fight off infection.⁸⁷ The body's process of releasing interferon helps fight not only bacterial infections, but viral and fungal as well.

Because of its antibacterial properties, tea may also help fight cavities by killing the bacteria in the mouth that lead to tooth decay.⁸⁸ Several European authors writing on tea in the 1500's and 1600's referenced its ability to treat fever, stomach aches, colds, scurvy, and pain of the bowels.⁸⁹

Even further, tea may be effective at fighting viral infections in the body. Research has been done to study the affect of tea on the influenza virus and even the AIDS virus. The tea catechins and theaflavin are believed to interfere with the virus and inactivate it.⁹⁰ Hepatitis patients may also benefit from drinking tea because it may help lower the levels of iron in their blood.⁹¹ The iron can lead to free-radicals which cause cirrhosis of the liver.⁹²

The ability of any product to potentially fight viruses is extremely valuable in the medical field in the wake of diseases like AIDS. Any product that may be able to help treat the AIDS virus would truly be a miraculous discovery. However, a note of caution is again necessary. As with cancer patients, AIDS patients are extremely vulnerable to advertising and solicitation from anyone who tells them that they may have found a treatment for an incurable disease, especially if that treatment is as close and as inexpensive as a few cups of tea.

3.

Tea as a Treatment for Other Ailments: Rheumatoid Arthritis, Osteoporosis, and Obesity

Tea has also been connected to the treatment of other diseases, although the link is more tenuous and the research more sparse. One study published in the *American Journal of Clinical Nutrition* found that older women who drank tea actually had higher bone mineral density.⁹³ This may help prevent osteoporosis.⁹⁴ Moreover, tea's antioxidant properties may help reduce rheumatoid arthritis in many of the same ways it may prevent cancer, and by decreasing inflammation caused by free-radicals in the bloodstream.⁹⁵

Claims about tea as a treatment for obesity come in many forms and include several treatments with herbal teas.⁹⁶ One study reported that men who were given a combination of caffeine and green tea extract burned more calories than those given only caffeine or a placebo.⁹⁷ It was reported that green tea catechins may be responsible for increased fat oxidation, which may lead to increased weight loss.⁹⁸ Additionally, tea may cause carbohydrates to be released more slowly, which lowers the blood sugar and increases the burning of fat.⁹⁹ Another study found that the antioxidants in tea enhance metabolism and green tea drinkers may burned up to seventy more calories a day.¹⁰⁰

4.

Herbal Teas

Herbal teas are not actually tea because they are not made from the *Camellia sinensis* plant, but instead are infusions of other plants in hot or boiling water. Some of the most popular and familiar herbal teas include Chamomile, Eucalyptus, Senna, Ginger, Raspberry Leaf, and Echinacea, although there are many more varieties. Some herbal teas are infusions of the very plant from which the tea derives its name, like Chamomile, whereas others contain many different ingredients and extracts from various sources and then name the tea according to the particular supplement they wish to advertise. This latter choice is used often with Echinacea and Ginger teas. The average consumer can easily be misled by the name “herbal tea” and not understand that they may be drinking a concoction of other plants and flowers that have no relation to traditional “real” tea. For this reason, regulation of health claims should cover both real tea and herbal tea together in the same way so that consumers will get the maximum protection. Herbal teas should not get an advantage over real tea in terms of the types of health claims they can make because the average consumer won’t notice that claims about real tea are not missing because they don’t exist, but only missing because of stricter regulation. Consumers will likely instead believe that herbal teas make more health claims because they are better for them and may actually succeed in preventing, treating or curing their condition. When regulation and laws are in place for consumer protection, the regulator needs to look at the claims from the consumers’ point of view to avoid grouping like products differently and only further confusing the consumer who essentially sees one product: tea. Therefore, this paper will discuss the regulation of both real tea and herbal tea.

Herbal teas probably make more health claims than traditional tea, and the claims are much more unsubstantiated. Some of the claims can only be described as “wild” because advertisers will claim that their herbal tea can treat very specific ailments.¹⁰¹ For example, health claims for herbal teas include the following:

1)

Senna, aloe, rhubarb root, buckthorn, cascara, and castor oil teas claim to act as stimulant laxatives and also aid in weight loss;¹⁰²

2) Chamomile tea claims to reduce stress and anxiety as well as aid digestion;¹⁰³

3) Fennel and Anise tea assert that they also reduce stress and can fight off colds and boost metabolism;¹⁰⁴

4) Peppermint tea claims to soothe sore throats and other cold symptoms;¹⁰⁵

5) Lobelia was used to treat asthma and bronchitis in the 19th century and is now claimed to enhance mental clarity and well-being;¹⁰⁶

6) Chapparal tea claims to be a natural antioxidant “blood purifier” as well as a treatment for cancer and acne;¹⁰⁷

7) Germander tea is marketed to assist in weight loss and treat obesity;¹⁰⁸

¹⁰³See Here's to Your Health—Drink Tea, available at: <http://www.mybackyard.com/current/217p1.htm>; Sharon Snider, *Beware the Unknown Brew: Herbal Teas and Toxicity*, FDA CONSUMER (1991), available at: <http://www.fda.gov/bbs/topics/CONSUMER/CON00007.html>.

¹⁰⁴See Snider, *supra* note 103.

¹⁰⁵See *id.*

¹⁰⁶See *id.*

¹⁰⁷See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., ILLNESSES AND INJURIES ASSOCIATED WITH THE USE OF SELECTED DIETARY SUPPLEMENTS (1993), available at: <http://www.cfsan.fda.gov/~dms/ds-ill.html>.

¹⁰⁸See *id.*

- 8) Ma Huang tea, squaw tea, and Mormon tea, all of which contain Ephedra, claim to boost energy and help control weight loss;¹⁰⁹
- 9) Ginger is purported to aid in digestion and treat nausea, especially related to pregnancy;¹¹⁰
- 10) Raspberry leaf tea claims to also reduce morning sickness in pregnant women, as well as lead to shorter labor and prepare the body for delivery;¹¹¹
- 11) Kombucha Mushroom tea (which contains no mushrooms) claims to induce a state of well-being as well as treat AIDS and cancer;¹¹²
- 12) Cho Low tea claims to lower cholesterol;¹¹³
- 13) Eucalyptus tea claims to clear mucous membranes to benefit respiratory health;¹¹⁴
- 14) Echinacea tea claims to boost the body's immune system by stimulating the production of immune proteins and interferon;¹¹⁵
- 15) Licorice tea is purported to act as a laxative;¹¹⁶
- 16) Chinese High Mallow tea claims to aid in weight loss;¹¹⁷
- 17) Kuding Tea declares that it can lower cholesterol and high blood pressure;¹¹⁸
- 18) Rooibos Tea (South African Red Bush Tea) asserts that it is a "miracle tea" for its anti-cancer and

¹⁰⁹See *id.*

¹¹⁰See Josef A. Brinckmann, Statement at FDA Public Meeting on Safety Issues Associated with Dietary Supplement Use During Pregnancy (2000); Respiratory Support, *at*: <http://www.a-healing.com/11028.html>.

¹¹¹See Brinckmann, *supra* note 110.

¹¹²See FDA Cautions Consumers on "Kombucha Mushroom Tea," (1995), *available at*: <http://www.fda.gov/bbs/topics/ANSWERS/ANS00650.html>.

¹¹³See No Evidence to Support Cholesterol Claims for Cho Low Tea (1989), *available at*: <http://www.fda.gov/bbs/topics/ANSWERS/ANS00151.html>.

¹¹⁴See Respiratory Support, *supra* note 110.

¹¹⁵See Immune System Boost, *at*: <http://www.a-healing.com/11033.html>.

¹¹⁶See Gentle Herbal Laxative, *at*: <http://www.a-healing.com/11035.html>.

¹¹⁷See <http://www.herbalassets.com>.

¹¹⁸See Imperial Kuding Tea, (Black Herbal Tea), *at*: <http://www.enjoyingtea.com/imblheteikut.html>.

anti-aging effects; it also claims, among other things, to treat colic in infants, high blood pressure, allergies, diabetes, headaches, digestive problems, skin conditions and depression;¹¹⁹

19) Tea containing Cat's Claw (an herb grown in the South American rainforest) claims to treat cancer, various types of infections, allergies, diabetes, AIDS, and stomach disorders, as well as generally boost the body's immune system;¹²⁰

20) Tea containing Jatoba tree purportedly fights bacterial, viral, and fungal infections and helps treat respiratory ailments like asthma;¹²¹

21) Tea containing Chuchuhuasi boasts its ability to relieve arthritis, rheumatism, and back pain because of its anti-inflammatory properties;¹²²

22) Tea containing Stevia asserts that it can help treat obesity, high blood pressure, and hypertension;¹²³

23) Tea containing Chanca Piedra claims to be effective at treating gallstones and kidney stones as well as viral infections;¹²⁴

24) Tea containing Pau d'Arco claims to treat cancer, respiratory and stomach disorders, fungal and parasitic infections, as well as lower blood sugar.¹²⁵

¹¹⁹ See GHS Rooibos Tea, at: http://www.antiaginglifeextension.com/rooibos_redbush_tea/default.asp?a=&c=&p=.

¹²⁰ See Shipibo Herbal Tea, at: <http://shipibotea.com/>.

¹²¹ See *id.*

¹²² See *id.*

¹²³ See *id.*

¹²⁴ See *id.*

¹²⁵ See *id.*

These health claims for herbal teas were compiled from FDA sources as well as from advertisements by companies trying to sell these teas. Many of the health claims allege that they are backed up by scientific studies, although almost always these studies are referenced vaguely, which inhibits the reader from finding out more about the research and its conclusions. Many of the claims are not supported by any scientific evidence and purport to be following ancient medicinal practices from Asia, Africa, and South America. However, simply by citing some support for the health claim, each source is affecting the way consumers think about and use the various herbal remedies offered in the market. To the average consumer it may not matter if the study was done in the United States or abroad or if the study was published in a reputable journal and evaluated by other scientists and researchers. Part of the problem with many of these health claims is that consumers either cannot or will not bother to find out further information and will take the health claim statements as proven instead of as preliminary evidence.

C. Harmful Effects of Tea

One may ask- what's the big deal? Drinking a little extra tea won't hurt anyone, so why all the concern?

There are four major risks associated with the health claims of tea. These can also apply more broadly to herbal and alternative remedies in general. First, although traditional tea is not as harmful as many other substances that people may use or overuse to help fight health problems, it can have some minor side effects.

Tea contains caffeine (unless decaffeinated like many green teas that are sold in the United States), which can affect the human body in several ways, causing insomnia, nervousness, and irregularities in heart rate.¹²⁶

While usually minor, these side effects can be harmful to people already suffering from these problems which

¹²⁶ See Unconventional Therapies- Green Tea, *available at*: <http://www.bccancer.bc.ca/PPI/UnconventionalTherapies/GreenTea.htm>. Because of the caffeine in green and black tea, one researcher notes that pregnant women and people with cardiac problems should limit their consumption of tea to two cups a day. *Id.* This is a bit ironic since many of the studies on the health benefits of tea state that in order to gain the benefits, one must consume more than four, or in some cases more than ten, cups of tea a day. This is especially inconsistent when people with cardiac problems should avoid too much caffeine and yet tea is supposed to be drunk in order to prevent and treat cardiovascular disease.

would only be exacerbated by consuming caffeine from tea. Many are quick to point out, however, that tea contains much less caffeine than coffee, approximately 40mg for a cup of tea compared to about 100mg for a cup of coffee,¹²⁷ and therefore it is not really a significant problem because many people have caffeine in their regular diets. Additionally, many people deliberately drink caffeine as a stimulant to promote alertness, and in this case, the side effect of tea is actually a positive one.

Second, herbal teas can be extremely dangerous and in some cases can be fatal if misused. The harmful physical effects of herbal teas are worth detailing because they are, unfortunately, too common. Laxative or weight-loss teas, like those containing senna, aloe, or buckthorn, are potentially fatal.¹²⁸ If overused (by either steeping the teas for too long or by drinking too many servings of the teas) they can cause diarrhea, vomiting, nausea, stomach cramps, constipation, fainting, and death.¹²⁹ The FDA has received many reports and complaints about these effects of dieter's teas.¹³⁰ To make matters worse, the FDA states that laxatives act on the colon, not on the small intestine where calories are absorbed, and therefore are not even effective at promoting weight loss.¹³¹ Therefore, people who use these teas to help them lose weight may unknowingly be putting themselves at great risk for a product that does not even work for its intended use. Furthermore, people with eating disorders such as bulimia and anorexia nervosa may try to use these herbal teas to quickly excrete any food they eat and cleanse their body, which only furthers their disease and puts them at serious risk.¹³² The FDA reports that four women's deaths have been linked to using laxative tea while suffering from an eating disorder.¹³³

¹²⁷Segal, *supra* note 4; Tea and Bone Health, *supra* note 93.

¹²⁸See Kurtzweil, *supra* note 102.

¹²⁹*Id.*

¹³⁰*Id.*

¹³¹*Id.*

¹³²*Id.*

¹³³*Id.*

Laxative teas are not the only herbal teas that come with potentially dangerous side effects. Chamomile tea has the potential to be fatal if the drinker happens to be allergic to it and does not know it. The FDA reported a 35-year old woman who went into anaphylactic shock after drinking Chamomile tea because she was allergic to it.¹³⁴ Chamomile is a member of the same plant family as ragweed, asters, and chrysanthemums, so people who are allergic to one of these plants have a greater risk of being allergic to the others.¹³⁵ Chaparral tea has been associated with the development of non-viral hepatitis and liver damage in several reported cases in the United States and Canada.¹³⁶ While this side effect is usually associated with chaparral taken in capsule form, some cases involved people who drank tea with chaparral as one of the ingredients.¹³⁷ Some distributors removed chaparral products from the market after this information was released, but some kept their products on the market awaiting further evidence.¹³⁸

Germander tea has also been linked to non-viral hepatitis after several reported cases occurred in France, leading to its prohibition in that country and its restriction in several others.¹³⁹ The herbal teas that contain Ephedra have all of the potential dangers that accompany Ephedra including hypertension, rapid heart rate, stroke, nerve and muscle damage, and memory loss.¹⁴⁰ The FDA's recent ban of Ephedra products affects these tea products, which should now be Ephedra free.¹⁴¹

The recent problem with Star Anise Tea is illustrative of several of the problems that arise with herbal supplements. Chinese star anise is a product generally recognized as safe (GRAS) by the FDA for use as a spice or flavoring; Japanese star anise is not GRAS, has been shown to be toxic, and should be used for decorative purposes only.¹⁴² The two are different species of the same plant. Unfortunately, when the star

¹³⁴ See Snider, *supra* note 103.

¹³⁵ *Id.*

¹³⁶ ILLNESSES AND INJURIES ASSOCIATED WITH THE USE OF SELECTED DIETARY SUPPLEMENTS, *supra* note 107.

¹³⁷ *Id.*

¹³⁸ *Id.*

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ See Final Rule Declaring Dietary Supplements Containing Ephedrine Alkaloids Adulterated Because They Present an Unreasonable Risk, 21 C.F.R. §119 (2004).

¹⁴² See FDA Issues Advisory on Star Anise "Teas," FDA Press Release (Sept. 2003), *available at:*

anise is dried and processed one cannot tell the two apart through visual examination. In 2001 to 2003, several incidents of illnesses were reported to the FDA after adults and infants ingested star anise tea.¹⁴³ Star anise is believed by some to help fight against colic in infants, although unsupported by scientific research, but it has also been shown to cause jitteriness, rapid eye movement, vomiting, and seizures.¹⁴⁴ The FDA could not pinpoint whether Japanese star anise was mistakenly being sold as Chinese star anise or whether the two had been unintentionally mixed together and sold as a tea.¹⁴⁵ Regardless of which one had occurred, the FDA warned consumers to avoid drinking any star anise tea until the problem could be determined.¹⁴⁶ This very recent incident illustrates that very similar herbs may have very different health effects, consumers are often persuaded to drink herbal teas that aren't proven to effectively treat anything, and it is extremely difficult under the current system for the FDA to deal with these problems once they occur. It is hard for the FDA to publicize these smaller yet important health risks, but it is easy for an herbal tea distributor to advertise its health claims to consumers.

Some herbal teas that used to be popular for their medicinal value have since been re-categorized as harmful to human health. Dangerous effects from comfrey tea made from comfrey root have been documented. Comfrey tea used to be popular for its general healing properties until it was discovered that the pyrrolizidine alkaloids it contains cause cancer in laboratory rats.¹⁴⁷ Upon this discovery Celestial Seasonings dropped Comfrey tea from its product line in the early 1980's and comfrey was banned in Canada in 1989.¹⁴⁸ Comfrey has also been implicated in liver disease, although only a few cases have been reported and were due to extremely

<http://www.fda.gov/bbs/topics/NEWS/2003/NEW00941.html>.

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

¹⁴⁶ *Id.*

¹⁴⁷ Snider, *supra* note 103.

¹⁴⁸ *Id.*; The United Kingdom, Australia and Germany have also banned the use of many comfrey products while some other countries have restricted its use to prescription only. See ILLNESSES AND INJURIES ASSOCIATED WITH THE USE OF SELECTED DIETARY SUPPLEMENTS, *supra* note 107.

excessive use of the herb.¹⁴⁹ Lobelia tea used to be used to treat breathing and respiratory problems, but has now been shown to cause vomiting, breathing problems (ironically), convulsions, and coma or death if used in large amounts.¹⁵⁰ Sassafras tea used to be used as a stimulant and blood thinner to treat rheumatism and syphilis, but it is now known to cause cancer in laboratory rats if used in large amounts.¹⁵¹ Sassafras was taken out of root beer production more than 40 years ago and has been banned from use in all food.¹⁵² The danger always exists that herbs we now believe are helpful for treating illnesses will eventually be found to actually do more harm than good. Nevertheless, even with this risk, people continue to consume all kinds of herbal teas based on preliminary accounts of their health benefits.

Third, there is a larger issue at stake when sellers are able to manipulate consumers and mislead them, even if it is with true or semi-true information. There is something different about a product claiming to affect human health without disclosing that it is completely up for debate whether the product actually works. Also, advertisements can pick and choose which data they want a consumer to see, and it is very easy to edit the content of a study to highlight the potential health benefits while downplaying, or leaving out completely, the potential side effects or health risks. Many advertisements also cite a supposed study without giving any background or information about it so that the consumer is further misled into thinking that the claims are substantiated. It is not just that consumers are duped into spending money on a product that they don't need- this happens every day; it is that people all over the country and the world believe that they are doing something good for their health or the health of their children when in fact they may just be putting themselves at more risk. When it comes to physical health, the standard for claims in advertising should be stricter because the consequences to consumers when a mistake occurs are far more significant than the loss of a few dollars, and may in fact be critical to their well being.

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

Fourth, there is an actual concrete danger to health if people with illnesses that are normally treated with prescription medicines substitute herbal remedies like tea for those drugs actually proven to help treat their disease or sickness.¹⁵³ For example, it could be a fatal choice for a cancer patient to forego chemotherapy for tea or another herbal remedy because they don't want the side effects that go along with chemotherapy when it is really the only option that could help them. Along similar lines, it would be ridiculous for a smoker to disregard the dangers of lung cancer because they also drink tea and they have read an article that cites a study showing that smokers who drink tea have a lower risk of developing lung cancer. It would be devastating to that person's health to choose tea as a preventative measure when instead they may have quit smoking. Finally, in the case of parents giving their children herbal remedies instead of seeking medical advice, the decision may have irreversible, long-term effects on the child's health. It would be deplorable if a child developed long-term respiratory problems because the parents treated her asthma or bronchitis with Eucalyptus and Echinacea tea instead of a prescription medication.

IV. THE PAST AND PRESENT REGULATION OF TEAS BY THE FOOD AND DRUG ADMINISTRATION AND THE FEDERAL TRADE COMMISSION

A. The Tea Importation Act and Its Repeal

Congress passed the Tea Importation Act¹⁵⁴ in 1897 after adopting an earlier version in 1893. The purpose of

¹⁵³ See 'MIRACLE' HEALTH CLAIMS: A DOSE OF SKEPTICISM, *supra* note 58.

¹⁵⁴ Tea Importation Act, 21 U.S.C. §41 *et seq.* (repealed 1996).

the Act was to protect American consumers from impure and inferior imported teas.¹⁵⁵ It became “unlawful for any person or persons or corporation to import or bring into the United States any merchandise as tea which is inferior in purity, quality, and fitness for consumption to the standards provided in section 43...”¹⁵⁶ The Act established a Board of Tea Experts who, under the supervision of the FDA, were responsible for inspecting any tea that entered the United States and certifying it as acceptable for importation.¹⁵⁷ No tea could enter the United States without going through this process, and no other beverage had this kind of regulatory scheme in place.¹⁵⁸ The FDA also promulgated many regulations under the Tea Importation Act to fulfill its mandates.¹⁵⁹ Among other areas, the regulations described in detail how the inspection process would take place and the process for appeals.¹⁶⁰

In 1996 Congress passed the Federal Tea Tasters Repeal Act,¹⁶¹ which repealed the entire Tea Importation Act. Congress’s reasoning behind the repeal of the Act was basically efficiency and monetary savings:

Because the safety of tea for human consumption is preserved under the FFDCA [Federal Food, Drug, and Cosmetics Act], the quality standards for tea imposed by the Tea Importation Act of 1897 and enforced by the FDA are no longer necessary. Repeal of the Tea Importation Act of 1897 would end the dual regulation of tea that occurs by virtue of the overlap between these two Acts. Upon repeal, imported tea would continue to be regulated by the FDA in accordance with the FFDCA in the same manner as instant tea, coffee, and other imported foods.¹⁶²

The repeal was probably long overdue, since the FDCA has been in place since 1938, and its predecessor, the

¹⁵⁵21 U.S.C. §41 (repealed 1996); H.R. REP. NO. 104-467(II), at 2-3.

¹⁵⁶21 U.S.C. §41 (repealed 1996).

¹⁵⁷H.R. REP. NO. 104-467(II), at 2-3.

¹⁵⁸*See id.*; Very few foods have actually been dealt with specifically through a Congressional statute. Most food policies are changed through FDA regulations, and Congress rarely becomes involved. Some of the other foods that have gotten special statutory attention include meat through the Meat Inspection Act in 1906, Oleomargarine through the Oleomargarine Act in 1950, saccharin under the Saccharin Study and Labeling Act in 1977 and the Saccharin Notice Repeal Act in 1996, and infant formula under the Infant Formula Act in 1980. *Milestones in U.S. Food and Drug Law History*, FDA BACKGROUNDER (May 1999), available at: <http://www.cfsan.fda.gov/mileston.html>.

¹⁵⁹*See* 21 C.F.R. §1220 *et seq.* (2004).

¹⁶⁰*See, e.g.*, 21 C.F.R. §1220.22, §1220.30, §1220.31, §§1220.71-1220.72.

¹⁶¹Pub. Law No. 104-128, 110 Stat. 1198 (1996).

Food and Drug Act, since 1906,¹⁶³ both of which would ensure that tea was safe to drink. The repeal did not result in any influx of low quality tea or any harm to American consumers, and the FDA has continued to regulate tea under the FDCA.

The Tea Importation Act, although no longer in existence, is still important today when considering how to regulate the tea industry. The very fact that our nation had a statute in place for over 100 years dealing exclusively with tea speaks to tea's historical importance to our society. Even though circumstances and needs have changed, it should not be forgotten that the regulation of tea was extremely important to lawmakers and played a role in the independence of our nation.

¹⁶³See *Milestones in U.S. Food and Drug Law History*, *supra* note 158.

B. The Food, Drug, and Cosmetic Act (FDCA)¹⁶⁴ The FDCA is currently the primary statutory source of authority under which the FDA regulates tea and other foods. It prohibits misbranding, adulteration, and contamination of foods, drugs, dietary supplements, and cosmetics in interstate commerce and mandates the admittance of FDA inspectors.¹⁶⁵ Tea clearly fits under the definition of food, which includes “articles used for food or drink for man or other animals.”¹⁶⁶ Tea is considered a food and is regulated as such unless it falls into another category, like a dietary supplement.

Most important in the area of tea and health is the regulation of labeling and misbranding. A food is considered misbranded if: “(1) its labeling is false or misleading in any particular.”¹⁶⁷ This is a relatively broad mandate and leaves up for debate what is considered false or misleading.¹⁶⁸ It is the regulators who have to make the decisions about whether something is misleading enough to pursue an action against the manufacturer or distributor.

While it may seem straightforward, the definition of “labeling” turns out to be extremely important because it determines the boundaries of the FDCA’s statutory reach. Labeling means, “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.”¹⁶⁹ If a statement or claim leaves the realm of labeling and enters advertising it then falls under the Federal Trade Commission’s (FTC) jurisdiction.¹⁷⁰ The line between labeling and advertisement is further blurred by the rise of the Internet. When a product is sold online and health claims accompany its picture, are these labels or advertisements? The FDA has refused to concede that Internet promotion is not labeling; it claims instead that under some circumstances websites may be considered labeling.¹⁷¹ The FDA argues that because courts have interpreted the phrase “or accompanying such article” very broadly and included “information designed to promote the distribution and sale of the product” in the definition of labeling, websites would certainly fit under

Therefore a substance that many would consider to be a food or dietary supplement might actually become a drug under this definition because of the claims the manufacturer makes about the substance's affect on the body or diseases. The average consumer would simply see tea as a food. But when a manufacturer or distributor starts making disease claims that same tea becomes a drug as defined under the FDCA.

Drugs are subject to much stricter rules under the FDCA, the most important of which is pre-market approval for "new drugs."¹⁷⁶ If a substance is a "new drug" then the FDCA states, "no person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug."¹⁷⁷ Because of the many disease claims being made for tea in the scientific community, if a manufacturer uses this information to claim on its label that tea may be able to treat or prevent diseases then it could fall under the FDCA definition of new drug. Any manufacturer wants to avoid being a new drug because the process for getting FDA approval is

¹⁷⁰See Part IV.D., *infra*.

¹⁷¹See Ctr. for Food Safety & Applied Nutrition, U.S. Food & Drug Admin., FDA Letter on Labeling Food Products Presented or Available on the Internet (2001), available at: <http://www.cfsan.fda.gov/~dms/labwww.html>. This letter is a response to a citizen petition asking the FDA to adopt a rule stating that information available through company websites does not constitute labeling under the FDCA.

¹⁷²See *id.* (citing *Korbel v. U.S.*, 355 U.S. 345 (1948); *U.S. v. 47 Bottles, More or Less, Jenasol RJ Formula "60"*, 320 F.2d 564 (3d Cir.1963); *U.S. v. Guardian Chemical*, 410 F.2d 157 (2d Cir.1969)). Many of the FDA's supporting cases have to do with drug labeling, which is stricter than food labeling. However, the FDA has seen fit to extend its arguments into the food sector and will likely continue to adhere to this position.

¹⁷³See Fed. Trade Comm'n, Health Claims on the Internet: Buyer Beware (Jun. 2001), available at: <http://www.ftc.gov/bcp/online/features/healthclaims.htm>.

¹⁷⁴See Part C.3., *infra*.

¹⁷⁶A new drug is defined as:

(1) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or (2) Any drug (except a new animal drug or an animal feed bearing or containing a new animal drug) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions. 21 U.S.C. §321(p).

¹⁷⁷21 U.S.C. §355(a).

both lengthy and expensive.

Additionally, the FDCA defines cosmetics as:

(1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.¹⁷⁸

Cosmetics are subject to their own regulation under the FDCA and it is unlawful to sell adulterated or misbranded cosmetics.¹⁷⁹ As with food, a cosmetic is considered to be misbranded, “if its labeling is false or misleading in any particular.”¹⁸⁰ Tea is more likely to be considered a cosmetic now more than ever because many manufacturers have begun to sell lotions containing both green and white tea.¹⁸¹

Finally the FDCA defines and regulates food additives. Food additives are defined as:

any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food...if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures...to be safe under the conditions of its intended use.¹⁸²

A food additive is considered to be unsafe unless, “there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.”¹⁸³ If an unsafe food additive is present in any food then that food is considered adulterated.¹⁸⁴ Herbal teas run this risk of being considered adulterated when they add herbs that are not

GRAS.¹⁸⁵

¹⁷⁹ See 21 U.S.C. §331.

¹⁸⁰ 21 U.S.C. §362(a).

¹⁸¹ See discussion in Part V.D., *infra*.

¹⁸³ 21 U.S.C. §348(a). Basically a food additive is unsafe unless it is authorized by regulation or is GRAS.

¹⁸⁴ 21 U.S.C. §342(a)(1)(2)(C).

¹⁸⁵ See, e.g., Warning Letter from FDA to Herbal Junction 1-2 (Jan. 14, 2004), available at: http://www.fda.gov/foi/warning_letters/g4495d.htm.

C. Amendments to the Food, Drug, and Cosmetic Act

The FDCA has been amended many times since it was passed in 1938.¹⁸⁶ Three specific recent amendments are relevant to the regulation of health claims for tea: The Food and Drug Administration Modernization Act of 1997, The Nutrition Labeling and Education Act of 1990, and The Dietary Supplement Health and Education Act of 1994. After these amendments, the FDCA now describes a different world for manufacturers who want to make health claims on the labels of their food or dietary supplements.

1. The Food and Drug Administration Modernization Act of 1997 (FDAMA)¹⁸⁷

The FDAMA amended the FDCA to allow manufacturers to make nutrient-content claims and health claims on their food labels under certain circumstances. The claims must be based on current, published, authoritative statements from “a scientific body of the United States with official responsibility for public health protection or research directly related to human nutrition or the National Academy of Sciences.”¹⁸⁸ This may include agencies like the National Institute of Health (NIH).¹⁸⁹ FDA has the authority to evaluate whether the proposed health claim is subject to “significant scientific agreement” and therefore if it will allow the claim on the food’s label.¹⁹⁰ FDAMA does not deal with dietary supplements because it only amended the portion of the FDCA that deals with food.¹⁹¹ All health claims made under this Act must go through the FDA’s pre-approval process.

¹⁸⁶See Hutt & Merrill, Food and Drug Law 13 (1991).

¹⁸⁷Pub.L.No. 105-115, 111 Stat. 2296 (1997) (relevant parts codified in parts of 21 U.S.C. §343(r)).

2. The Nutrition Labeling & Education Act of 1990 (NLEA)¹⁹²

The NLEA also amended part of the FDCA and provides for increased labeling of the nutritional value requirements for food and dietary supplements.¹⁹³ The FDA has further specified food nutrition labeling requirements in its regulations promulgated under the NLEA.¹⁹⁴ The nutrition panel on the food container must be labeled “Nutrition Facts” and must include serving size and the amount of calories, fat, and certain nutrients contained in the food.¹⁹⁵ The regulations also specify how health claims may be made on food labels.¹⁹⁶

The labeling requirements do not apply to some exempted foods, including “plain coffee and tea, some spices, and other foods that contain no significant amounts of any nutrients.”¹⁹⁷ Even if a manufacturer is exempt from the labeling requirements, it may still voluntarily include a nutrition facts panel on its food container.¹⁹⁸ It may be to the manufacturer’s advantage from a marketing standpoint to include the nutrition facts even when not required to do so because consumers have now grown accustomed to seeing the panel and may think it is strange for a product not to contain it. Also, consumers may not know that tea contains no significant amount of nutrients and therefore would like to see a nutrition panel containing all zeros for their peace of mind.

3. The Dietary Supplement Health and Education Act of 1994 (DSHEA)¹⁹⁹

Congress passed the DSHEA to amend the FDCA in 1994 as a compromise between regulating dietary supplements as food or as drugs.²⁰⁰ They are somewhere in the middle, although probably closer to food because they do not have to go through the same pre-market approval that is required for drugs.⁴⁴

The FDA describes the role of the DSHEA as follows: “[the provisions] define dietary supplements and dietary ingredients; establish a new framework for assuring safety; outline guidelines for literature displayed where supplements are sold; provide for use of claims and nutritional support statements; require ingredients and nutrition labeling; and grant FDA the authority to establish good manufacturing

As with foods, the manufacturer of the supplement is responsible for ensuring that its product is safe, that any claims made about the product are not false or misleading, and that any claims are substantiated by adequate evidence.²⁰² The FDA's role is largely in policing the supplements after they enter the market, much like with food.

The Act defines dietary supplement as:

(1) a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients: a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or a concentrate, metabolite, constituent or extract... (2) a product that is [a food for special dietary use as defined in §350(c)] and is not represented for use as a conventional food or as a sole item of a meal or the diet; and is labeled as a dietary supplement.²⁰³

If the product is a dietary supplement then it is governed by its own rules in the statute about the types of claims it can make related to health and its product.²⁰⁴ There are three requirements contained in the statute: a statement for a dietary supplement may be made if:

(A) the statement claims a benefit related to a classical nutrient deficiency disease and discloses the prevalence of such disease in the United States, describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans, characterizes the documented mechanism by which a nutrient or dietary ingredient acts to maintain such structure or function, or describes general well-being from consumption of a nutrient or dietary ingredient, (B) the manufacturer of the dietary supplement has substantiation that such statement is truthful and not misleading, and (C) the statement contains, prominently displayed and in boldface type, the following: "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."²⁰⁵

The statute essentially allows structure/function claims, which describe the role of the product or its ingredients intended to affect or maintain the structure or function of the human body,²⁰⁶ as long as the manufacturer has substantiation for the claim and provides the disclaimer described in part C. Structure/function claims may also include a description of general well being from the consumption of the ingredients.²⁰⁷ In order to make a structure/function claim on its label, the manufacturer must notify the FDA of the statement within 30 days of first making the dietary supplement available for sale.²⁰⁸ Compared to the rules governing drugs described above, these are rather lenient requirements.

If a food qualifies as a dietary supplement then it is also subject to the FDA's regulations dealing with dietary supplements promulgated under the Act. The regulations further clarify exactly what health claims the dietary supplement can make and how they can be made. While they can make structure/function claims, dietary supplements are prohibited from making disease claims or they will be regulated as a drug.²⁰⁹ The FDA has ten criteria for determining whether the product is making a disease claim, many of which are relevant to health claims for tea:

FDA will consider the context in which the claim is presented. A statement claims to diagnose, mitigate, treat, cure, or prevent disease if it claims, explicitly or implicitly, that the product: (i) Has an effect on a specific disease or class of diseases; (ii) Has an effect on the characteristic signs or symptoms of a specific disease or class of diseases, using scientific or lay terminology; (iii) Has an effect on an abnormal condition associated with a natural state or process, if the abnormal condition is uncommon or can cause significant or permanent harm; (iv) Has an effect on a disease or diseases through one or more of the following factors: (A) The name of the product; (B) A statement about the formulation of the product, including a claim that the product contains an ingredient (other than an ingredient that is an article included in the definition of “dietary supplement” under 21 U.S.C. 321(ff)(3)) that has been regulated by FDA as a drug and is well known to consumers for its use or claimed use in preventing or treating a disease; (C) Citation of a publication or reference, if the citation refers to a disease use, and if, in the context of the labeling as a whole, the citation implies treatment or prevention of a disease, e.g., through placement on the immediate product label or packaging, inappropriate prominence, or lack of relationship to the product’s express claims; (D) Use of the term “disease” or “diseased,” except in general statements about disease prevention that do not refer explicitly or implicitly to a specific disease or class of diseases or to a specific product or ingredient; or (E) Use of pictures, vignettes, symbols, or other means; (v) Belongs to a class of products that is intended to diagnose, mitigate, treat, cure, or prevent a disease; (vi) Is a substitute for a product that is a therapy for a disease; (vii) Augments a particular therapy or drug action that is intended to diagnose, mitigate, treat, cure, or prevent a disease or class of diseases; (viii) Has a role in the body’s response to a disease or to a vector of disease; (ix) Treats, prevents, or mitigates adverse events associated with a therapy for a disease, if the adverse events constitute diseases; or (x) Otherwise suggests an effect on a disease or diseases.²¹⁰

Even with these criteria set out in the regulations, it is still difficult sometimes to determine whether a health claim has crossed the line from structure/function to disease. When manufacturers are dealing with a product like tea for which there is scientific research available stating that tea may help prevent and treat certain diseases it is very tempting to use this science when marketing the tea. It may be very easy for a tea manufacturer to cross the line between structure/function and disease claim either unintentionally because of over-aggressive marketing, or deliberately by using the disease claim but then alleging that the line has not been crossed.

The DSHEA also deals with third-party literature that accompanies a dietary supplement's health-related claims. Essentially, a third-party publication may accompany the dietary supplement and will not be considered labeling if it:

(1) is not false or misleading; (2) does not promote a particular manufacturer or brand of a dietary supplement; (3) is displayed or presented, or is displayed or presented with other such items on the same subject matter, so as to present a balanced view of the available scientific information on a dietary supplement; (4) if displayed in an establishment, is physically separate from the dietary supplements; and (5) does not have appended to it any information by sticker or any other method.²¹¹

The key to this provision is the labeling exemption, because if the material is not considered a label then it cannot be considered misbranded under the FDCA.²¹²

Finally, even if not considered misbranded, a dietary supplement may be considered adulterated under the Act if it “presents a significant or unreasonable risk of illness or injury under (i) conditions of use recommended or suggested in labeling, or (ii) if no conditions of use are suggested or recommended in the labeling, under ordinary conditions of use.”²¹³ This provision may be important to herbal teas whose safety may be in question even when used in normal doses.

4. *Health Claims under the Current Law*

Together the NLEA, FDAMA, and DSHEA amendments to the FDCA and their accompany regulations dictate the current rules for health-related claims for foods and dietary supplements. These claims may take one of three forms: Health Claims, Nutrition-Content Claims, and Structure/Function Claims.²¹⁴

a. *Health Claims*

A health claim is a statement composed of a food or dietary ingredient and a disease or health-related condition.²¹⁵ There are three ways that a food may use a health claim on its label, two of which also apply to dietary supplements. First, the NLEA contains provisions for FDA-authorized health claims for foods and dietary supplements. The FDA, through promulgation of a regulation, may authorize a health claim after submission of a health claim petition, an extensive review of the scientific literature, and a determination that the nutrient/disease relationship is well established using the scientific agreement standard.²¹⁶ This is a high threshold to meet, and the FDA has only approved a few health claims under this regulatory mechanism, none of which relate to the components found in tea.²¹⁷

Second, the FDA may authorize the use of a qualified health claim for a food or dietary supplement that meets a lower standard of scientific evidence when there is emerging evidence that the product may reduce the risk of a disease or condition.²¹⁸ In this case a manufacturer may submit a qualified health claim petition to the FDA, which will then review the totality of the scientific evidence.²¹⁹ If the FDA agrees with the petitioner it will issue an enforcement discretion letter authorizing the claim as long as it is accompanied by qualifying language explaining that the claim is limited.²²⁰ Once one manufacturer's petition is granted any manufacturer may use the claim for that food or dietary supplement as long as it complies with the FDA's conditions of the enforcement discretion letter.²²¹ The FDA has approved several qualified health claims for cancer and coronary heart disease, the most relevant of which is antioxidant vitamins and cancer.²²² If tea manufacturers wanted to get qualified health claim approval, the approved antioxidant claim for Vitamins C and E would likely be a building block.

The FDA also recently clarified its evaluation of qualified health claims by adopting a ranking system for scientific evidence:

The highest grade, A or the equivalent, means that there is significant scientific agreement (SSA) about the health claim. It means that the evidence supporting the claim is derived from well-designed studies conducted in a manner consistent with generally recognized scientific procedures and principles. Such a claim requires no disclaimer and is therefore referred to as an unqualified health claim. A current example of a Grade A health claim is a claim relating calcium to reduced risk of osteoporosis. Under the new system, the grade of B would be assigned to those petitions for which there is good scientific evidence supporting the claim, but for which the evidence is not entirely conclusive. Grades of C would apply to claims for which the evidence is limited and inconclusive. The fourth level, D, would be given to claims with little scientific evidence to support them. Health claims graded B, C, or D are referred to as qualified health claims because they require a disclaimer or other qualifying language to ensure that they do not mislead consumers.²²³

The ranking system is part of a larger objective to increase enforcement against misleading statements on dietary supplements and increase consumer awareness about health levels of nutrients in food and dietary supplements.²²⁴

Third, as described in Part 1 above, a food manufacturer may make a claim based on authoritative statements under the FDAMA. This option is not available to dietary supplements. A food manufacturer may submit a notification for a health claim based on an authoritative statement of a recognized scientific body, which the FDA will review to determine if the scientific evidence is strong enough to constitute significant scientific agreement and therefore warrant approval.²²⁵ The manufacturer must submit its information to the FDA at least 120 days before beginning to market the product for its review.²²⁶ Even fewer claims have been approved under this format than under the NLEA process.²²⁷

b.

Nutrient Content Claims

Nutrient content claims are also authorized by the NLEA. They describe the level of a nutrient or dietary substance in the product or compare the level of the nutrient to that of another product.²²⁸ The FDA must approve a claim by adopting a regulation for it.²²⁹ Some common nutrient content claims include “free,” “high,” “low,” “reduced,” and “lite.”²³⁰ Most authorized claims involve nutrients for which there is an established daily value; but dietary supplements may also make nutrient content claims using simple percentage statements even if there is no established daily value.²³¹

c. Structure/Function Claims

Structure/function claims may be made about food and dietary supplements, but the two are regulated slightly differently. As noted in Part 3 above, dietary supplements must notify the FDA of their claims within thirty days of marketing their claims and must include a disclaimer on the label along with the claim, but they do not need FDA approval before they may include the claim on their labels. Foods, however, are not required to notify the FDA about their claims, nor must they include a disclaimer on their label.²³² Both foods and dietary supplements must refrain from making a disease claim and may not make false or misleading claims on their labels.²³³

D. The Federal Trade Commission’s Regulation of Advertising

The FTC’s role is a bit unusual in that almost all of the regulatory responsibility for food, drugs, and dietary supplements has been delegated to the FDA, except for the advertising niche, which has been delegated

to the FTC.²³⁴ The FTC ensures that advertisements of claims relating to the product are truthful, not misleading,²³⁵ and substantiated by some scientific evidence through its mandate to enforce laws against false advertising and unfair or deceptive acts or practices.²³⁶ This standard applies to all claims, express or implied, made by the manufacturer or distributor in virtually any marketing media.²³⁷ The standard is the same under the law for food, drugs, dietary supplements, and cosmetics, but the FTC has recognized that dietary supplements may require particular attention now because they have become increasingly popular over the past few years and are now marketed for a wide variety of uses.²³⁸ As with FDA regulation of labeling for food and dietary supplements, there is no pre-market approval for health claim advertisements and it is up to the manufacturer to self-enforce the FTC's rules. Any action by the FTC against the claim and the manufacturer will occur after the advertisement has been released to the public and its legality is questioned.

The FTC's first requirement, truthfulness without misleading the reader, is extremely important when dealing with health claims. With all of the new research on the health benefits of tea, an advertisement can easily become misleading if the manufacturer does not provide the information in a clear and accurate way. If the reader may be misled by the information in the advertisement then the manufacturer is required to include qualifying information that will inform the reader to the point where the advertisement is no longer misleading.²³⁹ This includes placing the qualifying language in a prominent location so that consumers will be able to read it easily in conjunction with the other information in the ad.²⁴⁰

²³⁴See 15 U.S.C. §53 (2004).

²³⁵See 15 U.S.C. §55.

²³⁶See 15 U.S.C. §52 (declaring that false advertisement and unfair or deceptive trade practices shall be unlawful).

²³⁷See FED. TRADE COMM'N, DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY 1 (2001).

²³⁸See *id.*

²³⁹See *id.* at 5

²⁴⁰*Id.* at 6.

Second, the FTC requires that claims must be substantiated and that advertisers have a reasonable basis for all express and implied claims.²⁴¹ Determining what is reasonable is difficult, and the FTC takes into consideration what claims are being made, how they are being made in the context of the entire ad, and how they are being qualified.²⁴² Health claims that may affect consumer safety are held to a higher standard, as are claims that may be difficult for consumers to understand because of the methodology of the research involved; the FTC will look at the totality of the evidence when deciding whether a claim has been substantiated.²⁴³

While the above-mentioned guidelines apply to all advertisement containing health claims, the FTC has recognized that dietary supplements deserve special explanation even though they are subject to the same rules.²⁴⁴ Dietary supplement advertisers use several types of claims that are not as common with other products: consumer testimonials, traditional claims, and the FDA disclaimer. If a manufacturer uses consumer testimonials to endorse its product they must not be deceptive and they must be able to be directly substantiated.²⁴⁵ The concerns over consumer testimonials apply whether or not the consumer making the statement believes it to be true or not. Anecdotal evidence of success by one consumer may be due to factors completely separate from the product they are endorsing, and it is much harder to verify whether this information is accurate.

Traditional use claims pose similar problems in that they are largely unverifiable and may be based on nothing

²⁴¹ *Id.* at 8.

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ *See id.*

²⁴⁵ *Id.* at 18.

more than legend and myth. The FTC believes that traditional use claims must either be substantiated by scientific evidence or presented to the consumer in such a way that it is clear that the claim is based solely on the history of the product's use.²⁴⁶ The advertiser must still have substantiation of the historical use of the product along with the dosage. When determining whether a traditional use claim is misleading, the FTC will take account of consumer beliefs about the product's uses and whether consumers generally expect that the type of claim being made is backed up by independent scientific research.²⁴⁷ If the FTC believes that a traditional use claim may present a substantial risk of injury to consumer safety then it may not be enough to simply explain that the claim is only based on historical use, and the advertiser may not be able to make the claim at all.²⁴⁸

Some manufacturers choose to include the dietary supplement label disclaimer in their advertisements, even though the law does not require it. The FTC favors this approach if it will help inform consumers who may otherwise believe that the FDA has reviewed the product's safety and efficacy.²⁴⁹ However, the FTC is quick to remind manufacturers that simply using the disclaimer does not otherwise cure a deceptive ad, especially if the ad deals with a disease claim.²⁵⁰

In addition to scrutinizing advertisements to insure their truthfulness, the FTC also tries to educate consumers about misleading advertisements. It provides press releases and advisories like the FDA, and provides consumers with information on how to report potentially false advertisements.²⁵¹ The FTC warns consumers to avoid false claims by being aware of statements that claim that the product is a cure-all for a wide vari-

²⁴⁶*Id.* at 20.

²⁴⁷*Id.* at 21.

²⁴⁸*Id.*

²⁴⁹*See id.* at 23.

²⁵⁰*Id.*

²⁵¹*See* 'MIRACLE' HEALTH CLAIMS: ADD A DOSE OF SKEPTICISM, *supra* note 58; HEALTH CLAIMS ON THE INTERNET: BUYER BEWARE, *supra* note 173.

ety of ailments or that uses words like “scientific breakthrough,” “miraculous cure,” “secret ingredient,” or “ancient remedy.”²⁵² In 1999 the FTC launched its program “Operation Cure All,” a law enforcement and consumer education campaign dealing with health fraud on the Internet.²⁵³ In its first two years it resulted in thirteen law enforcement actions and the removal of an estimated more than 100 websites’ fraudulent health claims.²⁵⁴

E. FDA Enforcement, Warning Letters, and Publication Advisories

The FDA has taken action against food and dietary supplement manufacturers, distributors, and marketers through its informal enforcement powers with warning letters and press releases as well as through its formal enforcement powers with seizures. Much of the FDA’s job can be done by preempting any violations before they occur, rather than going after the violator after the product has already entered the market. The FDA issues press releases and public advisories through its website,²⁵⁵ in addition to its guidance documents, and also sends general letters to manufacturers advising them of FDA policies.²⁵⁶ The FDA also gets some help from the mainstream media in warning consumers.²⁵⁷ If these approaches fail and the FDA believes

²⁵²MIRACLE HEALTH CLAIMS: ADD A DOSE OF SKEPTICISM, *supra* note 58.

²⁵³HEALTH CLAIMS ON THE INTERNET: BUYER BEWARE, *supra* note 173.

²⁵⁴*Id.*

²⁵⁵*See, e.g.*, Kurtzweil, *supra* note 102; Snider, *supra* note 103; ILLNESSES AND INJURIES ASSOCIATED WITH THE USE OF SELECTED DIETARY SUPPLEMENTS, *supra* note 107; FDA Issues Advisory on Star Anise “Teas,” *supra* note 142; FDA Cautions Consumers on “Kombucha Mushroom Tea,” *supra* note 112; U.S. FOOD & DRUG ADMIN., FDA WARNS AGAINST DIETARY SUPPLEMENT PRODUCT, “CHOMPER,” *available at*: <http://www.fda.gov/medbull/fdawarns.html>; No Evidence to Support Cholesterol Claims for Cho Low Tea, *supra* note 113.

²⁵⁶*See, e.g.*, CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., LETTER TO MANUFACTURERS REGARDING BOTANICALS AND OTHER NOVEL INGREDIENTS IN CONVENTIONAL FOODS (2001), *available at*: <http://www.cfsan.fda.gov/~dms/ds-ltr15.html>.

²⁵⁷*E.g.*, 20/20 (ABC television broadcast, Apr. 23, 2004) (discussing infomercials for dietary supplements with unsubstantiated

that a product is being labeled or marketed in violation of the law, it will likely start by sending a warning letter. The warning letter has a general format where it identifies the statements that the FDA believes are unlawful, cites the applicable law, often dealing with whether a product is GRAS or making a claim that qualifies it as a drug, and requests a response describing how the violation will be corrected.²⁵⁸ The FDA has sent several warning letters dealing with tea products, mostly on the Internet.²⁵⁹ It has also sent many more relating to dietary supplements in general.

If the warning letter fails to secure a change in labeling, the FDA is authorized to seize the products because they are misbranded or adulterated,²⁶⁰ seek to impose civil fines for violations,²⁶¹ seek injunction proceedings,²⁶² and seek criminal penalties.²⁶³ These enforcement mechanisms are less attractive to the FDA because they are more time consuming and any court action must be enforced by the Department of Justice and not by the FDA directly. The FDA statistically has favored informal enforcement. For example, in fiscal year 2002 the FDA sent 755 warning letters, conducted 18,572 inspections, and secured 5,025 recalls.²⁶⁴ In contrast, over the same period of time, it conducted only thirteen seizures, filed fifteen permanent injunctions,

health claims and noting that no pre-approval of the scientific data they use in marketing is required by law); Michael Specter, *Miracle In A Bottle: Dietary supplements are unregulated, some are unsafe-and Americans can't get enough of them*, THE NEW YORKER, Feb. 2, 2004, at 64 (describing Americans increased use of dietary supplements and some of their dangers).

²⁵⁸ See, e.g., Warning Letter from FDA to Diabetes Tea 1-2 (on file with author).

²⁵⁹ See Warning Letter from FDA to Reach4Life Enterprises (Nov. 16, 2000) (on file with author) (determining that the product Herba Green Tea Extract qualifies as a drug because it is being marketed as containing “the active ingredient polyphenol, which is recognized as a potent cancer preventer...but more importantly, the fact that Green Tea is in pure liquid form, all of the cancer fighting polyphenol enters your body.”); Warning Letter from FDA to Herbal Junction 1-2, *supra* note 185 (citing Livertea and Justice Herbal Enzyme Elixer Tea for its violation of FDCA for using non-GRAS ingredients in its tea, including una de gato, peony, ho shou w-u, maira pauma, chanca piedra, jatoba, and catuaba.); Warning Letter from FDA to Light Resources Unlimited, Inc. (Jan. 28, 2002), *available at*: <http://www.fda.gov/cder/warn/cyber/2002/CFSANlightresources.htm> (determining that Immune Power Herbal and Allergy Relief Herbal FormulaTM made claims that qualify it as a drug, including “for a true allergy, or for asthma, people should 1) take a complete combination of Dr. Wheeler’s natural supplements for the immune system...and 2) take a special herbal tea developed by a Canadian Medical Researcher, Immune Power Herbal and Allergy Relief FormulaTM.”); Warning Letter from FDA to R.H. Cosmetics, Corp. (Feb. 4, 1997) (on file with author) (citing tea tree oil as qualifying as a drug because it claims to “fight nail fungus...[is] ideal for skin problems such as pimples, cuts, bruises, burns, athlete’s foot and fungus...[and can] fight acne, purifies by killing bacteria.”).

²⁶⁰ See 21 U.S.C. §334(a) (2004).

²⁶¹ See 21 U.S.C. §335b(a).

²⁶² See 21 U.S.C. §332.

²⁶³ See 21 U.S.C. §333.

²⁶⁴ U.S. FOOD & DRUG ADMIN., THE ENFORCEMENT STORY Ch. 10: FDA Enforcement Statistics, *available at*: http://www.fda.gov/ora/about/enf_story/ch10/stats_charts.htm#chart14. This is actually the lowest number of warning letter sent by the FDA in the past ten years.

and secured 317 convictions.²⁶⁵ The Center for Food Safety and Applied Nutrition (CFSAN), which is responsible for food and dietary supplements sent 272 of the 755 warning letters, conducted eight of the thirteen seizures, and conducted 8,979 of the 18,572 inspections; it also accounted for only 920 of the 5,025 recalls.²⁶⁶ Based on these numbers, CFSAN accounts for a large portion of the enforcement compared to the four other divisions included in the report. When it comes to food and dietary supplements, the FDA conducts the largest number of inspections, sends the second largest number of warning letters (second only to the Center for Devices and Radiological Health), and conducts only a small number of recalls.²⁶⁷

The FDA recently instituted a new program relating to dietary supplements discussed in Part IV(C)(4), above, called the FDA's Consumer Health Information for Better Nutrition Initiative.²⁶⁸ During the six-month period under the Initiative from December 2002 to June 2003 the FDA sent 73 warning letters and conducted four seizures related to dietary supplements containing misleading health claims.²⁶⁹ In addition to increasing consumer awareness and enforcement, the FDA also acknowledged the importance of its joint efforts with FTC in order to fully focus on manufacturers' misleading claims.²⁷⁰

²⁶⁵ *Id.*

²⁶⁶ *Id.*; *see also id.* at Ch. 4: Center for Applied Nutrition, *available at*: http://www.fda.gov/ora/about/enf_story/ch4/cfsan_charts.htm.

²⁶⁷ *See* THE ENFORCEMENT STORY, *supra* note 264 at FDA Enforcement Statistics FY1998- 2002.

²⁶⁸ *See* FDA TO ENCOURAGE SCIENCE-BASED LABELING AND COMPETITION FOR HEALTHIER DIETARY CHOICES, *supra* note 223.

²⁶⁹ *Id.*

²⁷⁰ *See id.*

F. Limitations on FTC and FDA's Enforcement Powers²⁷¹

The FDA and FTC's enforcement powers intersect at the line between advertising and labeling. Unfortunately this is not always a bright line, and it may be difficult to determine when an advertisement becomes specific enough and in close enough proximity to the product to qualify as a label. If the FDA initiates and action against a manufacturer for a false or misleading claim it must also assert jurisdiction over the claim, mostly likely because it is a label. The manufacturer may, however, claim that it is instead an advertisement and therefore not subject to FDA authority but FTC authority instead.²⁷² If the FDA and FTC are not coordinating and working together then manufacturers may actually be able to prolong their distribution of a dangerous product. Therefore it is very important for the two agencies to work together when dealing with misleading claims that may be towing the line between label and advertisement.

The FTC recognizes the FDA's expertise in the area of food and drugs, and the two agencies can share reports with each other that lead to enforcement by the other agency.²⁷³ Consistency between the two agencies is also important because one would not want a health claim to be approved for a label but prohibited for an advertisement when the standard for labels is stricter. Furthermore, the FTC is responsible for all advertisements, not just for food and drugs, so it is possible that what the FDA considers top priority, the FTC considers less important. Nevertheless, when it comes to claims that may put consumers' health at

²⁷¹The food and drug industries can challenge the FDA enforcement powers in many ways; this topic is expansive and generally beyond the scope of this paper. However, it is important to remember that the FDA and FTC share some of the regulatory arena and that are actually regulating speech when they regulate advertising and labeling.

²⁷²Although this is technically possible, any smart manufacturer would resist this urge because it must deal with the regulators on a continuous basis in order to produce its product. It would be unwise to challenge a regulator for something like this if that regulator will have a large amount of discretion over you in the future.

²⁷³See DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, *supra* note 237 at 1.

risk hopefully both agencies agree that targeting the misleading claim should be top priority.

The First Amendment²⁷⁴ also represents a boundary for the FDA and FTC whether they are enforcing a statute expressly or one of their regulations. Of course, the statute and the regulations cannot violate the seller or distributors' First Amendment rights to engage in commercial speech. The recent constitutional issues in the courts have dealt with dietary supplement labeling. While the D.C. Circuit curtailed the FDA's authority to pre-approve all health claims for dietary supplements, the Second Circuit upheld the length of the FDA's approval process for health claims for dietary supplements against a First Amendment challenge.²⁷⁵ These First Amendment challenges to the FDA's regulations following the passage of the NLEA and DSHEA have definitely influenced the FDA's current rules regarding dietary supplement labeling. The law of the First Amendment is generally very complicated, and its intersection with the FDA's broad regulatory power only makes the analysis more complex. In general, the FDA and FTC may prohibit inherently misleading advertisements entirely under the First Amendment.²⁷⁶

In *Pearson v. Shalala*,²⁷⁷ the FDA faced a challenge to its pre-approval process for health claims.²⁷⁸ At that time, the FDA required pre-approval for all health claims that were to be placed on a label and each claim was evaluated under the "significant scientific agreement standard."²⁷⁹ A dietary supplement manufacturer challenged this rule claiming that it violated its freedom of speech because there was a more reasonable alternative available: a disclaimer.²⁸⁰ The Court applied the constitutional three-part test for commercial

²⁷⁴U.S. CONST. amend. 1.

²⁷⁵*See Pearson v. Shalala*, 164 F.3d 650 (D.C. Cir.1999); *Nutritional Health Alliance, et al. v. Shalala*, 144 F.3d 220 (2d Cir.1998).

²⁷⁶*See Pearson* 164 F.3d at 655.

²⁷⁷164 F.3d 650 (D.C. Cir.1999).

²⁷⁸These were health claims relating to a disease, not structure/function claims.

²⁷⁹*Pearson*, 164 F.3d at 651; *see also* Part IV.C.4., *supra*, for a discussion of health claims and this standard.

²⁸⁰*Pearson*, 164 F.3d at 655.

speech adopted by the Supreme Court in *Central Hudson Gas & Elect. Corp. v. Public Serv. Comm'n.*²⁸¹

The Court first found that the FDA does have a substantial government interest in regulating dietary supplement labels to protect public health and prevent consumer fraud.²⁸²

However, the Court was not persuaded that the FDA was directly advancing its interest in protecting public health with its “all or nothing” approach to labeling, nor that there was a reasonable fit between the FDA’s rule and its goal of consumer protection.²⁸³ The Court held that allowing health claims on the labels and including a disclaimer so as not to mislead consumers was the constitutionally preferred approach.²⁸⁴

Disclosure was favored over complete suppression of speech.²⁸⁵ While the FDA still requires pre-approval for some health claims using the significant scientific agreement standard, it now also has procedures for making qualified health claims on labels using a disclaimer, as well as structure/function claims.²⁸⁶ In this way the Court opened up more options to dietary supplement manufacturers who want to make health claims on their products, but it also left the discretion with the FDA to approve the label and the accompanying disclaimer based on its expertise.²⁸⁷

In *National Health Alliance v. Shalala*,²⁸⁸ a dietary supplement manufacturer challenged the FDA’s pre-approval process for unqualified health claims, this time arguing that the 540-day review period was an impermissible prior restraint on truthful speech.²⁸⁹ The Second Circuit, using the same Central Hudson criteria, found that the process was reasonable in relationship to the FDA’s “need to protect consumers before any harm occurs.”²⁹⁰ The Court in this case was more willing to defer to the FDA’s choice of

²⁸¹447 U.S. 557 (1980).

²⁸²Pearson, 164 F.3d at 655-56.

²⁸³See *id.* at 656.

²⁸⁴*Id.* at 654-55. The FDA was against allowing qualified claims with disclaimers because it felt that “there would be a question as to whether consumers would be able to ascertain which claims were preliminary and accompanied by a disclaimer and which were not.” *Id.* at 653 (*quoting* Food Labeling: General Requirements for Health Claims for Dietary Supplements, 59 Fed.Reg. 395, 405 (1994)).

²⁸⁵*Id.* at 657.

²⁸⁶See Part IV.C.4., *supra*.

²⁸⁷See Pearson, 164 F.3d at 659.

²⁸⁸144 F.3d 220 (2d.Cir.1998).

²⁸⁹*Id.* at 227.

²⁹⁰*Id.* at 228.

regulatory framework.

The First Amendment issue was more roundabout in the D.C. Circuit's decision in *Whitaker v. Thompson*.²⁹¹

The Court essentially held that if the FDA determines that a label health claim qualifies the product as a drug then the manufacturer cannot then claim that its freedom of speech is being infringed upon because the label is now an unlawful statement (because it has not been approved under the procedures for new drugs) and therefore is not entitled to First Amendment protection.²⁹² The Court noted that the reasoning may seem circular at first, but it refused to allow the manufacturer to use the First Amendment to challenge the FDA's decision that its claim was that of a drug, not a dietary supplement.²⁹³

Manufacturers may use constitutional claims as their last resort when the FDA has denied its petition for certain treatment of their health-related claims. Sometimes, however, the FDA faces a true challenge to its regulatory power when a manufacturer asserts a First Amendment claim. The FDA has to choose between a regulatory compromise that may avoid it having to go to court, and fighting the challenge head on and risking that the court will truncate its oversight power further than a compromise would have. If a manufacturer has nothing to lose by going to court then the FDA may have no choice but to fight and defend its broad delegation of authority against a potentially devastating result- constitutional preemption.²⁹⁴

V. THE MANY FACES OF TEA

A. Tea as a Food

Most tea, particularly traditional tea, is manufactured, purchased, and consumed as a food without much

²⁹¹ 353 F.3d 947 (D.C. Cir.2004).

²⁹² *See id.* at 953.

²⁹³ *Id.*

²⁹⁴ The FDA and FTC naturally feel that their consumer protection policies are completely consistent with the First Amendment protections. *See* FED. TRADE COMM'N, FTC STAFF PROVIDES THE FDA WITH COMMENTS ON FIRST AMENDMENT COMMERCIAL SPEECH DOCTRINE (2002), *available at*: <http://www.ftc.gov/opa/2002/09/fdaccomment.htm>.

thought being given to its other potential uses. This is especially true in the United States where four-fifths of the tea consumed is iced tea. To the average American, tea is just a substitute for juice or soft drinks. Of the potential categories under which tea may be classified, food is the most lenient in terms of regulation. Whether tea is a food depends on why it is being sold, not why it is being purchased and consumed. As a food, the manufacturer may not make any disease claims or unapproved health claims about the tea, but it may make structure/function claims that are not false or misleading.²⁹⁵ Tea as a food also may be exempt from the NLEA nutrition panel requirements if it contains no significant nutrients, and of course, it is not subject to the DSHEA. Generally, just like any other food, tea is regulated by the FDCA and is largely left alone unless the manufacturer starts making health-related claims about specific ingredients.

B. Tea as a Dietary Supplement

Tea may fit under the definition of a dietary supplement in two ways. Herbal tea is likely to be a dietary supplement because it is “an herb or other botanical.”²⁹⁶ Traditional tea may qualify as a dietary supplement, though much less often, if it is sold in extract form or intended to supplement the diet and labeled as such,²⁹⁷ as is more often now being done with green tea.²⁹⁸ Dietary supplement manufacturers may only make structure/function claims, not disease claims, without FDA approval. They must also notify the FDA of the content of their structure/function claim within 30 days of marketing it.

When tea is seen as a dietary supplement, the manufacturers are more likely to get into trouble for their health-related claims. First, they make take their structure/function claims too far and end up making

²⁹⁵ See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, U.S. FOOD & DRUG ADMIN., LABEL CLAIMS: STRUCTURE/FUNCTION CLAIMS, available at: <http://www.cfsan.fda.gov/~dms/labstruc.html>.

²⁹⁶ See 21 U.S.C. §321(ff)(1)(C)(2004).

²⁹⁷ See 21 U.S.C. §321(ff)(1)(F).

²⁹⁸ See Warning Letter from FDA to Reach4Life Enterprises, *supra* note 259 (advising Herba Green Tea Extract that its claims qualify it as a drug under the FDCA); see also Letter from Country Life to FDA (Mar. 3, 2001) (on file with author) (describing its statement for its product containing green tea extract).

a disease claim, which qualifies the tea as a drug. Second, they may believe that their tea is a food and therefore fail to comply with the labeling and disclaimer requirements for dietary supplements. Third, they may fail to notify the FDA of their structure/function claim if they believe their tea only qualifies as a food and not as a dietary supplement under the FDCA. Finally, they may fail to comply with the conditions regarding third-party literature under the DSHEA and risk being considered misbranded.

Many herbal products are clearly dietary supplements and are properly labeled as such. These products tend to run into problems when their marketing involves dissemination of scientific literature and they make the connection between the herb and a disease. At this point they are walking a fine line between dietary supplement and drug. Dietary supplement manufacturers are also torn in some ways between the FDA and the FTC. The DSHEA allows them to use third-party literature in connection with their marketing, as long as it is not false or misleading and is well balanced, while the FTC Act requires that the health claims be substantiated. Manufacturers may be tempted to let the third-party literature do too much marketing while ignoring the requirements in the FTC Act.

C. Herbal Tea and Food Additives

The ingredients in herbal teas may be considered food additives under the FDCA, especially when manufacturers combine many different herbs to make the tea available to affect many different health conditions. Herbal teas run the risk of being considered adulterated because they use herbs that are not GRAS.²⁹⁹ Also it may be difficult for manufacturers to get GRAS approval for herbs they would like to use because they are lacking in scientific evidence for that particular use of the herb, or because the FDA may consider the

²⁹⁹ See Warning Letter from FDA to Herbal Junction, *supra* note 185.

herb to be unsafe.³⁰⁰

D. Tea as a Cosmetic

Although a few years ago it would have seemed strange to even discuss tea as a cosmetic, it is now increasingly common to see lotions, moisturizers, and shower products containing tea, usually green tea.³⁰¹ One need only go to their local pharmacy or specialty store to find a wide variety of tea cosmetics. Tea is of course only one of many ingredients, but the name of the product often includes the word “tea.” The most recent example is from the well-known manufacturer, Origins, who now markets a line of white tea products including lotions.³⁰² Although the ancient uses of tea do include applying it to the skin for certain health conditions, the science of these claims is much newer and much more tenuous.

The statutory requirements for cosmetics are more lenient than food or dietary supplements. The label must still not be misleading, but there is not the same risk of adulteration or misbranding. The definition of adulterated cosmetics does not include non-GRAS additives whereas adulterated food does, and a cosmetic can make puffery claims about its effectiveness without substantiating them.³⁰³ However, cosmetics may not make “therapeutic claims that they may affect the structure or function of the body” or they will be considered drugs.³⁰⁴

³⁰⁰ See Agency Response Letter: GRAS Notice No. GRN 000013 (Jun. 2, 1999), *available at*: <http://www.cfsan.fda.gov/~rdb/opa-g013.html>.

³⁰¹ See A Perfect World: Intensely hydrating body cream with white tea, *supra* note 12.

³⁰² See *id.*

³⁰³ See OFFICE OF COSMETICS & COLORS, U.S. FOOD & DRUG ADMIN., COSMETIC LABELING (2003), *available at*: <http://www.cfsan.fda.gov/~dms/cos-labl.html>.

³⁰⁴ See *id.*; see also Warning Letter from FDA to R.H. Cosmetics Corp., *supra* note 259 (warning company for using tea tree oil to treat fungal infections and skin conditions).

Tea used as a cosmetic may sometimes cross the line between cosmetic and drug, especially because the manufacturer may only be adding tea to the product in order to make some kind of health claim.³⁰⁵ If the manufacturer just claims that the tea gives you “radiant skin,” then they are likely in compliance with the FDCA.

E. Tea as a Drug

Manufacturers and distributors no doubt do not intend to sell their tea as a drug. There is some mention in the literature of one day extracting the polyphenols from tea for use in a drug, but that day has not come yet. Whenever tea is considered to be a drug, it is because someone has gone too far in their marketing of the product and has made a disease claim. This usually results in the FDA issuing a warning letter informing the manufacturer to change, not its product, but its labeling and promotion.³⁰⁶

As with food, the manufacturer runs the risk of its product being considered misbranded because it is false or misleading. It also has not gone through the FDA’s new drug approval process. If tea, or one of its components is used as a drug in the future, there will have to be extensive testing into its effectiveness and safety before the FDA would approve its use.

³⁰⁵ See Green Tea 300, available at: <http://1800epharmacy.biz/greentea/index.html>. This product is an adhesive patch that you apply to your skin in order to give your body a continuous dose of green tea and claims to be 30 times more potent than liquid green tea. It claims that “the Green Tea Patch was designed to provide the constant supply of high potency green tea needed to achieve these weight loss results.” Interestingly, the website also contains the FDA dietary supplement disclaimer. It is unclear if this product is a cosmetic or a drug or both, and it is further unclear if it is at all safe.

³⁰⁶ See, e.g., Warning Letter from FDA to Light Resources Unlimited, Inc., *supra* note 259; Warning Letter from FDA to R.H. Cosmetics, Corp., *supra* note 259; Warning Letter from FDA to Reach4Life Enterprises, *supra* note 259.

VI. APPLICATION OF THE LAW TO SELECTED HEALTH-RELATED CLAIMS FOR TRADITIONAL AND HERBAL TEA

Advertisements for tea (traditional and herbal) are everywhere, and almost all of them are for green tea and herbal teas and contain information about tea and human health. Some provide a relatively balanced account of research and provide links to the studies for further information.³⁰⁷ Others provide no context for their health claims and often hide the FDA disclaimer in the fine print or, in the case of websites, on a different page altogether. Tea distributors range from well-established companies like Lipton, Twinings, Tetley, Bigelow, Salada, and Celestial Seasonings to small internet-based herbal supplement providers who offer only one kind of tea in their line of herbal products. Some of the claims, as discussed below, are only borderline rational and one would hope that the average consumer would never believe these claims. Unfortunately these distributors are still in business, which logically leads to the conclusion that someone out there is buying their products.

Several basic problems can occur with the promotion of health claims. First, the regulator must decide whether the claim is advertising or labeling. Second, they must determine if the claim is misleading under the FDCA or FTC Act. Claims vary in format and may include any imaginable design, making it harder for regulators to evaluate them. Some common problems include: the health claims may be completely true but only provide part of the scientific information, a disclaimer may be omitted, the claims may actually

³⁰⁷ See, e.g., Listing of Studies on Green Tea and Its Components, available at: www.celestialseasonings.com/research/greentea/bib_research.php (listing references for 508 published articles on the health effects of tea).

be false or misleading, the product may not physically be what it claims to be,³⁰⁸ or the product may be making a claim that qualifies it for treatment as a drug under the FDCA. From the consumers' standpoint all of these problems are troublesome because the consumers do not get all of the accurate information they need to make good, informed market decisions. From the regulators' standpoint each of these problems is treated differently under the law, and may in fact fall under different regulators' jurisdictions.

Today if someone wanted to find out information about the health benefits of tea they would most likely go to the Internet. Magazines would likely be the second choice. What the average consumer will find in these two sources is a wide array of advertisements touting tea's healthy properties. The Internet is full of unverifiable information, and health claims for tea are no exception.

Many advertisements appear at first to be informative web pages where the reader can learn about the latest studies and get a basic overview of tea's beneficial aspects. However, at the end of what looked like a well-balanced article, the reader finds all the information on how to buy the "miracle" product they just read all about. This strategy cannot really be called false, because the factual information is true and the average reader will probably somewhat discount the information they just read when they see that it came from a self-interested source. However, the information will have an impression on the reader, and at the very least they will probably remember that they read somewhere that it is healthy to drink tea. When determining whether a claim is misleading both the FDA and the FTC look at the totality of claim,³⁰⁹ so it is possible that even when a marketing tool contains technically true information it may still be misleading—hence the FTC's requirement that an advertisement be *both* truthful *and* not misleading.

³⁰⁸ See, e.g., FDA WARNS AGAINST DIETARY SUPPLEMENT PRODUCT, "CHOMPER," *supra* note 255 (claiming that product mistakenly labeled as containing plantain actually contained a digitalis-like substance).

³⁰⁹ See *U.S. v. Vitasafe Formula M*, 226 F.Supp. 266 (D.N.J.1964); DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR THE INDUSTRY, *supra* note 237 at 14.

One problem arises when the advertiser³¹⁰ spins the otherwise objective research in their favor, or takes statements out of context, so that the reader is confused about what the information really means. When it comes to products that may actually harm instead of help the consumer, this type of behavior can be dangerous. For example, Japanese Green Tea Online provides several pages of information about green tea research, but it only provides conclusions, citing “numerous studies.”³¹¹ Nowhere is the reader told about any of the caveats in these studies nor is there any way for the reader to get more information because there is absolutely no information given about any of the studies.³¹² Mixed in with the health information and at the end of the page the site provides links to their particular products based on what you have just read.³¹³ The website contains no qualifying language about the health claims and no disclaimer.³¹⁴ Given the fact that the site makes claims that green tea can help treat nine separate diseases and conditions, it seems that without the disclosure of some kind of qualifying information this site would be misleading under the FTC Act.³¹⁵ If this website is considered labeling then it would clearly violate the FDAMA and DSHEA prohibitions on disease claims without FDA pre-approval.³¹⁶

Mybackyard.com takes a similar but abbreviated approach.³¹⁷ They provide basic claims about how each kind of tea can improve your health and then state that “whichever you choose, you can’t lose!”³¹⁸ At the end of the page the reader can purchase the Numi Tea Sampler as one of its “Tools to Help You.”³¹⁹ As an advertisement, this website is probably borderline because it uses inconclusive language like “can” and

³¹⁰The term advertiser is used for its common meaning and does not mean to imply that the claim may not be considered labeling.

³¹¹See Benefits of Green Tea, at: <http://www.japanesegreenteaonline.com/health.htm>; Green Tea and Weight Loss, *supra* note 99.

³¹²See *id.*

³¹³See *id.*

³¹⁴See *id.*

³¹⁵The statements that are specifically troubling are, “Special Benefits of Green Tea: reduces high blood pressure, lowers blood sugar, fights cancer” and “If you drink green tea you can- lower cholesterol, increase thermogenesis (the body’s burning of calories), enhance fat oxidation.” *Id.*

³¹⁶See 21 U.S.C. §343(r)(6) (2004).

³¹⁷See Here’s to your Health—Drink Tea, *supra* note 103.

³¹⁸*Id.*

³¹⁹*Id.*

“may.” However its statement, “Green tea is especially helpful in reducing cancer risks” is troubling and may be misleading.³²⁰ It is less likely that this website would be considered a label because the connection between the health claims and products is more separated and the promotion of their specific tea is unclear. If it were considered labeling it would clearly violate the FDCA because it actually uses the terms “prevent or treat” when discussing various diseases.³²¹

EnjoyingTea.com makes health claims about their Imperial Kuding Tea.³²² It is actually unclear from their advertisement whether they are selling a black tea or an herbal tea because it is labeled “Black Herbal Tea” and grouped under the heading “specialty tea;” although from the description it does not appear that it could possibly be made from the *Camellia sinensis* plant.³²³ It also claims to be “extremely effective for lowering cholesterol and lowering high blood pressure [and] researchers found that people who drink *this* tea daily have a lower chance of getting a stroke or a heart attack.”³²⁴ However, it gives no further information on the health claims or the cited “research.” This website appears to be misleading under the FTC’s guidelines because it really is not clear what they are actually selling to you, it is quite expensive at \$56.98/lb, the traditional use claims and scientific claims are not qualified in any way, and the manufacturer’s ability to substantiate its claim is suspect.³²⁵ As labeling, this website would also violate the FDCA.³²⁶

SOTA Instant Japanese Green Tea makes many claims on its website, but their format makes it difficult to evaluate them.³²⁷ It quotes research directly in one column and provides information about the product in the other column on the same page.³²⁸ The main problem with their claims is that the research deals with green tea, but the product is *instant* green tea, which they claim allows you to absorb more of the nutrients

³²⁰ *Id.*

³²¹ See 21 U.S.C. §§343(r)(1)(b), (r)(6).

³²² See Imperial Kuding Tea, *supra* note 118.

³²³ See *id.*

³²⁴ *Id.* [emphasis added]. It is doubtful that an entire study focused on this particular tea.

³²⁵ See DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, *supra* note 237 at 8-9, 16.

³²⁶ See 21 U.S.C. §§343(r)(1)(b), (r)(6).

³²⁷ See SOTA Instant Japanese Green Tea, *available at*: <http://www.macrocap.com/Japanese.Green.Tea/Premium.htm>.

³²⁸ *Id.*

found in green tea.³²⁹ However, this may be a case where the link between the research and the health claims is weak, necessitating at least some kind of qualifying language. In terms of labeling, this product may be either a food or a dietary supplement in which case it would violate the FDCA³³⁰ or would require the disclaimer and a proper description of what ingredients the product contains.³³¹

Ancient Healing Ways Tea advertises many different herbal teas on its website and it makes structure/function claims for almost all of them.³³² However, at the end of each claim describing the health effects of the various herbs used in the tea it includes an asterisk and at the end of each paragraph it displays the FDA-disclaimer in the same font size and in an easily noticeable location.³³³ The Amazon Herb Company takes a similar approach to the disclaimer with its Shipibo Herbal Tea, but instead includes one disclaimer at the end of the health claims.³³⁴ This qualifying language for these structure/function claims seems to satisfy the both the FTC and FDA's rules on labeling. One caveat may be Amazon Herb Company's use of the herbs *Una de Gato* (Cat's Claw), *Jatoba*, and *Chanca Pedra* because the FDA has not determined that these herbs are GRAS for use in tea³³⁵ and the FTC has recognized that *Cat's Claw* is an herb for which exaggerated claims are often made.³³⁶

Some other advertisements and labels use the disclaimer in inconspicuous locations. The Green Tea 300 website is a good example.³³⁷ This green tea weight loss patch claims to be safer than diet pills and better at burning calories and fat than studies found green tea to be.³³⁸ It is unlikely that this evidence has been substantiated, and it seems misleading without some qualifying information. As labeling it would be making

³²⁹ *Id.*

³³⁰ See 21 U.S.C. §343(r)(1)(B).

³³¹ See 21 U.S.C. §343(r)(6).

³³² See various herbal tea advertisements at: www.a-healing.com.

³³³ See *id.*

³³⁴ See *Shipibo Herbal Tea*, *supra* note 120.

³³⁵ See Warning Letter from FDA to Herbal Junction, *supra* note 185.

³³⁶ See Health Claims on the Internet: Buyer Beware, *supra* note 173.

³³⁷ See *Green Tea 300*, *supra* note 305.

³³⁸ *Id.*

a disease claim in violation of the FDCA because it also claims to lower cholesterol.³³⁹ The Good Health Supplements' Rooibos Tea website is also a good example. After seven pages of discussion about the health benefits of the tea, finally on the eighth page (after the price list) there is a small note explaining that the tea is not intended to diagnose, treat, prevent, or cure any disease.³⁴⁰ The website violates virtually every rule dealing with misleading ads and labels. First, it cites several studies showing the health effects of *Camellia sinensis* tea, but it is an herbal tea, so the research, even if substantiated, is completely irrelevant to their product.³⁴¹ Second, it claims that Japanese research showed that “the anti-aging properties found in Rooibos far exceeded any other known plant of earth.”³⁴² Third, it claims to treat high blood pressure, diabetes, and several other diseases.³⁴³ If this were considered a label, it would be the example of how not to comply with FDA regulations. As an advertisement it is misleading in many respects: the science, even if true, does not support this particular product; there is no qualifying language for the scientific research or the personal testimonials; and finally, the disclaimer at the end is not sufficient to remedy the misleading information which proceeds it.³⁴⁴

Despite the above examples, some manufacturers do label correctly. The label on the Celestial Seasonings Wellness Tea Sampler Box is located in a relatively prominent location, especially when considering the size of the product. The disclaimer is on the side panel of the box below the structure/function claims. There is a lot of information on the box and everything is in small sized print. It is important that the products easily display their structure/function claim disclaimers because to many of us it is difficult to tell the difference between a general health claim and a structure/function claim. The claims need to be tempered by the disclaimers so that the consumer isn't misled by the abundance of positive information and the deliberate

³³⁹ *Id.*

³⁴⁰ See GHS Rooibos “Red Bush” Tea, *supra* note 119.

³⁴¹ *Id.*

³⁴² *Id.*

³⁴³ *Id.*

³⁴⁴ See DIETARY SUPPLEMENTS: AN ADVERTISING GUIDE FOR INDUSTRY, *supra* note 237 at 5-7, 16, 18-21.

absence of negative information about the tea.

VII. FUTURE REGULATION OF TEAS

The heart of the problem with regulating something like tea is that it plays multiple parts in our legal system at the same time. Because of all of the research on the health claims for tea, much of the information is now being used on labels and advertising for tea products.³⁴⁵ Additionally, manufacturers have been innovative about new uses for tea and tea extracts to capitalize on the new research. Therefore, a few decades ago tea was clearly a food, although some people may have used it privately to treat some conditions. Today, when tea is marketed for so many different purposes it can be seen as a food, food additive, drug, dietary supplement, and cosmetic all at the same time. This makes the regulators' job extremely complicated. Every time someone wants to sell tea they have to ask how they intend to market it and therefore which set of rules they must follow. This can be especially problematic for a manufacturer who sells traditional tea and many types of herbal teas because each product may have different labeling requirements.

Obviously every manufacturer wants to avoid being classified as a drug because they do not want to have to go through the pre-market approval process. Therefore, virtually every tea seller will end up avoiding using statements like disease claims that qualify it for drug status when marketing their tea. There are few

³⁴⁵Twinings recently announced that it would engage in a marketing campaign targeting health conscious women and highlighting the health benefits of its teas. See *Twinings taps health tack for Infusions tea*, PRECISION MARKETING, Apr. 2, 2004, at 5. Tetley tried a similar campaign in 2002 by "promoting Tetley as a source of antioxidants that keep your heart healthy." Britain's Advertising Standards Authority ruled that the ads were misleading and they were forced to discontinue the campaign. See Sam Solley, *Tetley- How Can Tetley Sell the Virtues of Drinking Tea?*, MARKETING, Oct. 31, 2002, at 13.

products where tea is used as a cosmetic (although they are increasing and becoming more mainstream). If the tea product does qualify for cosmetic status, it is usually because the manufacturer intended it to be as such and is well prepared for the regulation that accompanies cosmetics. Therefore, the real debate involves the line between food and dietary supplement. This issue will be grappled with by regulators as well as by manufacturers. Sometimes a manufacturer deliberately chooses to be a dietary supplement because they intend to market their product specifically for its structure/function claims and effects on the body. This is more common with herbal teas. Other manufacturers may end up in the dietary supplement category unintentionally, as often is the case with drug status. In this case, the manufacturer may just be wishing to include health information to help sell their tea but they still intend for it to just be a hot beverage. This is most likely to occur with black tea sellers because the health research on black tea is new and not as well documented. Green tea may lie somewhere in between because the research has been ongoing for many years now and the results are widely reported in the media.³⁴⁶

The question is how much control do we want to give manufacturers over the labeling of their products when consumers may be buying them for reasons that differ from why the manufacturer is selling them? Should tea marketed clearly as a food suffer stricter regulation because other manufacturers market it as a dietary supplement and consumers may confuse the two? If the sole concern were consumer protection then all tea (and probably many other products) would be regulated as drugs or something close to them for maximum protection; but this is not economically feasible. Regulation is a compromise and consumers want to be able to have choices in the market place even if it means that sometimes advertisers may mislead them.

³⁴⁶See Tom Vierhile, *Welcome to the green tea party*, BUSINESS & INDUSTRY, Jan. 2002, at 16 (discussing the new green tea products and the increasing attention green tea has received by consumers).

With the rise of the Internet and online advertising and purchasing the potential for consumer fraud is even higher.³⁴⁷ Regulators must now decide whether websites selling the tea should be treated as labels or advertisements or something completely new. When a consumer reads the description on a website and need only click the link next to it to buy the product, that website starts to look a lot more like a label. Moreover, manufacturers can get creative with the name of their products on their websites, and consumers may be confused between whether they are buying traditional or herbal tea. This is especially problematic when companies who are known for selling tea begin also to sell herbal tea, which is inconsistent with consumer expectations.

The cultural aspect of tea is also important when considering how to deal with health claims. Lawmakers do not want to deny people from different cultural backgrounds the use of traditional remedies if they are not harmful. Therefore, treating tea as a drug is not the answer, but increased disclosure about the inconclusive nature of the claims would be extremely helpful. Much of the hype over tea's benefits may be a passing fad, but it is the job of agencies like the FDA to be on top of this kind of issue in order to protect consumers.

VIII. CONCLUSION

The current regulatory framework makes it difficult for the FDA to monitor and police health claims made about tea. Most manufacturers consider their tea to be a food, and therefore provide the FDA with no notice about the health claims they include in their promotional materials. Herbal teas often recognize that

³⁴⁷The FTC reports that over 90million Americans use the Internet to find health-related information. Health Claims on the Internet: Buyer Beware, *supra* note 173.

they are dietary supplements, but many companies add herbs to their teas that are not GRAS or go beyond structure/function claims to disease claims, thereby exposing consumers to a health risk. It is up to the FDA to discover these violations in the marketplace. The FDA and FTC should require websites selling tea to provide a more accurate depiction of the science behind tea. Furthermore, disclosure on the labels of both traditional and herbal teas would help consumers accurately evaluate the health claims. Finally, herbal teas should have to specifically state that they are not traditional tea, since the harmful effects of herbal teas greatly outweigh those of traditional tea.

Tea will challenge lawmakers and regulators to develop a comprehensive policy that is equipped to deal with the wide variety of conditions that tea may affect and the evolving scientific evidence that will confirm or deny the manufacturers' claims. It is important at this stage in tea's development as a product, where the temptation to exaggerate tea's positive attributes is greatest, that the FDA and FTC closely monitor the claims made by tea distributors and take swift action in order to insure the safety and health of American tea consumers.