

How the Media Framed Weight-loss Drugs:  
A Content Analysis of Newspaper Coverage Of  
Prescription and Over-the-counter Weight-loss Drugs

by

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## ABSTRACT

This study explores how newspapers framed the weight-loss drugs Xenical® (orlistat) and Alli® (over-the-counter orlistat) during the time period of three months prior to their approvals by the U.S. Food and Drug Administration until one year after each became available on the market. As of June 2011, orlistat is the only weight-loss drug available for long-term use in the U.S. Newspapers are influential sources of information about health issues. Agenda-setting, framing, and priming in news articles can have a powerful effect on public perceptions and behaviors.

To conduct the content analysis, researchers first developed a codebook containing variables that described the sources of attribution and the features of each drug. They tested the codebook in a series of pilot tests to ensure inter-rater reliability. The sample of texts for the content analysis, drawn from LexisNexis Academic, contained 183 newspaper articles composed of 85 Xenical articles and 98 Alli articles. The overlap was 25% for inter-rater reliability as well as intra-rater reliability. Frequencies were tabulated using Predictive Analytics SoftWare, version 18.0.3.

Results demonstrated that Xenical and Alli were framed differently in some critical ways. For example, there were twice as many quotes from the manufacturer for Alli than for Xenical. Researchers concluded that the reporting on Alli was heavily influenced by the manufacturer's multi-media public relations campaign in the months prior to the market-release date.

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## DEDICATION

With great joy, I dedicate this thesis to my dear husband, and love of my life, Greg. Thank you for your patience and unending support. You are a truly incredible partner in all of life's endeavors.

## TABLE OF CONTENTS

	Page
LIST OF TABLES.....	v
CHAPTER	
1 INTRODUCTION .....	1
2 METHODS.....	5
3 RESULTS.....	11
4 DISCUSSION .....	22
REFERENCES.....	32
APPENDIX	
A LITERATURE REVIEW .....	45
B CODEBOOK .....	138

## LIST OF TABLES

Table		Page
1.	Newspapers in the Sample of Xenical Articles .....	14
2.	Newspapers in the Sample of Alli Articles.....	16
3.	Frequency Data: Xenical.....	19
4.	Frequency Data: Alli .....	20
5.	Inter-rater Reliability Data: Pilot Test.....	21

## CHAPTER 1

### INTRODUCTION

The objective of this research study is to examine the newspaper coverage in the United States of the weight-loss drugs Xenical® and Alli®, which are branded versions of the generic weight-loss drug orlistat. Orlistat works by preventing a portion of consumed dietary fat from being absorbed in the intestine. Xenical was approved by the Food and Drug Administration (FDA) in 1999 as a prescription-only weight-loss drug. In contrast, Alli, was approved by the FDA as an over-the-counter weight-loss drug in February 2007.

In the United States, two-thirds of adults are classified as overweight (body mass index [BMI] = 25.0 – 29.9) or obese (BMI  $\geq$  30.0), as determined by weight (kg) divided by height squared (m<sup>2</sup>) (Centers for Disease Control and Prevention [CDC], 2009). Excess weight is associated with increased risks of coronary heart disease, type 2 diabetes mellitus, hypertension, dyslipidemia, stroke, major depressive disorder, and other diseases (CDC, 2009). For many consumers, the desire to lose weight for cosmetic reasons may be as compelling as the desire to avoid obesity-related conditions.

Before orlistat, the most widely used prescription-strength weight-loss drugs of the past two decades have been fen-phen, dexfenfluramine (branded as Redux®), and sibutramine (branded as Meridia®). Fen-phen was a combination of fenfluramine and phentermine, both of which had FDA-approval for short-term use. During fen-phen's heyday in the mid-1990s, many physicians considered these two drugs to have a symbiotic relationship for weight loss and began

prescribing them “off label” as a duo, even though the combined use of these drugs had never been vetted by the FDA (Colman, 2005). In 1997, fenfluramine, half of fen-phen, was withdrawn voluntarily from the market upon the FDA’s request after the FDA received reports of cardiovascular and pulmonary damage. Dexfenfluramine, another appetite suppressant, had FDA approval for short-term use, but was recalled at the same time as fenfluramine due to similar adverse reports. Meridia was a prescription weight-loss drug that was approved for long-term use by the FDA in November 1997, the same year that fenfluramine and dexfenfluramine were recalled. Meridia modulates hunger and causes early satiety (Wadden, 2005) by inhibiting the reuptake of both serotonin and noradrenaline (Lean, 1997). But sales of Meridia remained low due to its modest efficacy and relatively high cost (Saul, 2005). Meridia was withdrawn from the market in October 2010 (FDA, 2010).

Many clinical studies were performed on orlistat to insure its efficacy and safety, as measured by markers of cardiovascular health outcome. As a gastrointestinal lipase inhibitor, orlistat does not act upon appetite or satiety controls but rather locally in the small intestine (Schwartz, 2008). Unlike earlier weight-loss drugs such as fen-phen, Redux, and Meridia, orlistat was not associated with increased cardiovascular risks. Xenical sales in the U.S. were \$146 million in the first seven months of post-market release in 1999 (Goetzl, 2000) but then declined quickly afterward and stayed low. Again, the modest amount of weight lost and the medication’s cost were deterrents to Xenical’s



commercial success. In addition, consumers did not respond well to the side effect of fecal incontinence when dietary fat intake was exceeded.

In 2004, when GlaxoSmithKline (GSK) purchased the rights to market an over-the-counter version of orlistat for \$100 million from Roche, the manufacturer of Xenical, Xenical sales in the U.S. were \$122 million (Gaynor, 2004). GSK spent another \$150 million on a large-scale multi-media branding and marketing program to launch Alli in the U.S. market in 2007 (Miley, 2009). GSK had high ambitions, expecting annual sales of Alli to reach \$150 billion (Ostrov and Molina, 2007).

Media coverage of weight-loss drugs can be studied using the concept of framing, which has its roots in agenda-setting theory (McCombs and Shaw, 1993). Framing can be defined as choosing to emphasize certain pieces of information about an object, while simultaneously excluding certain other pieces of information, for the purpose of increasing the salience of the emphasized information to the consumer. The more salient the information is, the more likely it is that the consumer will notice and remember it. The way that a weight-loss drug is “framed” in the media influences public opinion about its usage and affects people’s decisions to request a doctor’s prescription for the drug or, as in the case of Alli, to buy the drug without needing a prescription.

The purpose of this research project was to explore and compare how newspapers used frames to present Xenical and Alli to the American public, starting from three months prior to their FDA approval dates to one year after their market release date. Newspapers play an important role in disseminating

information about health issues and influencing opinions and behaviors and are well-suited to research because of their broad availability and ease of access to archived data (Crawley, 2007). Researchers used LexisNexis Academic to locate a sample of appropriate articles. To determine frames, articles were coded for types of news sources used and the presence or absence of specific features of each weight-loss drug.

## CHAPTER 2

### METHODS

The source of the articles for the content analysis was LexisNexis<sup>®</sup> Academic (Reed Elsevier, Miamisburg, OH). With more than 1,000 U.S. and foreign newspapers in its electronic archives, updated daily, LexisNexis Academic is the most comprehensive source of news articles available.

LexisNexis Academic uses SmartIndexing Technology<sup>™</sup>, which begins when a panel of experts comprising academics and professionals convenes to form the database's taxonomy (e.g., geographical locations, subject indices, key words or "tags"). Using a Delphi approach, the panel assigns strata of "vocabulary terms" – including companies' and individuals' names and other selectors not usually considered vocabulary – to be applied to the database. After each panel's final taxonomy is determined, LexisNexis Academic assigns the panel's terms to all newspaper articles in the database.

The periodic convening of expert panels and SmartIndexing Technology ensures that LexisNexis Academic stays current with its terminology, allowing the database to be valid and reliable, and allows database users to best capture the sample of articles that interest them. Updating LexisNexis Academic's taxonomy minimizes search with "noise" articles that are irrelevant to the search – those written by journalists named *Alli*, for example – and keeps the database current (e.g., a search using the geography index with the now-antiquated term *Soviet Union* would yield articles about Russia).

Selectors change over time. If expert-panel members search for newspaper articles and receive ambiguous results, LexisNexis Academic repeats the taxonomy-determining process with the cooperation of an expert panel. With the updated taxonomy determined, LexisNexis Academic then applies these revisions to all newspaper articles in its archives, both prospectively and retrospectively. In this manner, LexisNexis Academic ensures that the entirety of the database is labeled using the same taxonomy. As an example, in 1995, Bombay, India, was renamed Mumbai. A search using the narrow geographic index of Mumbai will yield pre-1995 results that referred to the city as Bombay, even though the word *Mumbai* does not appear in the newspaper article. Search results, therefore, do not vary over time because of human bias.

The date of the sample collection was November 23, 2008. Because the archives of LexisNexis Academic change over time as newspapers decide whether to provide full-text content of articles, searches for articles on other dates could yield different results. U.S. newspaper articles regarding Alli<sup>®</sup> (GSK, Philadelphia, PA) or Xenical<sup>®</sup> (Genetech/Roche Group, South San Francisco, CA) were drawn from LexisNexis Academic by using a Power Search and its Natural Language search function. The search statement contained the key terms *Xenical* or, later, *Alli*.

Xenical was approved by the Food and Drug Administration (FDA) on April 23, 1999, and released to the market on April 26, 1999. The range of the publication dates of newspaper articles was three months prior to FDA approval and during the 12 months following post-market release (i.e., January 23, 1999

through April 26, 2000). The same search protocol was used for Alli, which was approved by the FDA on February 27, 2007, and released to the market on June 14, 2007. Beginning three months prior to FDA approval and ending 12 months post-market release, the date range was specified as November 27, 2006, through June 14, 2008, as the search dates for Alli-related articles.

To increase the specificity of the results, the subject index “Medicine & Health,” not any narrower terms within that category, was selected as being relevant for the search. The United States was selected as the geographical location and newspapers as the source for the search of Xenical- and Alli-related newspaper articles. This search strategy yielded N = 226 Xenical-related articles and N = 384 Alli-related articles.

Because the *Dallas Morning News*, *Detroit Free Press*, and the *Chicago Tribune* were excluded from the generic “newspaper” source category previously mentioned, the search was repeated identically except the source was changed to McClatchy-Tribune News Service or Global News Wire for the first two and the third newspapers, respectively. Coverage of Xenical and Alli were minimal in these newspapers, but they were included to make the sample size more fully complete and because these three newspapers rank in the top-25 most-circulated articles, based on data from the Audit Bureau of Circulations (2008) for the six-month period ending March 31, 2008. The *Wall Street Journal*, although ranked second in the list of top-100 newspapers, was excluded from the sample because only article abstracts were available in LexisNexis Academic. Similarly, the *Arizona Republic*, which ranked tenth on the top-100 newspapers list, provided

only abstracts of business-related articles to LexisNexis Academic when the data were collected. The *Sacramento Bee* became available in LexisNexis Academic on January 1, 2002 and, thus, could not be a source of Xenical-related articles.

Xenical or Alli had to be covered in at least one full paragraph within an article to be included in the study sample. Additionally, an article had to have at least 200 words to be included in the content analysis. Duplicate articles were included to account for multiple exposures to readers across the United States. Article corrections and those that mentioned either weight-loss drug in passing were excluded. After cleaning both populations of articles, the final samples were 85 and 97 articles for Xenical and Alli, respectively. Data from the Audit Bureau of Circulations (2008) was used to determine if the articles in the samples were published in one of the top-100 newspapers based on weekday circulation for the six month period ending. Those that were, along with their rank, are indicated in the tables.

Two independent coders used a grounded-theory approach to develop a content-analysis codebook. Using a random number-generating program in Excel, articles were selected that were published prior to 1999 regarding Meridia<sup>®</sup> (Abbott Laboratories, Chicago, IL), a prescription-strength, weight-loss drug no longer sold in the United States, were used to determine relevant themes and key words until the coders reached a saturation point at which additional articles stopped contributing new ideas, concepts, and terms.

Two independent evaluators (100% overlap) coded newspaper articles in a series of eight pilot studies until Cohen's kappa ( $\kappa$ ) > 0.70 for all variables, which

indicated that the variables had been defined and operationalized adequately. According to Helme et al. (2006),  $\kappa < 0.40$  indicates marginal reliability,  $\kappa = 0.40 - 0.75$  indicates good reliability, and  $\kappa > 0.75$  indicates excellent reliability. Cohen's kappa is a conservative measure for calculating reliability in content analyses (Dutta and Boyd, 2007). Of the 21 variables for which a kappa score could be calculated,  $\kappa$  averaged 0.969 and  $\kappa$  ranged from 0.828 to 1.0. For 15 variables,  $\kappa = 1.0$ . The two coders entered all coding data directly into Excel spreadsheets to avoid potential transcription errors from double recording (i.e., hand-writing data into spreadsheets and then typing the data into Excel) (Riffe, Lacy, and Fico, 2005). When there was a conflict between the two coders, an independent researcher interceded to help resolve the conflict and update the codebook as needed. The iterative coding process helped to determine that some variables were irrelevant and should be excluded while new variables were added. The original version of the codebook contained 23 variables and the final version contained 30 variables.

For the content analysis, Coder 1 coded 100% of the 85 Xenical articles and the 98 Alli articles. For inter-rater reliability, Coder 2 coded 22 (25% of the 85) Xenical articles and 25 (25% of the 98) Alli articles. For intra-rater reliability, Coder 1 later re-coded 25% of the full sample of Xenical and Alli articles. Researchers aimed for  $\kappa > 0.70$ . For comparison, another content analysis used a sample of 395 articles with 20% overlap for inter-rater reliability and  $\kappa = 0.1 - 1.0$ , with a mean of 0.772 (Carlyle et al., 2008).

Frequency distributions of the raw data were calculated using Predictive Analytics SoftWare (PASW, v. 18.0.3, Chicago, IL). Frequencies were tabulated to demonstrate differences between the content of newspaper articles related to the two drugs.



## CHAPTER 3

### RESULTS

The content analysis included a total of 183 articles, 85 Xenical articles and 98 Alli articles. For the Xenical articles, 27 of the 85 were published in newspapers that were not ranked in the Top 100. Fifty percent of the Xenical articles that were ranked in the Top 100 ( $n = 58$ ) were published by newspapers in the top nine. These newspapers were *USA Today* (#1), the *New York Times* (#3), *The Daily News – New York, NY* (#5), *Washington Post* (#7), and the *Houston Chronicle* (#9). There were no articles were published by the *Wall Street Journal* (#2) due to lack of availability of the full-text versions.

For the Alli articles, all 98 articles were published in newspapers that were ranked in the Top 100, ranging from number one (*USA Today*) to number 97 (*Albuquerque Journal*). Fifty percent of the 98 Alli articles were published by the top seven ranked newspapers: *USA Today* (#1), the *New York Times* (#3), *The Daily News – New York, NY* (#5), *New York Post* (#6) and *Washington Post* (#7). There were no articles were published by the *Wall Street Journal* (again due to lack of availability of the full-text versions).

In the sample, Xenical articles were most frequently published in April 1999 ( $n = 31$ ) and May 1999 ( $n = 30$ ), reflecting the increased media production after Xenical's April 23, 1999 FDA approval date and the April 26, 1999 market release date. There was a dramatic decline in the number of articles published in June 1999 ( $n = 5$ ). Alli articles were most frequently published in June 2007 ( $n = 44$ ), which is understandable given the June 14, 2007 market release date.

February 2007 had the second-highest number of Alli articles published (n = 23), reflecting an increase in media production after the FDA approval date of February 27, 2007. Media interest in Alli had fallen by the end of 2007, with very few articles being published in the first half of 2008 (n = 4).

About half of the Alli articles were published before the market release (n = 46) and half were published after the market release (n = 52), whereas with Xenical, 97.6% of the articles were published after the market release date (n = 83).

In the category of news sources, there were several obvious differences. Alli articles contained twice as many quotes of attribution to dietitians, nutritionists, and registered dietitians (19%) than Xenical articles (9.4%). For Xenical, there were dramatically more quotes of attribution to scientists (35.5%) than for Alli (3.1%). Alli articles contained more than ten times as many more quotes of attributions to pharmacists (13.3%) relative to Xenical articles (1.2%). For Alli, there were more than twice as many quotes of attribution to the manufacturer (62.2%) than for Xenical (29.4%).

There were smaller differences in relation to the usage of other types of news sources. Quotes of attribution from a layperson were mentioned slightly more often in Alli articles (33.7%) than Xenical articles (27.1%). Quotes of attribution from a physician were mentioned slightly more often in Xenical articles (35.3%) than in Alli articles (27.6%). Quotes of attribution from psychotherapists were rarely mentioned in both Xenical articles (3.5%) and Alli articles (1.0%). The regulatory role of the FDA was mentioned in the majority of

Xenical articles (76.5%) as well as the majority of Alli articles (81.6%), though slightly more often in Alli articles.

The weight-loss drugs were characterized differently in several critical ways. Journalists neglected to report BMI standards in the majority of the articles; BMI standards were mentioned much less frequently in Alli articles (6.1%) than in Xenical articles (23.5%). Recommendations for changes in physical activity were mentioned in the majority of Alli articles (67.3%) but the opposite was true for Xenical (28.2%). The cost of Alli was mentioned 69.4% of the articles but the cost of Xenical was mentioned in just 45.9% of the articles.

The differences in frequencies were smaller in relation to other characteristics of the weight-loss drugs. Side effects were mentioned in almost every Xenical article (94.1%) and Alli article (93.9%). Recommendations for dietary changes were mentioned the majority of the time for both, though particularly more often for Alli (93.9%) relative to Xenical (76.5%). The drug's mechanism was mentioned in most of the Xenical articles (94.1%) and most of the Alli articles (90.8%). A promise of specific weight loss was mentioned in the majority of Xenical articles (77.6%) and Alli articles (75.5%). Contraindications (stating who should not use the drug) were mentioned in less than one-third of Xenical articles (29.4%) and Alli articles (31.6%). Recommendations for counseling were rarely mentioned in both the Xenical articles (1.2%) and the Alli articles (3.1%).

Rank <sup>a</sup>	Newspaper	Daily Circulation	Number of Xenical Articles	Mean <sup>b</sup> Word Count
-	<i>Charleston Gazette</i> (West Virginia)		1	439
-	<i>Ledger</i> (Lakeland, Florida)		1	779
-	<i>Lincoln Journal Star</i> (Nebraska)		1	473
-	<i>Portland Press Herald</i> (Maine)		1	655
-	<i>The Gazette</i> (Colorado Springs)		1	663
-	<i>The Herald</i> (Rock Hill, SC)		1	220
-	<i>The Washington Times</i>		1	631
-	<i>Idaho Falls Post Register</i> (Idaho Falls, Idaho)		2	713
-	<i>South Bend Tribune</i> (Indiana)		2	541.5
-	<i>The Augusta Chronicle</i> (Georgia)		2	578.5
-	<i>The Patriot Ledger</i> (Quincy, MA)		2	467.5
-	<i>The Times Union</i> (Albany, NY)		2	615.5
-	<i>Chattanooga Times Free Press</i> (Tennessee)		4	693
-	<i>Deseret News</i> (Salt Lake City)		6	567.8
1	<i>USA TODAY</i>	2,284,219	4	554.8
3	<i>The New York Times</i>	1,077,256	6	919.3
5	<i>Daily News</i> (New York)	703,137	2	427
6	<i>The New York Post</i>	702,488	1	376
7	<i>The Washington Post</i>	673,180	2	917.5
9	<i>The Houston Chronicle</i>	494,131	1	1,112
15	<i>The Star-Ledger</i> (Newark, New Jersey)	345,130	4	522
16	<i>The Philadelphia Inquirer</i>	334,150	1	784
17	<i>Plain Dealer</i> (Cleveland, Ohio)	330,280	2	496.5
18	<i>The Atlanta Journal and Constitution</i>	326,907	1	1,010
19	<i>Star Tribune</i> (Minneapolis, MN)	322, 362	1	1,994

Rank <sup>a</sup>	Newspaper	Daily Circulation	Number of Xenical Articles	Mean <sup>b</sup> Word Count
20	<i>St. Petersburg Times</i> (Florida)	316,007	2	462
21	<i>Chicago Sun-Times</i>	312,274	2	414.5
23	<i>The Oregonian</i>	304,399	1	987
29	<i>The Orange County Register</i>	250,724	2	713.5
30	<i>The Miami Herald</i>	240,223	1	1,974
31	<i>San Jose Mercury News</i> (California)	234,772	1	766
37	<i>The Seattle Times</i>	220,863	1	1,303
42	<i>Pittsburgh Post-Gazette</i> (Pennsylvania)	214,374	2	709.5
47	<i>Columbus Dispatch</i> (Ohio)	199,524	1	982
48	<i>Saint Paul Pioneer Press</i> (Minnesota)	191,768	2	825.5
53	<i>Times-Picayune</i> (New Orleans, LA)	179,834	2	382
55	<i>Buffalo News</i> (New York)	178,365	1	770
60	<i>Austin American-Statesman</i> (Texas)	170,309	3	839.3
64	<i>The Record</i> (Bergen County, NJ)	163,329	4	1111
68	<i>Fresno Bee</i> (California)	150,334	1	295
71	<i>Florida Times-Union</i> (Jacksonville, FL)	144,391	1	1,714
74	<i>Birmingham News</i> (Alabama)	140,438	1	632
79	<i>Seattle Post-Intelligencer</i>	129,563	1	701
97	<i>Albuquerque Journal</i> (New Mexico)	102,902	1	1,336
99	<i>The Post and Courier</i> (Charleston, SC)	100,400	1	914

<sup>a</sup>Rank = rank within the List of the Top 100 Daily Newspapers from BurrellesLuce, Data reflects figures from the Audit Bureau of Circulation for the six-month period ending 3/31/08. “–” indicates a newspaper that was not on the List of the Top 100 Daily Newspapers.

<sup>b</sup>Mean word count for Xenical article(s) from each newspaper. Data reflects word count from LexisNexis Academic, or calculated by averaging the word counts of multiple articles from a single newspaper.

Table 2  
Newspapers in the Sample of Alli Articles (n = 98)

Rank <sup>a</sup>	Newspaper	Daily Circulation	Number of Alli Articles	Mean <sup>b</sup> Word Count
-	<i>Chambersburg Public Opinion</i> (Pennsylvania)		1	644
-	<i>Chicago Daily Herald</i>		1	930
-	<i>Connecticut Post Online</i> (Bridgeport, Connecticut)		1	632
-	<i>Eureka Times-Standard</i> (California)		1	516
-	<i>Kalamazoo Gazette</i> (Michigan)		1	254
-	<i>Lancaster New Era</i> (Pennsylvania)		1	864
-	<i>Mobile Register</i> (Alabama)		1	1218
-	<i>Muskegon Chronicle</i> (Michigan)		1	1013
-	<i>Pasadena Star-News</i> (California)		1	489
-	<i>Patriot News</i> (Harrisburg, Pennsylvania)		1	902
-	<i>Riverfront Times</i> (St. Louis, Missouri)		1	545
-	<i>Saginaw News</i> (Michigan)		1	584
-	<i>San Gabriel Valley Tribune</i> (California)		1	716
-	<i>Sentinel &amp; Enterprise</i> (Fitchburg, Massachusetts)		1	871
-	<i>The Augusta Chronicle</i> (Georgia)		1	566
-	<i>The Bismarck Tribune</i>		1	778
-	<i>The Capital</i> (Annapolis, MD)		1	337
-	<i>The New York Sun</i>		1	570
-	<i>The Washington Times</i>		1	460
-	<i>Whittier Daily News</i> (California)		1	779
-	<i>Chattanooga Times Free Press</i> (Tennessee)		2	469
-	<i>Deseret News</i> (Salt Lake City)		2	511
-	<i>Lincoln Journal Star</i> (Nebraska)		2	840
-	<i>Flint Journal</i> (Michigan)		3	457.3
-	<i>Pittsburgh Tribune Review</i>		3	676.7

Rank <sup>a</sup>	Newspaper	Daily Circulation	Number of Alli Articles	Mean <sup>b</sup> Word Count
-	<i>The Times Union</i> (Albany, NY)		3	456
-	<i>The State Journal-Register</i> (Springfield, IL)		1	768
1	<i>USA Today</i>	2,284,219	3	480.3
3	<i>The New York Times</i>	1,077,256	3	808
5	<i>Daily News</i> (New York)	703,137	4	581.3
6	<i>The New York Post</i>	702,488	1	928
7	<i>The Washington Post</i>	673,180	1	904
8	<i>Chicago Tribune</i>	541,663	1	675
9	<i>The Houston Chronicle</i>	494,131	2	712.5
12	<i>The San Francisco Chronicle</i> (California)	370,345	1	1018
14	<i>The Boston Globe</i>	350,605	3	566.3
15	<i>The Star-Ledger</i> (Newark, New Jersey)	345,130	3	815
18	<i>The Atlanta Journal and Constitution</i>	326,907	2	780.5
19	<i>Star Tribune</i> (Minneapolis, MN)	322,362	1	1,064
20	<i>St. Petersburg Times</i> (Florida)	316,007	1	1,292
21	<i>Chicago Sun-Times</i>	312,274	3	561.3
24	<i>The San Diego Union-Tribune</i>	288,669	2	997
25	<i>Sacramento Bee</i> (California)	268,755	1	589
27	<i>St. Louis Post-Dispatch</i> (Missouri)	255,057	1	696
37	<i>The Seattle Times</i>	220,863	1	901
38	<i>Tampa Tribune</i> (Florida)	220,522	1	960
39	<i>South Florida Sun-Sentinel</i> (Fort Lauderdale)	218,286	2	875
42	<i>Pittsburgh Post-Gazette</i> (Pennsylvania)	214,374	2	535
47	<i>The Columbus Dispatch</i> (Ohio)	199,524	1	813
50	<i>Contra Costa Times</i> (California)	183,086	2	868.5
52	<i>Arkansas Democrat-Gazette</i>	182,212	2	652
55	<i>Buffalo News</i> (New York)	178,365	1	654
57	<i>Richmond Times-Dispatch</i> (Virginia)	175,265	3	620.3
58	<i>The Virginian-Pilot</i> (Norfolk, VA)	175,005	1	879
62	<i>Palm Beach Post</i> (Florida)	164,474	1	649
64	<i>The Record</i> (Bergen County, NJ)	163,329	1	511

Rank <sup>a</sup>	Newspaper	Daily Circulation	Number of Alli Articles	Mean <sup>b</sup> Word Count
74	<i>Birmingham News</i> (Alabama)	140,438	1	750
76	<i>The Providence Journal</i> (Rhode Island)	139,055	1	448
78	<i>The Daily News of Los Angeles</i>	137,344	2	755.5
89	<i>Tulsa World</i> (Oklahoma)	112,968	1	475
92	<i>The Post-Standard</i> (Syracuse, New York)	304,399	1	668
96	<i>The Philadelphia Daily News</i>	107,269	1	677
97	<i>Albuquerque Journal</i> (New Mexico)	102,902	1	597

<sup>a</sup>Rank = rank within the List of the Top 100 Daily Newspapers from BurrellesLuce, Data reflects figures from the Audit Bureau of Circulation for the six-month period ending 3/31/08. “–“ indicates a newspaper that was not on the List of the Top 100 Daily Newspapers.

<sup>b</sup>Mean word count for Alli article(s) from each newspaper. Data reflects word count from LexisNexis Academic, or calculated by averaging the word counts of multiple articles from a single newspaper.



Table 3  
 Frequency Data: Xenical

Feature of the Weight Loss Drug	Yes	No
Publication before the drug's market release?	2.4%	97.6%
Presence of a quote by a layperson?	27.1%	72.9%
Presence of a quote by a physician?	35.3%	64.7%
Presence of a quote by a dietitian?	9.4%	90.6%
Presence of a quote by a scientist?	35.3%	64.7%
Presence of a quote by a pharmacist?	1.2%	98.8%
Presence of a quote by a psychotherapist?	3.5%	96.5%
Presence of a quote by the drug's manufacturer?	29.4%	70.6%
Role of FDA in relation to drug mentioned?	76.5%	23.5%
BMI standards for drug usage mentioned?	23.5%	76.5%
Side effects of drug mentioned?	94.1%	5.9%
Promise of weight loss mentioned?	77.6%	22.4%
Mechanism of weight loss mentioned?	94.1%	5.9%
Contraindications of drug mentioned?	29.4%	70.6%
Recommendations for change in diet mentioned?	76.5%	23.5%
Recommendations for change in physical activity mentioned?	28.2%	71.8%
Recommendations for counseling mentioned?	1.2%	98.8%
Cost of drug mentioned?	45.9%	54.1%

Table 4

Frequency Data: Alli

Feature of the Weight Loss Drug	Yes	No
Publication before the drug's market release?	46.9%	53.1%
Presence of a quote by a layperson?	33.7%	66.3%
Presence of a quote by a physician?	27.6%	72.4%
Presence of a quote by a dietitian?	19.4%	80.6%
Presence of a quote by a scientist?	3.1%	96.9%
Presence of a quote by a pharmacist?	13.3%	86.7%
Presence of a quote by a psychotherapist?	1.0%	99.0%
Presence of a quote by the drug's manufacturer?	62.2%	37.8%
Role of FDA in relation to drug mentioned?	81.6%	18.4%
BMI standards for drug usage mentioned?	6.5%	93.9%
Side effects of drug mentioned?	93.9%	6.5%
Promise of weight loss mentioned?	75.5%	24.5%
Mechanism of weight loss mentioned?	90.8%	9.2%
Contraindications of drug mentioned?	31.6%	68.4%
Recommendations for change in diet mentioned?	93.9%	6.1%
Recommendations for change in physical activity mentioned?	67.3%	32.7%
Recommendations for counseling mentioned?	3.1%	96.9%
Cost of drug mentioned?	46.9%	53.1%

Table 5 Inter-rater Reliability Data: Pilot Test	
Variable	$\kappa$
Duplicative	1.0
Rank	1.0
Page Number	1.0
Word Count	1.0
Month	1.0
Date	1.0
Year	1.0
Day	0.926
Drug Code	- <sup>a</sup>
Publication before the drug's market release?	-
Presence of a quote by a layperson?	1.0
Presence of a quote by a physician?	0.828
Presence of a quote by a dietitian?	-
Presence of a quote by a scientist?	1.0
Presence of a quote by a pharmacist?	-
Presence of a quote by a psychotherapist?	1.0
Presence of a quote by the drug's manufacturer?	1.0
Role of FDA in relation to drug mentioned?	-
BMI standards for drug usage mentioned?	1.0
Side effects of drug mentioned?	1.0
Promise of weight loss mentioned?	0.891
Mechanism of weight loss mentioned?	1.0
Contraindications of drug mentioned?	0.904
Recommendations for change in diet mentioned?	0.904
Recommendations for change in physical activity mentioned?	0.904
Recommendations for counseling mentioned?	1.0
Cost of drug mentioned?	-

<sup>a</sup> =  $\kappa$  could not be computed because both coders put the same response for each answer, which was appropriate.

## CHAPTER 4

### DISCUSSION

In 2007, GlaxoSmithKline (GSK) spent \$150 million on a multi-media marketing plan to promote sales of the new over-the-counter weight-loss drug Alli (60 mg orlistat) to the American public (Miley, 2009). The prescription version, branded as Xenical (120 mg orlistat), had been approved by the FDA and sold since 1999. Acting locally in the intestine, orlistat works by preventing the absorption of 25% to 30% of dietary fat.

Anticipation of success was high; the manufacturer expected annual sales of Alli to reach \$150 billion (Ostrov and Molina, 2007). A February 2007 press release described the drug: “Approved for use by overweight adults in conjunction with a reduced-calorie, low-fat diet, Alli helps people lose 50 per cent more weight than with diet alone. Alli is the only FDA-approved weight-loss product available to consumers without a prescription, and it is the first clinically-proven over-the-counter product to be combined with a comprehensive support program” (GSK, 2007a). A company spokesperson described Alli, pronounced “ally”, as being an “ally or partner helping you to lose weight” (Leonard, 2007).

The extensive marketing plan included traditional branded print advertising in newspapers and magazines, television commercials, and an impressive Internet presence. In addition to banner advertising and videos about Alli posted on websites, GSK created several websites, including MyAlli.com and AlliConnect.com, to offer online support to users and to market the drug to potential consumers. The month before Alli became available, GSK built a multi-

media interactive exhibit called the Alli Experience in New York City's Union Square, a heavily traveled pedestrian zone, which was described in a press release as "a five-zoned sensory tour that leads to an interactive journey and multi-media education about weight loss realities" (GSK, 2007b). To reach consumers who were not able to visit the Alli Experience, a video tour of the exhibit was posted on the Internet (Alliupdates, 2011).

In addition, two books providing guidance on integrating Alli into a lifestyle modification plan were published. *The Alli Diet Plan: Your Essential Guide to Success with alli*, written by a physician who was also quoted in the GSK press release welcoming Alli. The other book was entitled *Are You Losing It? Losing Weight Without Losing Your Mind: Weight Loss Experts Give You Insights, Answers and Encouragement*. The author of the other book was cited as an author of this book as well and described as an M.D. and the director of the Center for Nutrition and Weight Management at Boston Medical Center. The other authors were a PhD and director for the Center for Obesity Research and Education at Temple University, a professional chef, and another PhD and founder and director of the Weight Management Center at the University of Pittsburgh Medical Center.

Sales of Alli were high for the first few months, but declined quickly. The unwelcome side effects of flatulent diarrhea when dietary fat intake exceeded the recommended low amount at each meal and the monthly cost contributed to consumer's eventual disillusionment with the product. Reports of severe liver injuries potentially associated with orlistat use began to surface and in 2009, the

FDA announced it was reviewing the safety of Alli and Xenical. In 2010, the FDA announced that both Alli and Xenical should carry warnings about possible liver damage, though technically there was no confirmed cause-effect relationship (FDA, 2010). Findings from a large clinical study in Canada in 2011 supported earlier associations found between orlistat and oxalate-induced acute kidney injuries in other clinical studies (Weir, 2011). Recently, GSK decided to stop selling Alli and offered the product line for sale to other drug manufacturers (Hirschler, 2011).

This study explored how newspapers framed both Xenical and Alli. Based on this content analysis, GSK was shown to have used an aggressive marketing strategy exerted a powerful influence on the media production process, which extended to newspaper journalism treatment of Alli.

Newspaper articles about Xenical and Alli starting from three months prior to their FDA approval dates to one year after their market release date comprised the study sample. (Xenical was approved on Friday, April 23, 1999, and was available to be prescribed the following Monday, April 26, 1999. Alli's approval date was February 27, 2007, and was available to the public four months later on June 14, 2007.) The difference in the time between FDA approval and market release was reflected in the production of articles about each weight-loss drug. While almost all of the Xenical articles were published after the market release date, about half of the Alli articles were published before the market release, reflecting the build-up of marketing efforts by the manufacturer. People were "counting the days" until Alli was available in stores.

Most of the Xenical articles in the sample were published in late April, right after the market release date, and May. In contrast, the highest number of Alli articles was published in June 2007, which is understandable given the June 14, 2007 market release date. February 2007 had the second-highest number of Alli articles published, reflecting an increase in article publication after the FDA approval date of February 27, 2007. Media interest in Alli had fallen by the end of 2007, with very few articles being published in the first half of 2008.

To evaluate the frames utilized in the articles, the sources to which quotes were attributed were assessed. Seven possible sources were coded: the layperson, physician, dietitian, scientist, pharmacist, psychotherapist, and drug manufacturer. Quoting from a particular source emphasizes that source's perspective in relation to the drug and transfers that source's credibility, and the group represented by that source, to the information being presented in the article. For example, an article that attributes a quote praising a weight-loss drug to a physician elevates the drug's status to being generally medically approved through the implication that this source is representative of the larger medical community.

Physicians and scientists were quoted in one-third of the articles about Xenical. Since Xenical requires a prescription, it makes sense that medical and scientific authority figures were represented most often in the sample. The manufacturer and the layperson were the next most-commonly cited sources of information in less than one-third of the articles about Xenical.

For Alli, the top news source was the drug manufacturer, cited in nearly two-thirds of the sample. It is surprising that the manufacturer was given such a

powerful voice in the majority of the articles, even given its ambitious media campaign, especially when the other types of sources were consulted so infrequently by comparison. The layperson was the next most common source, quoted in one-third of the sample. The scientific and medical communities were represented in a minority of the sample: Less than one-third attributed quotes to physicians, less than one-fifth quoted dietitians, and pharmacists, scientists, and psychotherapists were rarely mentioned.

The overreliance on the manufacturer as a news source is problematic because there is an inherent bias in the information provided to the journalist about the drug. Powers and Andsager (1999) studied media frames in newspaper coverage of the silicone breast implant controversy between women with implants who attributed serious health problems to the implants and the implant manufacturers. After a class action lawsuit was filed against Dow Corning and other implant manufacturers in 1994 and the court awarded a \$4.25 billion settlement to 145,000 registrants, Dow Corning launched a major media campaign to restore its image. The media campaign focused on three major newspapers: the New York Times, Chicago Tribune, and Wall Street Journal. The researchers used a coding scheme to examine news sources and to identify frames in articles published in those three newspapers between January 1992 and December 1996, dividing this time period into 1992-3 and 1994-96. Results indicated that in 1992-93, there was a focus on health risks as well as the actions of the implant manufacturer. Later reporting in 1994-96 demonstrated a decrease in reporting on health risks as the actions of the manufacturer became the sole focus of coverage.



While the manufacturer was the most commonly cited news source in both time periods, reporting about the manufacturer was more sympathetic in the later time period. News sources questioning the connection between the implants and health issues were more common in the later time period as well. The researchers concluded that the manufacturer's media campaign influenced reporting on the silicone breast implant controversy, resulting in more favorable treatment in newspaper articles. They caution that journalists should not rely too much on the manufacturers and their public relations staff who control health product information.

Depending too much on the manufacturer as a news source transforms a newspaper article into a cleverly disguised advertisement for the product. Hampl et al. (2006) wrote about the influence of direct-to-consumer (DTC) advertising of prescription medication on consumer behavior. Negative effects of DTC advertising include consumers' developing unrealistic expectations of the drug and increased pressure on health care providers to prescribe drugs to less-than-ideal candidates (Hampl et al., 2006). While most consumers have some skepticism about DTC advertising (Hampl et al., 2006), most trust newspapers to publish fair, unbiased articles about drugs, along with other health issues. The journalistic ideal of objectivity is eroded when reporters rely on drug manufacturer's press releases, public relations personnel, and physicians and scientists who are associated with the manufacturer (e.g. through administering the clinical trials) to provide information about a product without also seeking out the opinions of other credible experts in the scientific and medical community

who have opposing views. The danger of encouraging the usage of an over-the-counter product such as Alli is increased because any consumer can buy it without the guidance of a health care provider who can judge whether the drug is appropriate for the individual's health condition, given the drug's contraindications.

Layperson quotes, cited in one-third of the articles, frequently expressed excitement and positive sentiments about the drug. This is not surprising, again, due to the manufacturer's media campaign. As in DTC advertisements that use actors similar in demographic characteristics such as sex, age, and race to the audience to model positive attitudes toward the drug and show the drug's successful effects, attributing a positive quote about Alli from the layperson is an influential way of swaying public opinion in favor of Alli (Hampl et al., 2006).

Dietitians were represented much more often in relation to Alli than Xenical. Dietitians work in many settings, from clinical settings, in food service roles and community agencies, and are more accessible to journalists than doctors. Though dietitians have food, health, and nutrition expertise, they do not prescribe. It is likely that because a doctor's prescription is not necessary to buy Alli, journalists considered a dietitian's expertise to be sufficient.

Over three-quarters of the Xenical articles and slightly more than that for the Alli articles emphasize FDA approval status, which implies a guarantee of safety and effectiveness. Journalists rely on the government as a news source because it is perceived to be a credible authority on health information and is a relatively accessible source of information. The increased frequency of the

mentions of FDA approval status in relation to Alli reflects the manufacturer's branding of Alli as "the only FDA-approved weight-loss product available to consumers without a prescription" (GSK, 2007)

The majority of the reporting on both drugs neglected to mention BMI standards qualifying individuals as appropriate candidates for usage as well as the contraindications for use, e.g., pre-existing health conditions such as liver disease, pregnancy, eating disorders. The under-reporting of these critical bits of information contributes to the perception that the drug is appropriate for anyone who wants to lose weight for cosmetic reasons and promotes ignorance of the drug's health risks. Given the connection between orlistat and the reports of severe liver and kidney injuries, one wonders how much the omission of critical information from newspapers affected those consumers' decisions to use orlistat.

There were several similarities between how both drugs were characterized. Both were, not surprisingly, mentioned as promising a certain quantity of weight loss and working best in accordance with dietary changes. The mechanism by which each drug worked was often mentioned. Counseling was rarely mentioned for both drugs. Counseling information was specified as a variable because successful weight-loss strategies include changes in eating behavior and other lifestyle patterns, which counseling can help to support.

One key difference is that a recommendation for physical activity was more frequently mentioned in relation to Alli, which is sensible given the manufacturer's marketing strategy to position Alli as an important component in

an overall program involving a low-fat diet, regular exercise, and use of the Alli Web site for online social support.

Another logical difference is that the drug's cost was mentioned more often for Alli, makes sense given its OTC status and out-of-pocket cost. The monthly cost of Alli was \$60-70 versus \$100 for Xenical, which was covered by some insurance plans.

The findings in this study support the need for newspaper reporting that demonstrates scientific, including nutrition, knowledge when the topic is a weight-loss medication. Saguy and Almeling (2008) found through their content analysis of obesity frames in medical science media and mainstream news media that the journalists depended heavily on press releases for pre-packaged copy. They recommended that journalists seek skeptics in the medical and scientific community to offer opposing viewpoints in order to provide a well-rounded, unbiased perspective on issues. Moynihan et al. (2000) examined newspaper and television coverage of three prescription medications and found that news stories frequently provided inaccurate information about the drugs' benefits, risks, and costs and neglected to report the financial conflicts of interests between drug manufacturers and experts or study groups. The study found a need to improve the quality of medical reporting and suggested that journalists and editors use an evidence-based approach to medicine and focus their reporting on the magnitude of absolute and relative benefits of a drug, what groups of patients can benefit, the associated risks and costs, and the relationships between the sources of information about the medication (e.g., studies, experts) and the manufacturers

who will profit from the sales of the medication (Moynihan et al., 2000). While journalists need training in reporting on health issues, health practitioners need training in how to work with journalists to promote public health. Campo and colleagues (2009), in their analysis of newspaper coverage of articles about college binge-drinking, found a need for health experts to use media advocacy to add public health issues to the media agenda.

In conclusion, the way that Alli was framed in newspapers reflected the manufacturer's branding of it as a safe (implied by FDA-approval status), effective (implied by FDA-approval status) drug (requiring changes in diet and exercise) that was appropriate for everyone (due to the under-reporting of BMI standards and contraindications). One limitation of this study was the availability of newspaper articles through the LexisNexis Academic database. Future research should include a content analysis of the portrayal of weight-loss drugs in other types of popular media, such as magazines. It is important for nutrition professionals to gain insight into how the media influences behavior related to weight control.

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APPENDIX A  
LITERATURE REVIEW

## Section 1

### **History of FDA-Approved Weight-Loss Drugs**

Developing a safe, effective, affordable weight-loss medication could have a significant impact on the global problem of obesity and overweight, which affects 1.1 billion individuals worldwide (Padwal et al., 2007). In the United States, two-thirds of adults are classified as overweight (body mass index [BMI] = 25.0 – 29.9) or obese (BMI  $\geq$  30.0), as determined by weight (kg) divided by height squared ( $m^2$ ) (Centers for Disease Control and Prevention, 2009). The Brookings Institution estimated the total annual economic cost of obesity in the U.S. is \$215 billion (Hammond and Levine, 2010). Excess weight is associated with increased risks of coronary heart disease, type 2 diabetes mellitus, hypertension, dyslipidemia, stroke, major depressive disorder, and other diseases (Centers for Disease Control and Prevention, 2009).

Research data demonstrates that weight loss has beneficial effects on high blood pressure in overweight and obese individuals with elevated blood pressure, normalizes blood lipids in overweight and obese individuals with dyslipidemia, and improves blood glucose levels in overweight and obese individuals with type 2 diabetes (National Heart, Lung, and Blood Institute, 1998). Federal health authorities recommend an initial reduction of 10% of body weight over six months, then performing an assessment of health and weight status and setting additional weight loss targets afterwards as needed (NHLBI, 1998). Even a reduction of 5 -10% in body weight is associated with improvements in

cardiovascular risk factors and reduced incidence of type 2 diabetes mellitus (Padwal, 2007).

Researchers noticed a significant increase in the prevalence of obesity and overweight in the United States starting in the late 1970s (Flegal et al., 2002). Data collection on obesity trends and their connection with chronic diseases became a public health priority. Most researchers concluded that obesity was a chronic disease with genetic, behavioral, and environmental causes and that long-term maintenance of weight loss, rather than short-term weight loss, was crucial for maintaining health (Heal, Gosden and Smith, 2009). The prevailing belief that exercise, diet, and behavior modification alone are not considered sufficient long-term treatment for obesity led to rekindled interest in drug therapy (Manson, 1996).

For drug manufacturers, there is great market potential in identifying a successful weight-loss product. Marketdata Enterprises estimated that there were 75 million individuals attempting to lose weight in the U.S. in 2010, with 80% of them trying to lose weight on their own and making four weight-loss attempts per year (PRWeb Health, 2011). The U.S. market for weight-loss medications, commercial weight-loss chains (e.g. Weight Watchers) meal replacements, diet-food home delivery (e.g. NutriSystem), diet websites, and medically supervised weight-loss programs was valued at \$60.9 billion in 2010 (PRWeb Health, 2011). In contrast, prescription weight-loss drugs in the U.S. represent just a fraction of the weight-loss market, with combined sales of only \$154 million in 2009,

according to the most recent data available from IMS Health, a health care information company (Pollack, 2010a).

The weight-loss drug industry, however, has not fared well. In addition to generating low sales of existing products, manufacturers have not been successful at introducing new ones because they have not been able to earn regulatory approval. There have been no approvals granted for new weight-loss drugs in the past twelve years since the 1999 approval of orlistat, a gastrointestinal lipase inhibitor that is available both by prescription (Xenical, 120 mg, manufacturer: Roche) and over-the-counter (Alli, 60 mg, manufacturer: GlaxoSmithKline).

The Food and Drug Administration (FDA) of the United States is the regulatory agency that evaluates and approves new drugs prior to their entry into the marketplace. Like all other types of medications, drugs designed to treat obesity must undergo extensive scrutiny to be eligible for approval by the FDA. The FDA, however, must balance its duty to evaluate efficacy and safety with its obligation not to block or delay access to new drugs that could potentially improve the health of many people (Schweitzer, 1997).

In September 2010, Lorcqess (lorcaserin hydrochloride, manufactured by Arena Pharmaceuticals) failed to gain FDA approval because high doses of the drug caused tumor development in rats (Pollack, 2010b). The FDA defined Lorcqess's weight loss benefit for humans, as demonstrated in clinical studies, as "marginal" and requested further research on the carcinogenic potential of the drug (Pollack, 2010b). In October 2010, the FDA rejected Qnexa, manufactured by Vivus, despite its effectiveness at causing weight loss of 10.6% of initial body

weight after one year, compared with 1.7% initial body weight lost with placebo after one year (Pollack, 2010a). The concern about Qnexa, a blend of phentermine, a weight-loss drug approved for short-term use, and topiramate, an epilepsy and migraine medication known as Topamax and sold by Johnson & Johnson, was the long-term safety for pregnant individuals and individuals with heart problems (Pollack, 2010a). The FDA requested additional evaluations of safety for these populations. In February 2011, the FDA refused to grant approval of Orexigen Therapeutic's drug Contrave over concern about cardiovascular damage; the FDA demanded that the manufacturer conduct a large, long-term clinical trial to ensure that there would be no elevated risk of heart problems from using Contrave (Pollack, 2011).

The FDA's caution regarding new weight-loss drugs stemmed in part from the postmarket research findings about Meridia (sibutramine, manufacturer: Abbott Laboratories), a prescription weight-loss drug that modulates the reuptake of the neurotransmitters noradrenaline and serotonin (Wirth, 2001). Researchers conducting the Sibutramine in Cardiovascular Outcomes (SCOUT) trial, which lasted over five years and included over 10,000 individuals in Europe, Latin America, and Australia, found an association between Meridia and increased risks of heart attack and stroke in users with pre-existing heart disease, which is frequently asymptomatic. In October 2010, the FDA asked Abbott to stop selling Meridia.

The most widely used prescription-strength weight-loss drugs of the past two decades have been fen-phen, dexfenfluramine, Meridia, and Xenical. Fen-

phen was a combination of fenfluramine and phentermine, both of which had FDA-approval for short-term use. During fen-phen's heyday in the mid-1990s, many physicians considered these two drugs to have a symbiotic relationship for weight loss and began prescribing them "off label" as a duo, even though the combined use of these drugs had never been vetted by the FDA (Colman, 2005). In 1997, fenfluramine, half of fen-phen, was withdrawn from the market after reports of cardiovascular and pulmonary damage. Dexfenfluramine, another appetite suppressant, was recalled at the same time as fenfluramine due to similar adverse reports.

As of June 2011, the only weight-loss drug available for long-term use in the U.S. is orlistat. In 2010, U.S. regulators decided that Alli, the over-the-counter form of orlistat, should carry warnings about potential liver injuries, though a cause-and-effect relationship had not been established at the time (Food and Drug Administration, 2010). In April 2011, GlaxoSmithKline announced it would sell off the Alli product line, among other drug products, less than four years after it was launched in June 2007 (GlaxoSmithKline, 2011).

### **U.S. Food and Drug Administration (FDA)**

The FDA's regulatory role began with its creation as a federal agency in 1938; according to the Federal Food, Drug, and Cosmetic Act, the FDA required manufacturers to submit evidence of a new drug's safety before making the drug available for sale (Colman, 2005). Several amphetamine and amphetamine-like appetite suppressants, such as phentermine, were approved at this time. In 1962, in the wake of the thalidomide tragedy in Europe in which the morning-sickness



drug thalidomide was found to be the cause of many severe birth defects when taken in early pregnancy (Schweitzer, 1997), the law was amended to require that manufacturers provide evidence of a drug's safety and efficacy, obtained through long-term, well-controlled clinical trials. The FDA asked the National Research Council of the National Academy of Sciences to review almost 3,000 previously approved drugs. Without evidence of efficacy obtained through long-term clinical studies, however, the appetite suppressants were in danger of being removed from the market. Ultimately, the FDA agreed to allow them to remain on the market, but they were to be prescribed only for short-term use (a few weeks), which limited their usefulness, and they carried labels that warned against addiction. These two factors contributed to their gradual decline in popularity throughout the 1970s and 1980s. The introduction of fen-phen in the mid-1990s ended the demand for appetite suppressants (Colman, 2005).

Another popular FDA-approved weight-loss drug was phenylpropanolamine (PPA), a common ingredient in over-the-counter and prescription cold and sinus medications and over-the-counter weight loss products (FDA, 2005). PPA reduced food intake in studies on animals, and produced vasoconstriction in humans (Bray, 2008). PPA-based weight loss pills, such as Dexatrim, were available until 2000, when the FDA removed all medications containing PPA (including the decongestants) from the market because of reports that linked them to an increased risk of hemorrhagic stroke (Ahmad, 2008).

The pre-market FDA approval process for a new weight-loss drug is expensive and time-consuming. Before any research can be performed using

human subjects, toxicological and safety testing must be done on animals. The drug company files an Investigational New Drug (IND) application with the FDA and must obtain IND approval before beginning any testing on humans (Schweitzer, 1997).

There are three phases of clinical development: phase I studies use small groups (<100) of healthy subjects to investigate the safety and metabolism of the drug, phase II studies use multiple dose amounts and larger groups of subjects (several hundred) to explore short-term side effects and risks of the drug, and phase III studies are larger (several hundred to several thousand individuals), with trials held at hospital and outpatient settings using the dose and route of administration that will be marketed (Schweitzer, 1997). Most phase II and III clinical trials are randomized, double-blind, and placebo-controlled (Schweitzer, 1997). In phases I and II, overweight and obese subjects with a broad range of BMIs (27 kg/m<sup>2</sup> to 35 kg/m<sup>2</sup>) are treated to study how adiposity may affect the pharmacokinetics of a drug (FDA, 2007). In accordance with national guidelines on eligibility for pharmacotherapy for obesity (NHLBI, 1998), study participants are individuals with a BMI of at least 27 kg/m<sup>2</sup> (with co-morbidities (e.g. type 2 diabetes mellitus, hypertension, cardiovascular disease) or of at least 30 kg/m<sup>2</sup> (co-morbidities optional) (FDA, 2007).

After the completion of clinical testing, the drug company files a New Drug Application (NDA) containing all of the evidence from the clinical trials with the FDA; the FDA has 180 days to review the NDA, but can take more time depending on the amendments that need to be made to the NDA. In reality,

therefore, the FDA may take much more time to complete the review. In 2002, the average FDA review time for the 26 drugs approved that year was 17.8 months (Schweitzer, 1997).

The FDA has drafted guidelines for regulatory criteria of safety and efficacy for weight-loss drugs. According to the draft, the safety of a weight-loss drug can be determined in a study of 3,000 subjects randomized to active doses and 1,500 subjects randomized to placebo for one year of treatment (FDA, 2007). In reality, it is nearly impossible to predict the adverse event profile of a new drug due to the small sample size, the short duration of the trial, and the limited generalizability of the study population which typically excludes pregnant women, the elderly, individuals with multiple diseases, and individuals who are taking other medications that may interact with the drug being studied (Ahmad, 2003). Due to the increased risks of cardiac valvulopathy presented by fen-phen and dexfenfluramine in the past, the FDA looks for adverse effects on cardiac function when assessing a new drug's safety (Heal et al., 2009). The primary efficacy endpoint is a difference in mean weight loss between the intervention and placebo groups of at least 5%; this difference must also be statistically significant (Heal et al., 2009). In addition to weight reduction, which alone may provide only cosmetic and not medical benefits, the FDA requires improvements in obesity-related risk factors such as blood pressure, pulse, blood lipids, and (in individuals who have diabetes) glucose, insulin, and HbA1c (FDA, 2007).

In addition to overseeing drug approvals, the FDA is responsible for monitoring the post-market safety of drugs through its Adverse Event Reporting

System (AERS). Reports are submitted either from pharmaceutical companies, who receive information mainly from physicians and pharmacists, or from physicians, pharmacists, nurses, and other healthcare practitioners (Ahmad, 2003).

Dietary supplements fall into a different category for the FDA. The Dietary Supplement Health and Education Act of 1994 (DSHEA) released the FDA from the pre-market approval process of regulating dietary supplements, including those intended for weight loss (FDA, 1994). Instead, DSHEA granted manufacturers the freedom to decide if a product was safe enough to market. In contrast with the extensive process required for drug approval, there are no safety or efficacy standards in place for dietary supplements.

### **Fen-phen**

The first weight-loss drug to gain popularity in the 1990s was fen-phen, a combination of two appetite suppressants. Fenfluramine, approved in 1973, was manufactured and sold under the brand name Pondimin by American Home Products (FDA, 1997). Phentermine had been approved in 1959 and marketed under a variety of brand names, such as Fastin, Obephen, and Phentride (NIH, 2010). The combined use of fenfluramine and phentermine, however, was never FDA-approved yet physicians prescribed the drugs separately – but to be taken together – as an increasing number of consumers demanded a medical weight-loss intervention. Fen-phen became popular in the mid-1990s after the mass media publicized results from a small 1992 study that seemed to support fen-phen's

effectiveness as a weight-loss drug (Colman, 2005). In 1996, physicians issued 18 million “off-label” prescriptions for fen-phen (Connolly, 1997).

Both fenfluramine and phentermine suppress the appetite, though by different pathways in the hypothalamus. Fenfluramine binds with the serotonin reuptake pump, which inhibits reuptake and increases levels of the neurotransmitter serotonin circulating in the brain, which produces a feeling of fullness and decreases the appetite (PharmGKB, 2011a). Phentermine, an amphetamine, stimulates the production and maintains high levels of catecholamines, a type of neurotransmitters, (e.g. norepinephrine) that block hunger signals and suppress the appetite (PharmGKB, 2011b). Both drugs share similar adverse effects, such as anxiety, insomnia, tachyarrhythmia, hypertension, restlessness, dizziness, tremor, headache, dry mouth, unpleasant taste, nausea, vomiting, diarrhea, and/or constipation (Moyers, 2005).

Prior to fen-phen’s rise in popularity, there was scant scientific research to support its efficacy and safety. There was one study, published in 1984, in which 81 obese subjects were divided into four groups and treated for 16 weeks with either fenfluramine alone, phentermine alone, a combination of fenfluramine and phentermine (fen-phen), and a placebo (Weintraub, 1984). All of the participants were between the ages of 18 and 55 and body weights ranged from 30% to 80% above ideal body weight. They followed a calorie-restricted diet and a behavior modification program, and exercised regularly in addition to taking the medication. Using a double-blind, parallel-control design, researchers found that the group that received fen-phen achieved weight loss (10.1% of initial body

weight) equivalent to those who received the individual drugs (phentermine: 11.0% and fenfluramine: 8.4%) and significantly greater than that of those who received the placebo only (4.9%) (Weintraub, 1984). The phentermine group and the fenfluramine group experienced more cardiovascular side effects (e.g. palpitations) and central nervous system (CNS) side effects (e.g. sleep difficulties, nervousness, depression, fatigue, and increased dreaming) than the placebo group. Because researchers found that the group taking fen-phen experienced fewer cardiovascular and CNS side effects than the phentermine group, and because there was no significant difference between the fen-phen group and the placebo group in relation to these side effects, they concluded that fen-phen's seemingly reduced side effects made this drug combination a better choice than prescribing fenfluramine or phentermine individually. There was no significant difference in side effects between the fen-phen group and the fenfluramine group, however. The dropout rate was high, however; only 45 out of 81 subjects completed the 16-week trial. The 36 dropouts were distributed among the groups somewhat evenly; the fen-phen group had 8 out of 21 dropouts, the fenfluramine group had 10 out of 20 dropouts, the phentermine group had 8 out of 20 dropouts, and the placebo group had 10 out of 20 dropouts. Their reasons were almost evenly divided between drug-related causes and non-drug-related causes (Weintraub, 1984). The researchers followed up on the same small study population for a total period of four years. Subjects were treated with varying doses of fenfluramine and phentermine to determine how to compound these drugs so their greatest weight-loss properties could be achieved (Weintraub,

1992). During weeks 190 to 210, the medication was stopped, though the exercise, diet, and behavior modifications continued, and the lost weight was regained, demonstrating that fen-phen did not help with weight maintenance after its usage ended (Weintraub, 1992).

Because the FDA's steps to determine drug safety were not followed for fen-phen – not to mention the FDA's approval of “off label” use of medications – fen-phen's drug combination had never been formally and rigorously tested for adverse effects before being prescribed. Long-term use of fenfluramine and fen-phen were associated with heart and lung damage, ultimately leading to the withdrawal of fenfluramine from the market due to data showing the drug increased the risk of potentially fatal pulmonary hypertension (Abenhaim, 1996 and McMurray, 1985). In 1997, researchers at the Mayo Clinic reported they had conducted case reports on 24 subjects, none of whom had a history of cardiac disease, and found that fen-phen increased the risk of valvular heart disease. All 24 subjects were found to have damaged heart valves and eight had developed pulmonary hypertension (Connolly 1997). The FDA issued a warning against fen-phen in response to these findings. After receiving 75 reports of cardiac valvular damage after fen-phen use, the FDA issued a second warning about fen-phen. Finally, in September 1997, the FDA recalled fenfluramine after physicians reported that 30% of patients taking fen-phen had abnormal echocardiograms (FDA, 1997). Adverse events were reported with fenfluramine usage whether phentermine was combined with it or not; therefore, fenfluramine was identified as the drug responsible for causing the cardiac valvulopathy (FDA, 1997). Fen-

phen's legacy to subsequent weight-loss drugs in the U.S. was the stigma of danger, as well as the attraction of rapid and dramatic weight loss. Though phentermine is still approved for short-term weight loss, demand is low; sales of phentermine in 2009 were just \$36.5 million (Medical News Today, 2010).

### **Dexfenfluramine**

Marketed as Redux by Wyeth-Ayerst Laboratories, dexfenfluramine was approved by the FDA for short-term use for weight loss in 1996. Redux generated sales of \$206 million from July 1996 to July 1997 (Gerlin, 1997). It was recalled along with fenfluramine due to reports of cardiovascular and pulmonary damage in users (Kolata, 1997). A selective serotonin reuptake inhibitor (Swinburn, 1996), dexfenfluramine is the dextro-stereoisomer of fenfluramine (Lafreniere, 1992) and is as efficacious as fenfluramine but at half the dose (30 mg vs. 60 mg) (Guy-Grand, Crepaldi, LeFebvre, Appelbaum, Gries and Turner, 1989). Side effects include tiredness, diarrhea, dry mouth, polyuria, and drowsiness (Guy-Grand et al., 1989).

Results of clinical studies support dexfenfluramine's efficacy for up to six months. In a double-blind, placebo-controlled trial on 84 obese subjects on a reduced-fat, ad libitum diet, after 12 weeks, the treatment group had lost significantly more body weight and body fat (particularly in the abdominal region) as compared to the placebo group. Blood lipid levels among individuals who took dexfenfluramine were significantly lower than their peers', thereby reducing cardiovascular risk factors for those who took the medication (Swinburn, 1996). In a randomized, double-blind, placebo-controlled, multi-center study on



822 obese subjects, Guy-Grand and colleagues (Guy-Grand et al., 1989) examined the efficacy of dexfenfluramine, combined with energy restriction, in enhancing weight loss over a one-year period of active treatment. The researchers showed that mean weight loss was significantly greater in the treatment group than the placebo group at the six-month mark and after one year, when the mean weight loss in the treatment group was 9.82 kg and the mean weight loss in the placebo group was 7.15 kg . Almost all of the weight loss in both groups occurred during the first six months of treatment. The greater amount of weight regain in the placebo group during the second six months suggested that dexfenfluramine prevented weight regain in the treatment group, though it did not continue the weight reduction process after the plateau was reached at six months (Guy-Grand et al., 1989).

Another randomized, placebo-controlled study by Andersen and colleagues showed a significant difference in weight loss between the active treatment group and the placebo group at six months, but not after 12 months, indicating the plateau effect (Andersen, 1992). Long-term studies ( $\geq 6$  months) did not support continuing benefits of dexfenfluramine. Pfohl and colleagues (1993) conducted a follow-up study three years later with research participants who had been treated with dexfenfluramine for a one-year period and found that the results of dexfenfluramine in the long term were comparable to those of behavior therapy alone (Pfohl, Luft, Blomberg and Schmulling, 1993). Any benefit from its continuous long-term administration as an adjunct therapy to

other weight-loss interventions did not outweigh its potential cardiovascular and pulmonary risks.

### **Sibutramine (Meridia®)**

Branded as Meridia® by Abbott Laboratories, sibutramine was a prescription weight-loss drug that was approved for long-term use by the FDA in November 1997, the same year that fenfluramine and dexfenfluramine were recalled. Meridia was available in the United States for nearly 13 years, till October 8, 2010, when the FDA asked Abbott to voluntarily recall the drug due to evidence that the drug was associated with a 16% elevated risk of adverse cardiovascular events. Abbott immediately complied with the FDA's request.

Till then, over 3 million prescriptions were filled between 2002 and 2010 (Reuters, 2010). Meridia modulates hunger and causes early satiety (Wadden, 2005). By inhibiting the reuptake of both serotonin and noradrenaline, Meridia had the potential for greater efficacy than dexfenfluramine, which acts only on serotonergic mechanisms, and phentermine, which acts only on noradrenergic mechanisms (Lean, 1997).

In the U.S., FDA approval was based on the results of clinical studies that demonstrated that approximately 60% of subjects who were treated with Meridia compared to 30% of subjects who received the placebo lost greater than 5% of their baseline body weight (FDA, 2010). For example, in a randomized one-year trial of 224 obese subjects who received lifestyle-modification counseling, the daily use of 15 mg sibutramine doubled the amount of weight lost in overweight subjects and increased the number of subjects who achieved 5 – 10% weight loss

by three to four times compared to placebo and the same counseling (Wadden, 2005). Three doses – 5 mg, 10 mg, and 15 mg - were approved by the FDA (FDA, 2010). The typical daily dosage of sibutramine was 10 mg to start, with a recommendation to increase to 15 mg in four weeks if weight loss was not sufficient. Common side effects found during the clinical studies included an increased heartbeat, increased blood pressure, palpitations, headache, anxiety, dizziness, dry mouth, anorexia, insomnia, constipation, and headache (FDA, 2010).

In European Union countries, Meridia was approved in 1999 only under the condition that the manufacturer was required to conduct a long-term, post-market clinical trial to examine the effects of sibutramine on cardiovascular health. Concerns came from the side effects of the increases in heartbeat and blood pressure that were noted in the pre-approval clinical trials.

In October 2010, the FDA requested that Meridia be withdrawn from the market. The randomized, double-blind, placebo-controlled trial that had been required by European regulatory authorities was called Sibutramine in Cardiovascular Outcomes (SCOUT). Between 2003 and 2009, approximately 10,000 overweight or obese subjects in Europe, Latin America, and Australia participated in SCOUT. They had either a history of cardiovascular disease and/or type 2 diabetes mellitus plus at least one cardiovascular risk factor, e.g. hypertension, dyslipidemia, smoking, or diabetic nephropathy (James, 2010). The results of SCOUT showed that the long-term use of sibutramine increased the risk of primary cardiovascular events (e.g., non-fatal myocardial infarction and stroke,

cardiovascular death) in patients with pre-existing cardiovascular disease by 16% (James, 2010) while the difference in weight loss between the treatment group and the placebo was a modest 2.5% (FDA, 2010). The benefit of slightly increased weight loss was not enough to justify the increased cardiovascular risk.

### **Orlistat (Xenical and Alli®)**

On April 23, 1999, the FDA approved orlistat, branded Xenical® in the United States by manufacturer Hoffman-La Roche, as a prescription weight-loss drug for overweight adults with a BMI of at least 30, or 27 with at least one obesity-related risk factor (FDA, 2011). Canada and many countries in Europe, South America, and Southeast Asia/Pacific approved orlistat as well (Lucas, 2001). The safety and efficacy of orlistat was established in many long-term clinical studies prior to its approval. As a gastrointestinal lipase inhibitor, orlistat does not act upon appetite or satiety controls but rather locally in the small intestine, where it is minimally (< 2%) absorbed (Schwartz, 2008). Unlike earlier weight-loss drugs such as fen-phen, Redux, and Meridia, orlistat was not associated with increased cardiovascular risks.

Orlistat works by binding to pancreatic lipase in the small intestine, decreasing the hydrolysis and absorption of dietary triglycerides (Schwartz, 2008). The standard prescription dosage of 120 mg three times daily prevents approximately 30% of dietary fat from being digested, which creates an energy deficit that leads to weight loss (Lucas, 2001) and undigested fat is excreted in feces. Orlistat is meant to be used in conjunction with a reduced-calorie, low-fat diet as well as a regular exercise program. The inhibition of lipid digestion

decreases the absorption of fat-soluble vitamins, so a multivitamin supplement is recommended to ensure against vitamin deficiencies when taking orlistat (Lucas, 2001). Excessive intake of dietary fat can lead to uncontrollable excretion of undigested dietary fat, which causes diarrhea and anal leakage, referred to as “treatment effects” by Hoffman-La Roche. This unpleasant consequence is a form of aversion therapy since it discourages the individual from choosing to eat foods high in fat (Lucas, 2001).

Orlistat sales were \$146 million in the first seven months of post-market release (Goetzl, 2000) but then declined quickly afterward and stayed low. In 2009, U.S. sales of Xenical were just 34 million Swiss francs (approximately \$34.4 million U.S. dollars) (Roche, 2010). The timing of Xenical’s 1999 introduction to the U.S. market was unfortunate; consumers and physicians were skittish to try a new weight-loss drug in the wake of the 1997 recall of fen-phen (Thomaselli, 2007). Consumers were not as impressed by the relatively modest weight loss caused by Xenical as opposed to the rapid weight loss caused by fen-phen (Morrow, 1999). The unpleasant side effect of fecal incontinence was also responsible for Xenical’s low popularity. The cost of a one-month supply of Xenical in 2006 was about \$100 and was not covered by most insurance plans (Saul, 2006).

In the following research studies, orlistat therapy was found to be effective for weight loss and weight maintenance in obese and overweight adults. Orlistat was well-tolerated by subjects, the gastrointestinal side effects did not often cause many subjects to withdraw, and the theoretical possibility of deficiencies in fat-

soluble vitamins resulting from orlistat use occurred infrequently. In these studies, a placebo run-in phase was used to assess the effects of any diet, physical activity, and lifestyle modifications separately from the effects of the drug treatment.

Davidson and colleagues (1999) conducted a two-year, randomized, double-blind, placebo-controlled trial on obese adults (BMI range: 30 – 43 kg/m<sup>2</sup>) and found that subjects treated with orlistat (either 60 mg or 120 mg) lost significantly more weight ( $8.76 \pm 0.37$  kg) than subjects who received the placebo ( $5.81 \pm 0.67$  kg) after the first year (Davidson and colleagues' names here, 1999). Orlistat treatment demonstrated efficacy for weight maintenance in the second year as well. The subjects who received 120 mg orlistat had significantly less weight regain ( $3.2 \pm 0.45$  kg, 35% regain) than those who had received 60 mg orlistat ( $4.26 \pm 0.57$  kg, 51.3% regain) or placebo ( $5.63 \pm 0.42$  kg, 63.4% regain). Treatment with 120 mg orlistat after two years was associated with a greater decrease in mean waist circumference compared to placebo ( $-4.52 \pm 0.8$  cm for orlistat group vs.  $-2.38 \pm 1.0$  cm for placebo,  $P < 0.05$ ), as well as with improvements in fasting low-density lipoprotein cholesterol and insulin levels. Treatment with 120 mg orlistat after one year was associated with a greater decrease in systolic blood pressure in the treatment group ( $119.4 \pm 0.5$  to  $118.6 \pm 0.6$  mm Hg) than in the placebo group ( $118.6 \pm 0.9$  to  $119.6 \pm 1.3$  mm Hg),  $P = 0.002$ ). The 120 mg dose of orlistat showed greater benefits than the 60 mg orlistat, but both were significantly more effective for weight loss, weight maintenance, and improving cardiovascular risk factors than placebo.

Another two-year, multi-center, randomized, double-blind, placebo-controlled study with 783 overweight or obese subjects (BMI range: 28 – 43 kg/m<sup>2</sup>) by Rossner and colleagues (2000) demonstrated similar results. Two doses of orlistat were tested, 60 mg and 120 mg. After two years, weight loss was significantly ( $P < 0.001$ ) higher for the 120 mg orlistat group (9.7%) and the 60 mg orlistat group (8.6%) than the placebo group (6.6%). After one year of treatment, 38.3% ( $P < 0.001$ ) of subjects in the 120 mg orlistat group and 31.2% ( $P = 0.002$ ) of subjects in the 60 mg orlistat group had lost > 10% of their body weight, compared to 18.8% of subjects who had received the placebo ( $P < 0.001$ ). Additionally, significantly more individuals in the orlistat groups lost > 5% of their body weight after both the first and second years of treatment than subjects who had received the placebo ( $P < 0.001$ ). Orlistat users had significantly less weight regain compared to placebo users too. Weight loss > 10% was maintained by a greater proportion of 120 mg and 60 mg orlistat recipients (28.2% and 29.0%, respectively) than placebo recipients (18.6%) after two years. Orlistat users also had a greater decrease in waist circumference (6.2 cm and 6.0 cm in the 120 and 60 mg orlistat groups, respectively) than placebo users (4.7 cm) after one year. Orlistat users had significantly improved lipid profiles as well (Rossner, 2000). Only 6% of subjects withdrew from the study due to adverse effects of the drug treatment; overall, orlistat was well-tolerated. No clinical symptoms of vitamin deficiencies were noted, and serum levels of fat-soluble vitamins stayed within normal ranges, though levels of vitamins D (25-OH vitamin D) and E, and

$\beta$ -carotene were significantly lower in the orlistat groups than in the placebo group.

Hauptman and colleagues (2000) found similar benefits to orlistat in a two-year, randomized, double-blind, placebo-controlled, multi-center study with 635 obese (BMI range: 30 – 44 kg/m<sup>2</sup>) subjects in primary-care settings where some dietary guidance was provided during the lead-in phase (Hauptman, Lucas, Boldrin, Collins, and Segal, 2000). Weight loss after one year was significantly higher for subjects in both the 120 mg orlistat ( $7.94 \pm 0.57$  kg) and 60 mg orlistat ( $7.08 \pm 0.54$  kg) groups than for subjects in the placebo group ( $4.14 \pm 0.56$  kg). Proportionately more subjects in the 120 mg group (50.5%) and the 60 mg group (48.8%) lost > 5% of their starting body weight compared to placebo users (30.7%;  $P < 0.001$ ). Significantly more orlistat recipients (34%,  $P < 0.001$ ) maintained a weight loss of  $\geq 5\%$  after the second year of the study as well compared to 24% of the placebo users. Serum lipid profiles and blood pressure markers showed greater improvements in orlistat users relative to placebo users. Orlistat was well-tolerated by subjects.

The benefits of orlistat treatment for obese individuals with type 2 diabetes heavily outweigh the side effects. Hollander and colleagues (1998) conducted a one-year, randomized, double-blind study that demonstrated orlistat's benefits to overweight and obese (BMI range: 28 – 40 kg/m<sup>2</sup>) adults with type 2 diabetes who were taking oral sulfonylureas as prescribed (Hollander, Elbein, Hirsch, Kelley, McGill, Taylor, Weiss, Crockett, Kaplan, Comstock, Lucas, Lodwick, Canovatchel, Chung, and Hauptman, 1998). Subjects received either



120 mg orlistat (n = 163) or placebo (n = 159) and an energy-controlled diet. After one year, mean weight loss was significantly greater in the orlistat group ( $6.2 \pm 0.45$  kg) than in the placebo group ( $4.3 \pm 0.49$  kg) ( $P < 0.0001$ ). Twice as many subjects in the orlistat group (49%) than in the placebo group (23%) lost  $\geq 5\%$  of initial body weight ( $P < 0.0001$ ). Orlistat treatment was associated with significant improvement in glycemic control, as evidenced by decreases in HbA1c ( $P < 0.0001$ ) and fasting plasma glucose ( $P < 0.0001$ ) and reductions in the dosages of oral sulfonylurea medications ( $P < 0.0001$ ). The orlistat group also had significantly greater improvements in lipid parameters: greater reductions in total cholesterol ( $P < 0.0001$ ), LDL cholesterol ( $P < 0.0001$ ), triglycerides ( $P < 0.05$ ), and LDL-to-HDL cholesterol ratio ( $P < 0.0001$ ). Orlistat was well-tolerated overall; the gastrointestinal side effects of excessive dietary fat intake were mild to moderate and were not often associated with withdrawal from the study. Seven of the participants in the treatment group dropped out of the study due to gastrointestinal events while two participants in the placebo group dropped out for the same reason. In the orlistat group, 85% of the initial 163 subjects completed the study, compared with 73% of the initial 159 subjects in the placebo group. Fat-soluble vitamin levels remained within the normal ranges, and vitamin supplementation was required for only a few subjects.

Reinforcing earlier studies on animals that showed that dietary composition influences insulin sensitivity independently of body weight, a study treating a sample of 47 obese (BMI range:  $32.1 \pm 0.4$  kg/m<sup>2</sup>) female subjects with orlistat vs. placebo demonstrated that reducing dietary fat intake through

decreased absorption had beneficial effects on insulin resistance, as well as on body fat composition. Tiikkainen and colleagues (2004) administered a hypocaloric diet and either 120 mg orlistat three times daily (for a daily total of 360 mg orlistat) or placebo (Tiikkainen, Bergholm, Rissanen, Aro, Saminen, Tamminen, Taramo, and Yki-Jarvinen, 2004). At baseline, the two groups had similar ages, weights, BMIs, waist-to-hip ratios, body fat composition, insulin sensitivity, and dietary intakes regarding macronutrient composition and alcohol and fiber intake. The goal was to induce a moderate amount (8%) of weight loss over 3 to 6 months in both groups and compare the effects on markers of insulin sensitivity, on serum fatty acid composition, and on body fat composition.

The researchers measured whole-body insulin sensitivity (M-value) and serum fatty acids using the euglycemic insulin clamp technique, which simulates glucose uptake by the body's tissues and demonstrates insulin sensitivity. This method requires the subject to fast for 12 hours, then inserting a catheter into a vein in the left upper arm in order to pump a continuous infusion of insulin and glucose over a two-hour period (plasma glucose was measured every five minutes in order to maintain and adjust the rate of glucose being infused) and inserting another catheter into a vein in the same hand in order to withdraw samples of blood every 30 minutes during the two-hour period to measure serum free insulin and free fatty acid concentrations. Before the insulin infusion, they took samples of blood to measure fasting glucose, glycosylated hemoglobin, triacylglycerols, total and LDL cholesterol, free fatty acids, fatty acid composition of serum

phospholipids, and serum free insulin concentrations. They measured body composition by magnetic resonance imaging.

Weight loss occurred gradually over time in both groups at a similar rate; average weight loss in the orlistat group was  $7.3 \pm 0.2$  kg ( $8.3 \pm 0.1\%$ ), which was similar to the placebo group's average weight loss of  $7.4 \pm 0.2$  kg ( $8.2 \pm 0.1\%$ ). Ten of the original 47 subjects did not achieve at least an 8% weight loss and were withdrawn from the study. Dietary intake was similar in both groups throughout the study.

After the weight loss, in both groups, insulin sensitivity (M-value) increased similarly and serum fasting insulin concentrations decreased similarly. There were no changes in both groups to fasting plasma glucose, glycosylated hemoglobin, and serum fasting fatty acids. There were no significant differences between the two groups in mean serum free acid concentrations during the insulin infusion, which were slightly slower after the weight loss compared to baseline. There was a significant decrease in serum LDL cholesterol in the orlistat group, from  $3.5 \pm 0.2$  mmol/L to  $3.0 \pm 0.1$  mmol/L ( $P < 0.01$ ) but not in the placebo group; the difference in groups was significant ( $P < 0.05$ ). In the placebo group, serum HDL cholesterol increased slightly but significantly from  $1.28 \pm 0.06$  mmol/L to  $1.34 \pm 0.07$  mmol/L ( $P < 0.01$ ) but there was no change in the orlistat group, from  $1.31 \pm 0.1$  mmol/L to  $1.29 \pm 0.1$  mmol/L ( $P < 0.01$ ); the difference between groups was not significant. Both groups had significantly lower twenty-four hour systolic blood pressure after weight loss and twenty-four hour diastolic blood pressure was also lower in both groups, but not significantly so.

Treatment with orlistat provided an advantage over placebo by improving body fat composition through decreased dietary fat absorption. While both groups achieved similar losses in body weight and fat mass, and similar decreases in subcutaneous fat, the orlistat group lost significantly more intraabdominal, or visceral, fat than the placebo group. This resulted in a lower, and more favorable, ratio of intraabdominal fat to subcutaneous fat. In the placebo group, the ratio of intraabdominal fat to subcutaneous fat did not decrease significantly.

There were differences in serum fatty acid concentrations between groups. The proportion of monounsaturated fatty acids increased significantly in the orlistat group but not in the placebo group. The proportion of palmitic acid (16:0), which is the most common saturated fatty acid in serum phospholipids, increased significantly in the orlistat group and not in the placebo group. The proportion of the essential fatty acid linoleic acid (18:2n-6), the most common polyunsaturated fatty acid in serum phospholipids, decreased in both groups, but to a greater extent in the orlistat group. The reduction in this essential fatty acid, which has been reported in other studies on orlistat, may counteract the improvements to cardiovascular risks from orlistat treatment (e.g. the lower ratio of intraabdominal to subcutaneous fat). Researchers concluded that dietary fat composition, by affecting serum fatty acid composition, may have a stronger influence on metabolic processes than the total amount of dietary fat. Weight loss, regardless of whether it was achieved by orlistat or placebo, resulted in improvements for all subjects. Orlistat, through reducing the total amount of dietary fat that was

absorbed, or through changing the composition of dietary fat that was absorbed, may have influenced the intraabdominal and subcutaneous fat stores.

Exclusion criteria might have caused these studies to have limited external validity concerning the greater obese population (Lucas, 2001). These studies demonstrated orlistat's efficacy for inducing weight loss and causing improvements in many obesity-related risk factors in otherwise healthy overweight and obese adult subjects. But in real life, overweight and obese individuals commonly have multiple comorbidities such as hepatic, gastrointestinal, renal, cardiovascular, psychological, and endocrine disorders as well as type 2 diabetes. The complicating effects of these comorbidities are difficult to control in research settings.

On February 7, 2007, a lower dose of orlistat was approved for over-the-counter sale by the FDA (FDA, 2007). At 60 mg, this half-strength version of orlistat was branded as Alli® by GlaxoSmithKline, which had paid Hoffman-La Roche Laboratories \$100 million for the over-the-counter marketing rights to the drug. Many of the research studies on orlistat prior to its FDA approval had tested a 60 mg dosage as well, so additional research studies on Alli were not required (Schwartz, 2008).

With the introduction of Alli, consumers had an FDA-approved alternative to over-the-counter herbal weight-loss drugs that did not have the FDA's approval (Bray, 2008). Until 1998, the main ingredient in over-the-counter weight-loss drugs was phenylpropanolamine (PPA), which caused vasoconstriction and was used in cold and sinus-relief medications (FDA, 2000). Because a few small

studies showed PPA caused short-term weight loss, the drug was combined with other ingredients and marketed as over-the-counter weight loss products under various names (Bray, 2008). PPA was, however, recalled from the market in 1998 due to the FDA's concern that the vasoconstrictive effect would lead to hypertension and an increased risk of stroke (FDA, 2000). From 1998, when PPA-based products were withdrawn, until 2007, when Alli was introduced, consumers' only option for over-the-counter weight-loss drugs was a variety of herbal products whose safety was unknown.

Alli works identically to Xenical. Though the dosage is half the prescription amount, Alli reduces dietary fat absorption by approximately 25%, as opposed to by 30% by Xenical. Like Xenical, Alli has the same "treatment effects" as Xenical and the same theoretical potential to decrease the absorption of fat-soluble vitamins with long-term use. Also like Xenical, Alli is taken three times daily and should be used when individuals consume a low-fat diet and exercise regularly. Though a doctor's visit is not required to begin using Alli, users have access to a social-support network through a free Web site, [Alliconnect.com](http://Alliconnect.com), sponsored by GlaxoSmithKline and moderated by paid experts. Additionally, a 152-page booklet providing behavioral and dietary instructions comes packaged with the product.

U.S. sales of Alli were \$155 million in the first six weeks after it was launched in June 2007. But sales of Alli fell after those initial weeks and steadily declined. Sales never regained the initial momentum. According to GlaxoSmithKline's 2007 annual report, sales of Alli for the entire first year were

\$247.2 million (Miley, 2009). The following year, sales had fallen by 53% to \$131 million (Miley, 2009). Consumers might have been repulsed by Alli's "treatment effects" as well as the cost: A one-month supply of Alli in 2007 ranged from \$60 to \$70 (Thomaselli, 2007). An "industry executive" listed the challenges of marketing Alli in *Advertising Age*: "diet-pill stigmas, a challenging economic climate and lazy human nature-as well as a horrendous side effect" (Miley, 2009). Consumers expecting rapid weight loss may have been disappointed because Alli is intended to cause gradual and moderate weight loss (Miley, 2009). One wonders if the low-fat diet, exercise, and other lifestyle modifications that the manufacturer recommended in conjunction with Alli were sufficient to cause weight loss, making Alli unnecessary.

The FDA was first made aware of a possible link between orlistat use and severe liver injury in 1999. Potential orlistat-associated cases of severe liver injury, including the need for organ transplant and culminating as the cause of death, have been reported since, with an uptick when Alli entered the marketplace. Orlistat – sold as Xenical or Alli – remains available to U.S. consumers, however, because the FDA has not confirmed orlistat causes severe liver injury and because the causal relationship, if valid, occurs rarely (FDA, 2010). The FDA conducted a post-market adverse effect study of Xenical and Alli and determined that of approximately 40 million people around the world who have taken orlistat, 12 cases, all outside the U.S., had possible Xenical-associated severe liver injuries. Within the U.S., only one case – an individual who had used Alli – linked orlistat with severe liver injury. Xenical was not

associated with any cases of severe liver injury in the United States. The FDA warned consumers to be vigilant of symptoms that indicate liver damage and ordered package labeling to be changed to include the reports of rare, yet severe liver injury.

Purchasing Alli over the counter could mean visiting a traditional retail store, but it could also mean ordering the drug online via an Internet retailer (Fox, 2005). One danger of purchasing Alli, or any other medication, from an Internet source is that the product could be fake. In 2010, the FDA warned that a counterfeit form of Alli was being sold online, including eBay.com (FDA, 2010). The product, instead of 60 mg orlistat, contained varying amounts of sibutramine, which is no longer sold in the United States. Sibutramine is contraindicated for individuals with cardiovascular disease because it can increase the risks of strokes and heart attacks. In some cases, samples of counterfeit Alli contained megadoses of sibutramine. No counterfeit Alli was discovered being sold in retail stores.

The main difference between Xenical and Alli is Alli's over-the-counter accessibility, at least in theory. Actually, Xenical is available for sale on the Internet as well. Though it is not supposed to be sold without a prescription from a physician, Xenical is available from Web sites such as Xenical Direct (Xenical Direct, 2011), which offer a "free, online consultation" before purchasing the product. The consultation consists merely of a handful of questions about the consumer's height, weight, and medical history prior to the screen that prompts the consumer to order the product. The Web site asks for a physician's name and address, but does not require a prescription to complete the transaction. There is



nothing to prevent Xenical, like many other medications designed for a specific use by a specific population, from being ordered by individuals who should not be taking it, such as children, pregnant women, or individuals with liver or gallbladder disease.

Alli's days of being available on the market are ending, however. In April 2011, GlaxoSmithKline announced it would sell off the Alli product line, among other drug products, less than four years after it was launched in June 2007 (GSK, 2011).

## Section 2

### **Framing Theory**

Research studies based on framing theory have proliferated in the fields of sociology, economics, linguistics, social-movements research, policy research, communication science, political communication, public-relations research, and health communication (Van Gorp, 2007). There is, however, no universal theoretical model of framing, even within a single field. Among mass communication researchers, there is controversy regarding the meaning of frames and framing, the cognitive processes involved in framing and how framing relates to other media-effects models such as agenda-setting and priming.

Framing theory can be applied to various types of news media coverage of a broad range of issues. This study applies framing theory to newspaper coverage of the weight-loss drug orlistat in its prescription form as Xenical (120 mg orlistat) and its over-the-counter version, Alli (60 mg orlistat). There are no other studies that investigate the framing of weight-loss drugs in the research literature.

The frame used to describe an issue, as noted by Entman (2004), is a powerful communication tool because the frame determines whether people pay attention to the issue, how they understand it, how and whether they remember it, and how they assess the issue and decide to take action. The way that a weight-loss drug is framed in the media influences public opinion about its usage and affects people's decisions to request a prescription for the drug (e.g., Xenical) or to buy the drug over the counter (e.g., Alli).

Generally speaking, frames help to organize information. Tversky and Kahneman's (1981) research in prospect theory revealed the power of frames to affect people's perceptions of the options in decision-making situations.. From a cognitive point of view, frames are the mental structures in an individual's mind that organize and manage information arriving from the outside (Scheufele, 2000). On the other hand, the constructionist perspective defines frames as ubiquitous social constructions that are inseparable from culture as a whole (Van Gorp, 2007).

This study applies a classic journalism-oriented approach to the concept of framing, viewing it as a process that happens during media production and performed by the individual creating the communicating text, i.e. the reporter writing a newspaper article. Framing involves selecting certain pieces of information about a topic to emphasize, while simultaneously excluding certain others for the purpose of increasing the salience of the selected portions to the consumer (Entman, 1993). The more salient information is, the more likely it is that consumers will notice and remember it. Building a frame requires selecting traits to describe the topic; by definition, while some traits are included, others must be excluded. Emphasizing selected traits enhances their salience in two ways: the audience perceives the selected traits to be more important than others when making a judgment about the issue, and is able to recall those selected traits quickly when thinking about the issue (Weaver, 2007).

Because the nature of reality is somewhat subjective, there are multiple ways to view and describe a situation or a topic. A frame promotes a specific

viewpoint on the issue by emphasizing certain traits over others. Aubrey (2010) demonstrated in a two-part study that frames have a powerful influence on how individuals perceive advice on health behavior change. The two components of the research were a content analysis of 426 cover headlines of the five highest-circulating U.S. women's health magazines (Shape, Fitness, Self, Health, and Women's Health) that investigated frames of health advice and an experiment on 103 college-aged women that demonstrated the connection between their exposure to articles from women's health magazines that used either appearance-focused frames or health-focused frames and their resulting responses about self-objectification, body shame and motivations to exercise, as measured by questionnaires specifically designed to assess these variables.

For the content analysis, researchers consulted the Audit Bureau of Circulation's list of the top-100 magazines, by circulation, and chose the top five magazines targeted at women and about health: Shape (circulation: 1.7 million), Fitness (1.6 million), Self (1.5 million), Health (1.4 million), and Women's Health (1.2 million). The strategy for finding articles from each publication was to select two issues randomly from each of six consecutive years from 2003 to 2008. The unit of analysis was the cover headline of a story that appeared on a magazine cover. Each of the 55 magazine covers had between five and 12 (mean = 7.82, SD = 1.59) cover headlines. The coding scheme identified several possible frame categories, including appearance frame (defined as instructing readers to change a behavior in order to look better), body competence frame (defined as instructing readers to change a behavior in order to improve a physical function,

such as fitness, strength or flexibility), and health frame (defined as instructing readers to change a behavior in order to enhance an intrinsic, but not cosmetic, aspect of health). A weight-loss frame category was added because there were many cover headlines about weight-loss that could be classified in both the appearance frame and health frame categories.

Three coders trained for 15 hours, refining the coding scheme in multiple iterations of a pilot study, before coding the final sample of articles independently. Reliabilities, measured using Cohen's kappa, were calculated based on the coding of four magazine issues that were not part of the final sample.

Out of the 426 cover headlines, 33.3% (n = 142) were coded as appearance frames and 29.3% (n = 125) were coded as health frames, 19.0% (n = 81) were coded as weight loss frames, and 3.3% (n = 14) were coded as body competence frames. The remaining 15% (n = 64) cover headlines were classified as other/miscellaneous. Researchers found that appearance frames were used just as often as health frames and much more often than body competence frames. Therefore, the appearance-related traits about health advice were the most often selected, and became most salient in the audience's mind, relative to intrinsic health-related traits and body competence-related traits.

Because most of the articles about weight loss emphasized losing moderate amounts of weight, the researchers concluded that the focus of these articles was cosmetic rather than medical and speculated that if these articles had been coded in the appearance frame category instead of in a separate weight loss frame category, then the majority of all the frames (52.3%, n = 223) would be

classified as appearance frames. Appearance frames would dramatically outweigh health frames in this case.

In the second part of the study, an experiment was conducted among a sample of 103 women, aged 18 to 30, at a public Midwestern university. They were assigned to review six magazine articles, each 100-200 words in length, from women's health magazines (e.g. *Self*, *Shape*, *Fitness*). Subjects were assigned to view articles that were coded as utilizing either appearance frames (n = 53) or health frames (n = 50). Then the subjects completed questionnaires designed to assess self-objectification, body shame, and motivations to exercise. Among readers who were assigned to review the articles containing appearance frames, their responses exhibited increased body shame and increased appearance-related motivation to exercise in comparison to the readers who were assigned the health frames. Researchers suggested that in the long term, appearance frames of health advice promote an extrinsically-motivated approach to health that is focused on enhancing looks, but emphasizing looks rather than health can be counterproductive because it can lead to body shame when individuals feel their looks fall short of their high expectations. Health frames which focus on intrinsic motivations (e.g. feeling more energetic) rather than on cosmetic improvements may be more likely to lead to long-term success at adopting health behavior change.

Frames are powerful communication devices. A frame can define a problem in a particular way, imply the causes of a problem, make a moral judgment, and promote solutions to the problem at hand (Entman, 1993). Saguy

and Almeling (2008) studied the joint influence of medical science media and the mainstream news media on the creation of frames that define obesity as a social problem. They created a codebook to analyze how obesity was presented in a sample of texts that included 20 scientific articles from two special issues about obesity by the Journal of the American Medical Association (JAMA) in 1999 and 2003, eight press releases related to the studies covered in those JAMA issues, and 128 articles from newspapers that also discussed the studies in the JAMA issues (60 articles were relevant to the 1999 JAMA issue and 59 were relevant to the 2003 JAMA issue). To locate the news articles, they utilized the LexisNexis database and entered the search terms “obesity” OR “weight” in the full text AND “American Medical Association” in the full text for three months after each of the JAMA issues was published. All of the articles were classified in LexisNexis as either General News (n = 66), World News (n = 8), News Wires (n = 24), Business News (n = 21), University News (n = 4), or Medical News (n = 5). All articles were at least 500 words to allow sufficient space for the themes to develop in the texts for coding. Articles from peer-reviewed journals were excluded to insure that the sample was taken from news sources rather than scientific publications. To locate the press releases on any of the JAMA articles from those two issues on the World Wide Web, they used the Google logarithmic search engine. They created combinations of the article title and author, the year of publication, and the word “embargoed” in the searches. Among the eight press releases in the sample was an official JAMA press release for each issue, two

press releases from the National Institutes of Health (NIH) on the research studies they funded, and press releases from the lead author's academic institution.

The codebook contained over 200 variables for the scientific articles, the article abstracts, the press releases, and the news media sample. Their tests of intercoder reliability had a mean of 90%. They measured dramatization of the obesity problem by coding for whether or not the article presented obesity as a public crisis, an epidemic, used war metaphors such as “battle of the bulge” or “time bomb”, or blurring the lines between the categories of obesity and overweight (e.g. describing an individual with a BMI > 40 as representative of the overweight U.S. population, rather than the obese population). One way to mitigate alarmist reporting about obesity is to acknowledge the scientific debates over the risk of obesity, such as the extent of the health risks that are associated with obesity, the appropriateness of current weight guidelines, and whether physical fitness is attainable despite overweight or obesity. Therefore, the codebook included measures of whether these scientific controversies were discussed. To measure how the medical and news reports assigned blame for obesity, they coded articles for the assertions that obesity is caused by bad individual choices, including those related to diet and exercise, social or structural factors (e.g. restaurant portions, food advertising), and genetic factors. They coded for proposed solutions to the overweight and obesity problem, such as individual changes to exercise or diet, policy changes, weight-loss drugs, and weight-loss surgery.



Results of the study suggest that the news media, consistent with the scientific reports from which they draw, portray obesity as a crisis. The news media, however, exaggerate the perception and the scope of the obesity problem by using frames that dramatize overweight and obesity describing it as not just a crisis, but as an epidemic and a war, and confusing the categories of obesity and overweight. The news media are more likely than the science media to assign individual blame for overweight and obesity. The news media reinforce a one-sided view of the obesity issue by not reporting on the scientific controversies in the research literature about obesity (perhaps body weights that exceed the norm are not indications of pathology, but rather natural diversity in human body size and perhaps obesity poses less health risks than some believe). The authors recommend that news reporters temper their alarmist tone by quoting from skeptical experts who can advocate for opposing viewpoints.

In addition to these findings, they discovered that weight-loss drugs were mentioned as a solution to the obesity problem in 20% of the 1999 science sample and in 30% of the 1999 news sample, and in 2003, weight-loss drugs were discussed in 60% of the science sample and 25% of the news sample. In the news media, weight-loss drugs were repeatedly stated to be ineffective and inferior weight-management tools in relation to behavior modification.

External factors such as social norms and values, organizational constraints, journalistic routines, and ideological or political orientations of journalists influence the usage of frames (Scheufele, 1999). As public discourse about an issue evolves, issues are reframed, reflecting changes in cultural

attitudes. Lawrence (2004) studied the changes in frames of obesity over time by reviewing samples of news texts between 1985 and 2003 consisting of 136 page-one stories from all sections and editorials about obesity published in the *New York Times* and 89 abstracts of U.S. prime-time evening broadcast television news segments about obesity. Changes in obesity frames reflected the shift in public opinion from attributing obesity to individual causes to linking obesity to environmental causes.

Lawrence identified a continuum of discourse, with individualizing frames on one end and systemic frames at the opposite end. Individualizing frames emphasize personal responsibility and define the afflicted individual as the sole cause of the problem and the source of the solution. Systemic frames take a broader view of the issue and use government, business, and social-structural factors, rather than the individual affected by the issue, to define the cause and solution of the problem. Frames about obesity and many other public health issues, in reality, are neither only individualizing nor systemic, but contain elements of both approaches. As the public debate about obesity moved from the individualizing end of the continuum to the systemic end between 1985 and 2003, the public policy environment became more receptive to policy changes that directed the government to take ownership of the obesity issue and highlighted the need for change from stakeholder institutions. There were different types of frames used to portray obesity throughout this time period.

To identify the multiple, competing frames about obesity, research was conducted by reading articles from news sources and scholarly publications,

books, Web sites, and via personal interviews with health experts. Frame categories included biological, behavioral, and environmental frames. The biological frame aligns with the individualized approach and with a medicalized view of obesity that defines its causes as purely physiological and contained within the obese body itself (e.g. genetic disposition). Behavioral causes of obesity (e.g. lack of exercise) focus on individual choices, but can also be seen as responses chosen from a limited range of options, dictated by the environment. The environmental frame places the causes of and solutions for obesity (e.g. marketing of junk food in schools) in the realm of external influences and public policy choices.

The sample of texts included 136 page-one articles from all sections and editorials from the New York Times between 1985 and 2003 and 89 abstracts of the evening network news stories about obesity between 1985 and 2003, drawn from the Vanderbilt Television News Archives. The year 1985 was chosen as a starting point because during that year, the National Institutes of Health declared, for the first time, that obesity posed a major threat to public health. Each news article text was coded for its topical focus and the claims made about the causes of and solutions for obesity. For the television news abstracts, the topical focus of each story was coded, but the abstracts did not provide enough textual detail to allow for coding for specific claims about obesity. To establish generalizability of the data from the news sample in this study, articles about obesity were selected from ten other major newspapers using the Nexis database and coded as well.

A coding scheme was developed for the content analysis. Two individuals performed the coding independently. There were 72 possible points of agreement. The coders reached 87% agreement initially, which increased after points of disagreement were discussed and found to be results of errors in missing phrases and not true differences in coding.

Results of the coding of the news articles and television news abstracts showed similar patterns in the changes of the frames that were used over time. The prevalence of the environmental frame and the behavioral frame increased dramatically in relation to the biological frame between 1985 and 2003. These patterns were consistent with the frames used in the sample of newspaper articles drawn for generalizability.

Kim and Willis (2007) reached similar conclusions in their content analysis of how the news media frame responsibility for obesity, which showed a similar shift away from frames that emphasized individualized causes and solutions toward frames that focused on societal causes of and solutions for the obesity epidemic. Their research focused on a sample of 300 articles published in six major U.S. newspapers (*the New York Times*, *the Washington Post*, *Chicago Sun-Times*, *the San Francisco Chronicle*, and *the Houston Chronicle*) and 200 transcripts from news stories aired by three major television networks (ABC, NBC, and CBS) between January 1995 and August 2004. To locate both the articles and transcripts in the LexisNexis database, they used the keywords “obesity” or “obese” in the fields for headline, lead paragraphs, or index terms. The search yielded 4,552 articles and 1,476 transcripts. Duplicates and irrelevant

articles (e.g. pet obesity) were excluded. The researchers took a systematic sampling to reach the final sample of 300 articles and 200 transcripts.

The codebook designated four main frame categories: personal causes (e.g. consuming too much food), societal causes (e.g. lack of physical activity programs in schools), personal solutions (e.g. medications such as weight-loss drugs), and societal solutions (e.g. taxing unhealthy food). After undergoing training and conducting pilot studies, two coders coded the articles and transcripts. Intercoder reliability, corrected for agreement by chance (Scott's pi), was calculated by coding a random subsample of the data ( $n = 75$ , or 15%). The range of intercoder reliability was 0.74 to 0.86 with a mean of 0.81.

Findings demonstrated a dramatic rise in overall news coverage of obesity. In 1995, there were 277 articles published in the six newspapers, but in 2003 there were 950 articles published. There was an increase in network news coverage from 163 news items in 1997 to over 280 items in 2003. As hypothesized, personal causes of obesity were mentioned far more often than societal causes by a ratio of 2.4 to 1 (291 mentions of personal causes vs. 119 mentions of societal causes). Personal solutions to obesity were mentioned much more often than societal solutions to obesity, for a ratio of 4.3 to 1 (512 mentions of personal solutions to 118 mentions of societal solutions). Mentions of societal causes of obesity increased from less than one in ten references in 1995 to over five in ten in 2004. The rise in usage of news frames that emphasize societal responsibility for obesity reflects the evolving definition of obesity as a public health issue rather than an individual health issue.

In addition, mentions of medical treatments (e.g. weight-loss drugs and gastric bypass surgery), a subcategory of the personal solutions category, decreased significantly after 1997, the same year that the FDA removed the weight-loss drug fen-phen from the market. The authors attribute this decrease in coverage to the publicized side effects of weight-drugs and complications of gastric bypass surgery.

Framing is a powerful way of shaping public opinion. Knowing how framing in the popular media works can help health care practitioners understand how their patients interpret the health information they receive from newspapers, magazines, television, and the Internet. Public health advocates, working with journalists, can encourage the usage of frames that emphasize the benefits of supporting policies designed to improve the long-term health of society despite short-term costs to individuals and stakeholders who are resistant to change.

### **Related Theories: Agenda-setting and Priming**

Communication scholars frequently apply framing theory, agenda-setting theory, and priming theory to analyze how mass media influence the opinions and behaviors of audiences (Scheufele and Tewksbury, 2007). While the news media guide the audience's thinking about issues being covered (framing) and direct the audience's attention toward certain issues by choosing what to report on (agenda-setting), priming occurs when an individual audience member views a television news broadcast or reads a news article and certain features of the story activate the formation of perceptions about how to judge the issues being presented

(McCombs,1997). Framing, agenda-setting, and priming are distinct, yet related concepts.

Agenda-setting theory asserts that the set of issues that the news media covers determines what the public perceives as important (McCombs, 1997). Agenda-setting does not, however, state that the news media push a particular viewpoint for or against the issue, only that the issue is important enough to be on the media agenda and therefore should be on the public agenda. Setting the news media agenda is a routine that occurs during news production as certain topics are chosen to report on and topics are prioritized relative to each other (McCombs and Shaw, 1972).

McCombs and Shaw introduced agenda-setting theory in 1972 with the publication of their research on the effects of newspaper coverage on setting the public agenda. Their study focused on Chapel Hill, North Carolina, voters' attitudes regarding the 1968 United States presidential election. They interviewed 100 citizens between September 18 and October 6, 1968, about their perceptions of the central issues of the campaign and compared those to the actual content in the news media. Researchers developed a coding scheme containing 15 categories of campaign issues and other campaign news to analyze the content of news collected from major media sources: the Durham Morning Herald, Durham Sun, Raleigh News and Observer, Raleigh Times, New York Times, Newsweek, and NBC and CBS evening news broadcasts (McCombs and Shaw, 1972). Results revealed a strong correlation between the issues covered in the news and what the public thought were the key issues of the campaign (McCombs and Shaw,1972).

Agenda-setting is one of the many functions illustrated by the gatekeeping concept, a popular metaphor for describing how a series of decisions to include and exclude information lead to the production of media (McQuail, 2005). Gatekeeping in mass communication can include decisions about selecting which news items to transmit, how to manipulate news messages, when to disseminate news, and overall, how to construct social reality using news information (Shoemaker, 2001). Four types of news gates, or gatekeeping-factors, influence the development of news content: the reporter's judgment about what is newsworthy, journalistic norms and practices that dictate how sources and reporters work together, economic restrictions in news production, and technological limitations (Livingston and Bennett, 2003).

The news media can influence public opinion in favor of interest groups, policymakers, and journalists themselves because the quantitative amount of attention given to a topic by these stakeholders is a factor in creating the media agenda (Scheufele and Tewksbury, 2007). Subsequent studies have examined the relationship between the media agenda and the public agenda, expanding the concept of the agenda to include personal issues (e.g. health) as well as political issues (McCombs, 1993).

Agenda-setting can play a powerful role influencing public opinion and, therefore, action, regarding health-related issues. According to Yang and Stone's 2003 research, people receive 80% of their information about news and public affairs from mass media, compared to 20% from interpersonal communication (Jones, Denham, and Springston 2006). Jones, Denham, and Springston (2006)



compared the effects of mass media (magazines, newspapers, and television) and interpersonal communication on breast cancer screening practices among college-aged women and their middle-aged mothers (n = 284). They hypothesized that mass media would be more influential on screening adoption rates among the older women than the younger women because they would be more likely to have been personally affected by breast cancer in some way and to seek information about it from media sources. They also hypothesized that for the younger women, interpersonal communication (specifically from their mothers) would be more influential than mass media on breast cancer screening practices, because they were less likely to be affected by breast cancer personally and less likely to seek out information about it from media sources. Researchers distributed questionnaires to college-aged women and their mothers about their exposure to media sources of information about breast cancer (e.g. television, magazines, newspapers), breast cancer screening practices (e.g. breast self-exams, mammograms), interpersonal sources of information about breast cancer (e.g. friends, relatives, physician), and family history of breast cancer. Consistent with the hypotheses, findings showed that the mothers received most of their information from media sources, while the daughters received most of their information from interpersonal sources. Among the mothers, reading a news magazine article about breast cancer had highly significant ( $P < 0.001$ ) effects on the frequency of undergoing mammograms. Discussing breast cancer with a relative was predictive of more frequent screening practices among the younger women. It is logical to conclude that the daughters relied on their mothers for

information about breast cancer, consistent with the two-step flow of information theory of communication. By providing news coverage on breast cancer, the media placed breast cancer on the public agenda. Agenda-setting increased the salience of breast cancer information to the audience of older women, who transmitted the information to their daughters.

Communication scholars have defined two levels of agenda-setting. The first level focuses on the salience of one issue relative to others in the news (Weaver, 2007). By granting specific issues a great deal of news coverage or conspicuous placement (e.g., the front page of a newspaper above the fold), the news media can influence the audience to consider those issues more important than others (Scheufele and Tewksbury, 2007).

The second level of agenda-setting examines the salience of the attributes, or characteristics, of an issue (Weaver, 2007). The most salient characteristics form a set of criteria that the audience uses to form opinions and make judgments about the issues (McCombs, 1993). There is conflict in the research literature about whether or not the second level of agenda-setting is synonymous with framing.

McCombs conceives of framing as an extension or refinement of agenda-setting (Scheufele and Tewksbury, 2007). He defines framing as emphasizing certain characteristics of an issue, which increases their salience (Scheufele, 2000), which sounds equivalent to his explanation of the second level of agenda-setting as using a set of the most salient characteristics of the issue to judge the issue: (McCombs, 1997).

Different conceptual definitions of framing complicate the debate. A constructionist view of framing defines framing as a cultural phenomenon that is far larger than agenda-setting. McCombs, Shaw, and Weaver (1998) and Tversky and Kahneman (1973) tend to accept framing as similar to agenda-setting because they view both processes as being based on the concept of accessibility, or retrievability, of information from the memory.

On the other hand, some researchers who also take a cognitive view of framing argue that framing and agenda setting are based on different theoretical premises and are therefore inherently different. Scheufele points out that framing, by manipulating linguistics to describe an issue, causes an individual to utilize an existing paradigm or schema to interpret the information about the issue (Scheufele, 2000). This is a very different cognitive processing model than accessibility. In addition, framing goes beyond selecting which attributes to emphasize (the definition of the second level of agenda setting) and attempts to control the audience's perceptions about multiple dimensions of the issue by using semantic techniques that imply causes and solutions, make assessments, and define issues subjectively (Weaver, 2007).

Yet another alternative conceptual distinction between the second level of agenda-setting and framing is that the salience of frames is based on the relevance of the traits used to describe the issue (Entman, 1999). Entman points out that research by Nelson and colleagues in 1996 and 1997 reinforces the view that some frames resonate more because certain emphasized characteristics are

perceived to have greater importance to the issue, and not because they are more accessible in the audience's memory.

Priming theory frequently intersects and overlaps with framing theory and agenda-setting theory. While agenda-setting is a media routine that turns the audience's attention toward certain issues and framing is a journalistic approach that shapes how the audience perceives issues presented in the news, priming is a cognitive process that occurs in the mind of the individual when exposure to news content activates a set of criteria for evaluating the issues or subjects being covered (Scheufele and Tewksbury, 2007). The concept of priming originated as a speculation by Weaver, McCombs, and Spellman in their 1975 study of the effects of Watergate news coverage. The trio proposed that through priming, the media influence audiences to use specific standards to judge political figures, with these standards leading toward or away from a particular political conclusion (Weaver, 2000).

The term priming was first used in Iyengar and Kinder's 1987 research experiments, which revealed a connection between the agenda-setting effects of television news reports and audience opinions of the U.S. president. They concluded that this connection was the effect of priming, defined as increasing the salience of particular issues or attributes and therefore more easily accessed in the memory and used to form beliefs (Weaver, 2000). Priming can influence the audience's opinion in positive and negative directions. An analysis of agenda-setting and priming effects used a sample of front-page articles about the economy from two leading Israeli newspapers during five election years and data

from public-opinion surveys from the same time period. The study revealed that priming can take a positive, negative, or neutral tone toward an object or attributes and sway public opinion in that direction as well (Sheafer, 2007).

In the communication-research literature, there is widespread agreement that priming is an extension of agenda-setting. Studies on priming position agenda-setting as the independent variable and priming effects as the dependent variable (Scheufele, 2000). Studying priming is equivalent to studying the effects of agenda-setting on public opinion (Weaver, 2007). Both agenda-setting and priming are founded on the principle of accessibility; people use the most readily accessible, or retrievable, information from their memory to make decisions (Scheufele and Tewksbury, 2007).

While priming has much in common with agenda-setting, priming differs from framing. Framing has a broader range of functions than priming. In contrast to agenda-setting and priming which are based on accessibility, framing relies on a model of information-processing that is based on influencing how information is received and categorized (Weaver, 2007). Framing is based on the principle of applicability; framing creates a connection between two concepts, e.g. by persuading the audience to believe that Attribute A is applicable to Issue B (Scheufele and Tewksbury, 2007). A key distinction is that the passage of time affects accessibility (and therefore the effects of agenda-setting and priming) far more than applicability (and therefore the effects of framing) (Scheufele and Tewksbury, 2007).

Framing, agenda-setting, and priming are interrelated models of how the news media affect the formation of opinions and influence behaviors. By understanding how these mechanisms work, practitioners in health-related fields can partner with the media more effectively to increase the effectiveness of health campaigns aimed at the public.

## Section 3

### **Mass Communication Theories**

Newspapers, the focus of this research study, continue to be highly trusted sources of health information. A 2002 Gallup Poll on the use of media reports of health and medical news found that 64% of respondents reported having a great deal or a moderate amount of trust in information received from newspapers (Minnesota Medical Association, 2003). There is no doubt that television, radio, newspapers, magazines, and the Internet influence the attitudes and behaviors of billions of individuals to some extent. But this amount of influence varies greatly in different circumstances. Research on how mass communication works has generated many theoretical models, shaped by history, politics, social science, and technology (McQuail, 2005).

This section will contribute to an understanding of how messages from the mass media, in the form of newspaper articles, contribute to people's decisions about health behaviors such as using weight-loss drugs. Major mass communication theories include the magic bullet (or the hypodermic needle) theory, cultivation theory, McGuire's communication/persuasion model, and the diffusion of innovation theory.

#### **Magic Bullet Theory**

From the turn of the century until the 1930s, people believed that the mass media, in the form of newspapers, film, and radio, had an extremely powerful influence on public opinion. Political propagandists used film to create support for World War I. Messages from advertisers influenced consumer behavior. Public

concern about the effect of movies on the actions of individuals, especially on young people, led to a series of psychological experiments from 1933 to 1935 known as the Payne Fund Studies. The results, which some believed were based on flawed research methodology, seemed to support the idea that the audience was incapable of resisting the powerful messages being transmitted through movies (Martinson, 2004).

Results of the Payne Fund Studies reinforced magic bullet theory (or hypodermic needle theory), an approach which dominated early communications research, in which the audience plays a passive role and the media has “immediate, uniform, and powerful effects” on anyone exposed to its messages (DeFleur, 1998). The metaphor of the media as “a dangerous drug or a killing force that directly and immediately penetrate a person’s system” was widely accepted (Martinson, 2004). Brown’s 1937 article “Media of Propaganda” demonstrated society’s deep concern about the power of the press, the radio, and the motion picture to incite support for war among an audience unable to resist mass media’s messages (Brown, 1937).

Progressive propaganda critics presented an alternative paradigm to traditional magic bullet theory. They focused on the role of institutions in creating the media messages designed to sway public opinion and they viewed the audience as having the potential to resist media messages through critical thinking (Sproule, 1989). The work of progressive propaganda scholars was considered a “socially divisive anachronism” during the post-World War II era and fell out of favor in the field (Sproule, 1989).



In 1938, a CBS radio broadcast presented a fictional production of “War of the Worlds.” Designed to entertain the public, the broadcast had the unintended effect of discrediting magic bullet theory by eliciting a non-uniform response from the audience (Martinson, 2004). There was no single mass response to the broadcast describing a Martian invasion of the planet; some people thought it was a real news story and reacted with panic and fear, but others did not (Martinson, 2004). This was a direct contradiction of one of the chief tenets of magic bullet theory, the expected uniformity in the audience’s reception of and response to the media’s message (Sproule, 1989). Data from the radio station revealed that the level of education was the best way of predicting whether the listener would accept the information as real (Martinson, 2004).

In the wake of the “War of the Worlds” program, the media’s influence began to be perceived as limited and dependent on audience-related factors (DeFleur, 1998). The “direct effects” model of the media evolved into “limited effects, minimal effects, conditional effects, and the ‘two-step flow’” (Servaes, 1995). A study in Erie County, OH, of the 1940 United States presidential elections generated the concept of the “two-step flow of communication” (Servaes, 1995). Instead of a direct relationship between the “stimulus” and “respondent”, as in the magic bullet theory, there is a “two-step flow” of influence (McQuail, 2005). According to the two-step model of communication, the media’s messages flow to opinion leaders who then disseminate the information to people on whom they are influential (Katz, 1957). The population is divided into two groups: “active” and “passive” participants, or “opinion leaders” and

followers” (Servaes, 1995). In the late 1940s, Lazarsfeld and his colleagues in Columbia University’s Bureau of Applied Social Research asserted that media effects are dependent on an individual’s pattern of media consumption and social network, which tend to create support for pre-existing opinions rather than changing them (Scheufele, 2007).

### **Cultivation Theory**

Cultivation theory originally focused on the long-term influence of television viewing on the audience’s perceptions of reality, but has been expanded to include the cumulative effects of consuming all forms of mass media. The original cultivation theorist, George Gerbner, viewed television as an enculturating force in society whose job is to condition viewers by presenting views of reality that support the established social order (Gerbner, 1976). Exposure to television reinforces norms of “social reality” by presenting the television version of reality as “what most people do”, as well as portraying norms for individual behavior by showing “personal reality” with which the viewer identifies (Austin and Meili, 1994).

A cultivation analysis compares the perspectives represented on television with views expressed by the audience; the hypothesis is that the greater the amount of television watched, the more the audience’s views will correspond to the version of reality shown on television (McQuail, 2005). Gerbner created a system of cultural indicators, or cultural messages, being expressed through television (Potter, 1993).

Gerbner's 1976 study revealed that heavy exposure to television (greater than 4 hours per day), which presents a more violent version of reality, creates excessive fears about danger and mistrust (Gerbner, 1976). Hammermeister and colleagues (2005) found an association between watching television at least two hours daily and exhibiting negative psychosocial health characteristics such as loneliness and depression (Hammermeister, Brock, Winterstein, and Page, 2005). Many studies have established that heavy television viewing is associated with negative health conditions such as obesity, poor nutrition, body image issues, and aggressive behaviors; television programs display adverse health behaviors such as smoking cigarettes, alcohol abuse, and illicit drug use and television content commonly includes messages condoning violence, exaggerated sexuality, and distorted body-image (Hammermeister, 2005). Hampl and colleagues (2006) used cultivation theory to explore the cumulative effects of direct-to-consumer (DTC) advertising for prescription medications on consumer behavior; they suggested that continual DTC advertising fosters among consumers a sense that an illness is more prevalent in society than it actually is and that the prescription medication being advertised would wholly resolve a particular health issue (Hampl, Bramlett-Solomon, and Wharton, 2006).

In their cultivation analysis that focused on the influence of children's television programming on children's food preferences and views about nutrition, Signorielli and Staples (1997) reported a strong positive correlation between watching more television and preferring an unhealthy foods over healthy one, and a strong positive correlation between watching more television and perceiving

unhealthy foods to be healthy. They concluded that the pervasive television messages promoting unhealthy foods to children are a factor in creating misconceptions about nutrition and weight issues among children.

Cultivation theory has its limitations, however. As in the magic bullet theory and the two-step flow of communication, in cultivation theory, the underlying assumption is the audience is passive, not active, and accepts messages from mass media uncritically (Hesse-Biber, Leavy, Quinn, and Zoino, 2006). Austin and Meili (1994) demonstrated that parental role modeling modified television's influence on children's intentions about drinking alcohol. Hesse-Biber and colleagues note that despite that the barrage of messages from the media idealizing an extremely thin female body shape and promoting this ideal as a realistic and attainable goal, there are some women who are able to resist these destructive messages; more research is needed to determine the psychological and social factors that protect against developing eating disorders (Hesse-Biber et al., 2006). Potter (1993) argues that the concepts on which cultivation theory is based should be redefined in order to strengthen its value as an analytic tool.

### **McGuire's Communication/Persuasion Matrix**

McGuire, a Yale psychology professor, created a theoretical model that explains the range of audience responses to the mass media's messages. In direct contraction of the magic bullet theory's assumption of a single uniform interpretation of media messages by the audience, he developed a communication/persuasion matrix consisting of a system of inputs and outputs

that describes how audience responses to mass media vary based on characteristics of the communication. In the matrix, the input variables are the column headings and the outputs are the row headings; each cell contains the relationship between the two, as determined through empirical research or theorizing (McGuire, 2000).

There are five types of input communication variables: source (who says it), message (what is said), channel (via which medium e.g. newspaper), receiver (to whom), and target (aimed at changing what) (McGuire, 2000). The output steps are the twelve possible outcomes of being persuaded by the communication, such as message exposure, attention, liking, comprehension, skill acquisition, yielding, memory storage and agreement, information search and retrieval, deciding, behaving, reinforcement, and postbehavioral consolidation (Bull, 2001). These output steps precede behavior change, the goal of the communication campaign (Glik, 2007). McGuire recommends success at each output step in order to optimize the likelihood of behavior change; he attributes many communication failures to focusing on only one or two of the output steps and neglect of the others (Bull, 2001).

McGuire's communication/persuasion matrix is a classic theoretical model within the discipline of health promotion and communication; practitioners must optimize the input variables in order to plan a communication campaign that persuades people to change health behaviors (Glik, 2007). For example, while designing the message, there are many factors to consider. The message category, one of the five categories of input variables, can be subdivided into categories

such as type of argument, inclusions and omissions, ordering, extremity, and style; the style subcategory can be further divided into variables such as intensity, complexity, humor, and literalness vs. figurative language (McGuire, 2000). All of these factors within the message category, combined with the other categories, contribute to the overall success of the persuasive communication.

Using McGuire's model of inputs and outputs as an analytical framework, Bull and colleagues (2001) evaluated the impact of three types of printed health education materials (HEMs) about weight loss on an audience of 198 overweight adults who were interviewed and who completed questionnaires before and after viewing the HEMs (Bull, Holt, Kreuter, Clark, and Scharff, 2001). They assessed psychosocial, demographic, and physical characteristics of the receivers; psychosocial characteristics included the participants' weight locus of control, readiness to lose weight, level of self-efficacy, and existing knowledge of the information in the HEMs, and age, gender, level of information, and BMI, as calculated from measured height and weight, were recorded as well. Other inputs that were assessed included the preparedness to read printed materials (a channel factor), the perceived credibility and attractiveness of the HEMs (source factors), and the perceived degree of informativeness, encouragement, usefulness, and applicability to one's life of the HEM (message factors). Researchers measured ten output variables: exposure, attention, liking, understanding, skill-acquisition/learning how, yielding, memory storage/agreement, information search and retrieval, deciding, and behaving. They reported that early output steps (attention, liking, and understanding) and the mediating output steps (recalling,

keeping, and rereading HEMs) were associated with attractiveness of the materials, encouragement, level of information, and application to one's life. Behavior change was more likely among participants who had higher self-efficacy and had received customized HEMs. They concluded that not all output steps were necessary for behavior change and that the HEMs perceived applicability to one's life was the most important input variable for predicting the success of the HEM (Bull et al., 2001).

Houts and colleagues (2006) reviewed nineteen peer-reviewed health education studies which examined the role of pictures in health communications (an input variable which falls into the category of message factors), and assessed attention, comprehension, recall, and adherence which align with the output steps, attention, comprehension, memory, and acting on the decision (Houts, Doak, Doak, and Loscalzo, 2006). Health communication topics included wound care, instructions on when to take medicine, and breast self-examination. Results showed that pictures do have significant potential to improve the effectiveness of the health communication, especially among a low-literacy population, but interpretations of the messages can vary according to many factors such as cultural differences. They recommend evaluating the success of the communications materials through follow-up interviews, in a clinical setting, that assess the outcomes of attention, comprehension, memory, and acting on the decision (Houts et al., 2006).

Kelly and colleagues (2009) administered a randomized telephone survey among five underserved zip codes to assess the input characteristics of their target

population during the design phase of a public health campaign to encourage awareness of cancer family history and to promote usage of an Internet-based cancer risk assessment tool (Kelly, Sturm, Kemp, Holland, and Ferketich, 2009). They developed a system of measuring receiver variables (e.g., demographics, worry), source variables (e.g., credibility, attractiveness), channel variables (e.g., modality, efficacy), message variables (e.g., type of appeal, discrepancy from initial position), destination variables (e.g., attitude change vs. behavior change, immediate vs. delayed). Results regarding receiver characteristics showed that race (African American vs. Others) resulted in few statistically significant differences and that a lower level of education was associated with a lower likelihood to seek information from the Internet. The most preferred source of information was a family member. All channels were rated highly, especially the Cancer Information Service and public libraries. Regarding the message factors, they found that there was little need to promote the importance of knowing one's cancer family history, as most already agreed, but that designing a message to encourage action, such as sharing cancer family history with a physician, was more appropriate. Results regarding destination factors showed the need to promote behaviors to assess cancer risk such as seeking computerized risk assessment tools (Kelly et al., 2009).

### **Diffusion of Innovation**

With the publication of his classic 1962 book *Diffusion of Innovations*, Everett Rogers popularized the diffusion of innovation theory to explain how new ideas spread throughout society. Diffusion is a specialized form of



communication because the content of the messages is perceived as new and therefore carries a degree of risk, or uncertainty (Rogers, 2002). There are four stages in adopting an innovation: knowledge of the innovation, persuasive communication about the innovation, the decision to adopt or reject the innovation, and confirming the acceptance of the innovation. An innovation is more readily diffusible if it is compatible with existing beliefs, easy to try, observable, is perceived as low risk, and offers relative advantages to the status quo (Smith, 2004).

One can classify the population in terms of readiness to accept new ideas: first are the innovators (2.5 %), then the early majority (13.5%), the late majority (34%), the late adopters (34%), and finally, the laggards (16%) (Rogers, 2002). A successful community nutrition program that increased the practice of exclusive breastfeeding for the first six months among mothers in Ghana demonstrated the classic early adopters/late adopters pattern of adopting innovation (Smith, 2004). The diffusion of exclusive breastfeeding spread with ease throughout the social group because it met the ideals of “compatibility, trialability, observability, not being too risky, and relative advantage” (Smith, 2004).

Vermeer and colleagues (2009) conducted a qualitative study in the Netherlands using the diffusion of innovation model to assess the feasibility of a variety of interventions aimed at reducing portion sizes of foods, e.g. offering a self-portioning option in which the customer selected the portion size of the food (Vermeer, Steenhuis, and Seidell, 2009). They held semi-structured hour-long interviews with 22 individuals, using an interview guide that explored perceptions

of the relative advantage, risks, complexity, and communicability of each portion-size intervention (Vermeer et al., 2009).

Nanney and colleagues (2007) conducted a survey of 675 educators from 48 states to evaluate their awareness of, and subsequent adoption of, a nationally disseminated dietary curriculum called High Five, Low Fat (H5LF) (Nanney, Haire-Joshu, Brownson, Kostele, Stephen, and Elliott, 2007). The survey asked about key factors influencing the adoption of a dietary curriculum: time required, communicability, complexity, risk commitment, complexity, relative advantage, compatibility, relative advantage, and impact on social relations (Nanney et al., 2007). Compared to non-adopters of the curriculum, adopters of the curriculum were almost 8 times more likely to identify training time as a factor influencing adoption and almost 7 times more likely to identify the CD training method as a factor influencing adoption.

Rogers emphasizes the effectiveness of the mass media in the first stage of the process, spreading information about the innovation (Servaes, 1995). Barker (2004) described a successful program to increase vitamin A status through food-based programs in Nepal, where health issues due to vitamin A deficiencies contribute to the country's high infant and mortality rate. The Market Access for Rural Development program focused on promoting fruit and vegetable crops and used nutrition demonstration households with kitchen gardens to increase production and consumption of foods rich in vitamin A. The number of households with kitchen gardens increased by tenfold (from fewer than 100 to 1131) within a year of the launch of a communications campaign that

educated women about the risks of vitamin A deficiencies and the benefits of cultivating kitchen gardens with foods rich in vitamin A. The program's success was in part due to an increased focus on promoting awareness of the program itself and providing information on its benefits to the target families (Barker, 2004)

## Section 4

### **Health Behavior Theories**

Rich in theory-based interventions, the research literature about health behavior change focuses on why and how individuals and communities adopt new health behaviors. This section reviews the health belief model, social cognitive theory, the transtheoretical model, and hope theory. Within each of these theoretical models, the mass media plays a role in influencing consumers in the arena of decisions about health, nutrition, and usage of weight loss products. According to the health belief model, the content of media messages can induce dieting behavior by increasing perceptions of susceptibility and severity of obesity and decreasing the perceived barriers to change. Social cognitive theory acknowledges the interactive influence of media and society on creating the media agenda about nutrition-related topics. The transtheoretical model shows that media messages about weight loss may resonate with people contemplating change. In hope theory, individual and collective hopes for weight loss can be inspired by media campaigns.

### **Health Belief Model**

For over half a century, the health belief model has provided a useful set of principles for designing and evaluating health interventions. The theory explains an individual's likelihood of making a behavioral change according to a subjective cost-benefit analysis that takes into account the individual's perceived susceptibility to an illness, perceived severity of the illness, perceived benefits of the new health behavior, and the perceived barriers to executing the new health

behavior (Becker, Maiman, Kirscht, Haefner, and Drachman, 1977). Perceived susceptibility, or vulnerability, to a specific negative health outcome is a perception of risk that varies among individuals. The perception of a disease's severity, with respect to medical, social, and financial consequences, differs among individuals as well. An individual will adopt a new health behavior if the perceived benefits of the action outweigh the perceived barriers, such as financial costs or inconvenience (Janz and Becker 1984 p. 2). While not explicitly mentioned in the health belief model, demographic and structural variables influence health behavior as well; for example, socioeconomic status and educational level may affect perceptions of susceptibility to and severity of disease as well as perceptions of benefits and barriers (Champion and Skinner, 2008).

In addition to the four classic constructs, a key element of the health belief model is the cue to action, which is a stimulus to the health behavior; cues to action are assumed to be widely available in the environment (Becker et al., 1977). Mass media messages encouraging the consumption of fruits and vegetables, discouraging sedentary behavior, and promoting weight loss are examples of cues to action. Insufficient attention, however, has been given to the role of cues to action in the health behavior change research literature (Johnson and Meischke, 1993).

Ogden and Hills (2011) recognized the importance of cues to action as they explored themes from the health belief model during qualitative interviews with 34 adults who had maintained successful long-term (> 3 years) behavioral

changes in weight through diet and exercise (n = 24) or stopped smoking (n = 10). They reported that life crises such as relationship break-ups and adverse health events served as triggers (similar to cues to action) for behavioral change in the short term. For example, one subject said that having his fourth heart attack at the age of 37 caused him to commit to taking orlistat to help him lose weight . They found that one condition for sustaining long-term behavioral change was the belief in a connection between the individual's behavior and resolving the health issue; this concept is related to the construct of perceived benefits of the health behavior in the health belief model (Ogden and Hills, 2011).

The original health belief model was based on taking action to avoid disease, but since then, the motives for changing health behavior have been expanded to include achieving better health, improved body image and greater social acceptance, and avoiding or treating obesity (Becker et al., 1977). Key theoretical assumptions include the importance of the individual's internal locus of control over behavioral change rather than on environmental or community factors and the idea that health is a highly-valued goal (Janz and Becker, 1984). Another underlying premise is that cognitive processing is responsible for decision-making related to health behavior (Glik, 2007).

There is debate in the literature about the role of self-efficacy in initiating health behavior change. Rosenstock, Strecher, and Becker (1988) proposed adding the concept of self-efficacy, or competence at performing the intended behavior, as a distinct construct of the health-belief model because enacting long-term behavioral change, such as modifying dietary habits, requires an individual

to have high self-efficacy. Other researchers, such as Janz and Becker, include self-efficacy in the category of perceived barriers (Janz and Becker, 1984).

The health belief model traditionally looks at initiating behavior change in the short term. Sun and colleagues (2007) conducted a community-based intervention promoting the consumption of iron-fortified soy sauce through mass media and interpersonal communication among Chinese women at risk of iron-deficiency anemia; the outcome measures were based on the concepts of the health belief model (Sun, Guo, Wang, and Sun, 2007). Both the control and intervention groups in the rural (n = 193) and urban (n= 179) populations were exposed to newspaper and television media messages about iron-fortified soy sauce. The intervention groups also received nutrition and health lectures and health counseling about iron deficiency, calendars containing information about iron-fortified soy sauce, and gift bags of iron-fortified soy sauce. Before and after the intervention, researchers administered a questionnaire, using Likert-type scales, which included items designed to assess the subjects' perceived benefits of using iron-fortified soy sauce and perceived barriers (for example, a fear of the taste of dishes being altered). Researchers concluded that the intervention was successful because knowledge, purchase, and use of iron-fortified soy sauce increased and because perceptions of iron-fortified soy sauce were improved, as measured by the increase in scores regarding perceived benefits and the decrease in scores regarding perceived barriers (Sun et al., 2007).

Petrovici and Ritson (2006) utilized the health belief model to predict dietary health preventive behavior in an at-risk Romanian population. Results of

administering face-to-face questionnaires to 485 adults showed that health motivation, perceived diet effectiveness, and knowledge about nutrition were significant factors in predicting positive behaviors related to diet; they were surprised to find that the perceived threat of disease had a negative rather than the expected positive association with dietary health preventive behavior. They concluded that future health interventions should clarify the connection between health behavior and outcomes in order to improve perceived benefits among the public (Petrovici and Ritson, 2006).

The health belief model lends itself well to qualitative, exploratory research. Liou and Bauer (2007) used the concepts of the health belief model, among other health behavior theories, to design an interview guide used in a study of dietary determinants in obesity. They conducted semi-structured interviews with 40 Chinese American adults between the ages of 18 and 30 in the New York City metropolitan area. Interview questions included explicit questions about the benefits of a healthier diet and barriers to eating healthfully. To assess perceived severity, they asked: “What are some health consequences of obesity?” They investigated the theme of perceived susceptibility through questions such as: “Do you think obesity is a health concern for Chinese Americans? Do you personally feel susceptible to obesity?” What are the major causes of obesity in Chinese Americans? Are US-born or foreign-born individuals more prone to this condition?”. They found that the perceived benefits of eating healthfully and being physically active included having a decreased risk of illness and a longer life span. The perceived barriers were the availability of convenient fast food,



mass media advertising, the lack of available and affordable healthy foods, lack of social support for healthful eating, and taste preferences for foods high in fat and refined carbohydrates. They found that sixty percent of the participants felt susceptible to obesity. They identified peer support and mass media as cues to action. Environmental factors were perceived to have the strongest influence on food behavior and risk of obesity. They determined that social support is necessary for maintaining positive health behaviors (Liou and Bauer, 2007).

In the health belief model, the mass media can play an important role in communicating the benefits of a health behavior, minimizing barriers, and promoting perceptions of susceptibility and severity, in addition to presenting cues to action. Larsson and colleagues (2004) incorporated the health belief model into a questionnaire sent to an intervention group (n = 261) and a comparison group (n = 206) to evaluate a health intervention that promoted the usage of emergency contraceptive pills using several channels, including a mass media campaign that spread information through advertising in the local newspaper and student newspaper, mounting posters in universities and student clubs and advertising on buses (Larsson, Eurenus, Westerling, and Tyde, 2004). They concluded that the intervention was successful at increasing the likelihood of taking action if necessary (using emergency contraceptive pills) and that perceived barriers of side effects declined over time in the intervention group.

In a review of forty-six studies based on the health belief model, researchers reported that perceived barriers is the construct that had the strongest correlation with the specific health behavior being studied (Janz and Becker,

1984). This result may be attributed in part to the relative simplicity of operationalizing this construct, whereas perceived susceptibility, perceived severity and perceived benefits may be more difficult variables to operationalize, or to standardize across research studies. A limitation of the health belief model is that a standardized scale for each construct, in relation to a specific health behavior being studied (e.g. getting a mammography vs. a colonoscopy), and in relation to a specific target population (e.g. segmented by race, age, socioeconomic status, and gender), does not generally exist in the research literature (Champion and Skinner, 2008). The predictive power of the health belief model depends on the accuracy of operationalizing and measuring each construct; therefore, the health belief model's strengths may lie in explaining rather than predicting. It was created, after all, by a group of social psychologists at the U.S. Public Health Service in the 1950s in order to make sense of the public's failure to comply with medical recommendations to prevent disease or obtain screening tests for early detection of disease (Janz and Becker, 1984).

The health belief model may be more powerful in explaining some health behaviors than others. While researchers Johnson and Meischke acknowledge the value in the model's applicability to preventive health behavior, they did not find it to be useful when applied to information-seeking about breast cancer mammography screening in magazines (Johnson and Meichke, 1993). They conducted telephone interviews with 366 women over the age of 35 and asked questions about health-related factors such as demographics, direct experience with breast cancer, salience of breast cancer information (related to perceived

susceptibility and perceived severity), and beliefs about medical procedures related to cancer in addition to their information-seeking behavior. They concluded that for this particular health behavior, information carrier factors (such as editorial tone) are more important than health-related factors; the health belief model traditionally does not address the nuances of information delivery. They found the “two-step flow” communication theory, with magazine editors as the opinion leaders and readers as the followers, to be more relevant to information-seeking health behavior than any health behavior theories (Johnson and Meischke, 1993).

There are many related concepts among the health belief model and other health behavior change theories. They are perhaps most useful in combination rather than in isolation. The inherent differences in the range of health behaviors make it very difficult for one theory to fit all of them. Health behaviors do not exist in isolation from other non-health behaviors either. Other theoretical models, as in the Johnson and Meischke study, may be more appropriate in some cases.

### **Social Cognitive Theory**

Social cognitive theory is the most common foundation for weight management interventions and is frequently used to create physical activity interventions (Palmeira, Teixeira, Branco, Martins, Minderico, Barata, Serpa, and Sardinha, 2007). In social cognitive theory, human behavior arises from a dynamic interaction of internal, behavioral, and environmental factors that influence each other bi-directionally (Bandura, 2001). Social cognitive theory

evolved from social learning theory, which posits that expectancies and perceived incentives guide behavior changes (Rosenstock, 1988). When concepts about human cognition and processing were integrated into social learning theory, it was renamed as social cognitive theory (Viswanath, 2008). Social cognitive theory is based on the principle of reciprocal determinism, in which people and their environments are continually shaping and changing each other. Neither solely dependent on environment, nor predestined to act according only to internal beliefs, individuals are “self-organizing, proactive, self-reflecting, and self-regulating” (Bandura, 2001).

The capacity for observational learning is a key component of social cognitive theory, in which individuals can learn, not only from their own trial and error experiences, but also through observing the behavior and outcomes of others (Young and Cline, 2005). There are four processes involved in observational learning: attention, retention, behavioral production, and motivation (Bandura, 2001). Young and Cline (2005) utilized the concepts of observational learning in their study of 225 direct-to-consumer prescription drug advertisements in 18 consumer magazines; they found that the advertisements contained visual and textual cues (e.g. medical rewards, gaining freedom, and achieving normality in one’s life) to motivate consumers to communicate with their health-care providers about usage of the advertised drug.

According to Bandura, “health is a social matter, not just an individual one” (Bandura, 2004). While environmental factors influence behavior, people’s behavior shapes social systems (Bandura, 2001). Sustaining health behavior

change, therefore, requires individuals to change their environment to support the new behavior.

The mass media is a powerful environmental determinant of health behavior. Media often contributes in negative ways to reinforcing unhealthy behaviors, however. In order to improve the collective health status of society, the mass media must be transformed into a force that facilitates positive health behaviors such as achieving and maintaining a healthy weight, eating a balanced diet that includes vegetables and fruits, getting regular physical activity, and abstaining from smoking.

In the social cognitive view, mass media has two main modes of influence. In the direct pathway, media can provide information about health behavior change, demonstrate social models of change, offer motivations, and provide strategies for change, e.g. by covering nutrition and health issues and by influencing consumers' purchasing decisions (Bandura, 2004).

In the socially mediated pathway, the media helps individuals connect with social networks and community settings, which offer interpersonal social support, guidance, and motivation for health behavior change (Bandura, 2004). Critical evaluations of the outcomes of public health campaigns that utilize the media are essential (Noar, 2006).

Through the process of agenda-setting, "people are producers as well as products of social systems" (Bandura, 2001). Campo and colleagues (2009) applied social cognitive theory to their analysis of newspaper coverage of articles about college binge-drinking (Campo, Askelson, Mastin, and Slonske, 2009).

They examined strategies for addressing college-binge drinking in 255 articles from 32 major U.S. publications over a period of ten years between 1997 and 2006. They found that while there was a mix of individual-focused and environment-focused strategies for addressing college binge-drinking, there was a general lack of coverage of the issue and a lack of evidence-based strategies being presented in favor of describing actual health interventions which were not established based on scientific evidence. They identified a need for media advocacy, which involves working directly with the media to frame college-binge drinking as a public health issue. Media advocacy goals would include placing college-binge drinking on the public health agenda and emphasizing the need for evidence-based solutions to be incorporated into practice (Campo et al., 2009).

Mass media communication can affect perceived norms, influence individual attitudes about the health behavior, enhance perceived susceptibility to an illness, and increase self-efficacy or confidence about taking action, which in turn affect health behaviors (Randolph, 2004). Editorial content of women's magazines is a highly influential force on setting social norms regarding women's health behaviors. Cho and colleagues (2010) analyzed 250 articles about tanning and skin cancer risk and prevention from eight popular women's magazines from 1997 to 2006 and reported that the focus was primarily on skin cancer prevention and the adverse consequences of suntanning; however, there is a need for more coverage of consequences of tanning bed use and for more recommendations to use multiple methods of sun protection in addition to sunscreen, such as staying in the shade and wearing protective clothing (Cho, Hall, Kosmoski, Fox, Mastin,

2010). Improving the quality of health-related messages in women's magazines would contribute to social norms that promote positive health behaviors.

Self-efficacy, the belief that an individual is capable of taking action, is a key social cognitive construct which is essential for initiating and sustaining behavior change (Bandura, 2004). Palmeira and colleagues (2007) utilized social cognitive theory and three other health behavior change theories to predict short-term weight loss among 142 overweight and obese women participating in a 16-week weight loss intervention that included weekly group education sessions that included content on exercise, nutrition, and behavior modification; results showed that self-efficacy regarding weight management, as measured by a questionnaire, was the strongest predictor of weight loss (Palmeira et al., 2007).

One effective way of increasing self-efficacy beliefs is through vicarious experiences gained through social modeling (Bandura, 1998). The individual identifies with social models who are similar to themselves and who have taken action to change their health behavior. Social models provide strategies for overcoming challenges presented in the environment. The mass media can present positive social modeling for the purpose of health promotion. Conversely, negative social modeling in the media can adversely affect health promotion efforts. Using rhetorical and content analysis, Dutta and Boyd (2007) examined depictions of the "smoking man" in advertising and editorial content in three popular men's magazines and found that men who smoked were portrayed as independent, mysterious, sensual, and belonging to another place; these images of smoking men embody the masculine ideal of rugged individualism. They

recommend creating media content that specifically counteracts these images (Dutta and Boyd, 2007).

Mass media messages should focus on both individual and environmental changes to optimize the power of reciprocal determinism in reinforcing healthy behaviors. Campo and Mastin (2004) studied 406 articles addressing overweight and obesity in African-American women's magazines and mainstream women's magazines from 1984 – 2004; in their content analysis, they found 60 strategies for preventing and treating overweight and obesity and that the focus of these strategies was overwhelmingly on individual behavior rather than on environmental factors. Individual behavior-focused changes, such as participating in moderate or regular exercise and eating a balanced diet or fewer calories, comprised 83.3% of the strategies. Cognitive or affective strategies related to personal change, such as increasing self-acceptance, were less common, at 21.7%. Environmental changes, such as getting support from family and friends and removing cues that trigger eating, made up just 6.7% of the strategies. They concluded that in order to improve rates of overweight and obesity in society, public health practitioners should advocate for mass media content that focuses more on changes that can be made in the environment. They also found that strategies related to self-efficacy, were presented much less frequently in African-American women's magazines than in mainstream women's magazines (Campo and Mastin, 2004).

The social cognitive view of mass media is empowering because in the tradition of reciprocal determinism, people are capable of creating a media



environment of their own choosing. The mass media have the potential to have a broad impact on public health issues. Studying the media's effects on health attitudes and behaviors is a critical first step to designing a media environment that promotes the collective health of society.

### **Transtheoretical Model**

Prochaska and DiClemente (1977) developed the transtheoretical model to explain the process of behavioral change in the context of smoking cessation. Also known as the stages of change model, this popular health behavior theory has been applied to interventions focusing on dietary change, physical activity, and the cessation of alcohol and drug use (Resnicow, McCarty, and Baranowski, 2003). For example, public health practitioners utilized the transtheoretical model to design the National 5 A Day campaign, targeted to a broad audience of Americans in various modes of readiness to change, which promoted awareness of the benefits of higher fruit and vegetable intake and taught skills for increasing fruit and vegetable intake through community-based channels and mass media (Heimendinger, Van Duyn, Chapelsky, Foerster, and Stables, 1996).

While researchers have found the model to be useful for classifying individuals into stages of readiness for dietary change (specifically in studies that explore low fruit and vegetable intake), it has been used less successfully to predict behavior change based on the stage of the individual (Resnicow et al. 2003). The conceptual distinction between increasing fruit and vegetable intake and quitting smoking could be the reason that the transtheoretical model is a better fit for nutrition behaviors that are more similar to the addictive behavior of

quitting smoking, such as eliminating alcoholic beverages, rather than modifying one's diet.

There are two dimensions of the transtheoretical model: 1) the six sequential stages of behavior change, delineated according to pre-defined time periods, and 2) a group of constructs that describe the cognitions and behaviors that characterize moving through the stages of change (Palmeira et al., 2007). The stages of behavior change are precontemplation, contemplation, preparation, action, maintenance, and termination. An individual who is a precontemplator is unmotivated to change and has no intention to change within the next six months, whereas an individual who is a contemplator has resolved to take action within the next six months. An individual in the preparation stage intends to change within the next 30 days and has made some behavior changes that indicate commitment to taking action. In the action stage, the individual's behavior changes have existed for less than six months. The maintenance stage requires the new behavior to have persisted for over six months. Regression through the first five stages is possible. An individual in the termination stage, however, has successfully adopted the behavior change and will not regress to a previous stage (Prochaska, Redding and Evers, 2008).

The constructs of the transtheoretical model include the 10 processes of consciousness-raising, dramatic relief, self-reevaluation, environmental reevaluation, self-liberation, helping relationships, counterconditioning, reinforcement management, stimulus control, and social liberation; research demonstrates that the adoption of these activities indicates readiness to progress

through the stages of change. (Prochaska et al. 2005). Consciousness-raising, for example, is promoting awareness of the causes, effects, and solutions to a problem behavior among the audience. Effectively-designed mass media campaigns can facilitate a receptive population to move from the precontemplative and contemplative stages into the preparation or action stages.

Two additional concepts are important in the transtheoretical model. Decisional balance, the weighing of the pros and cons of the behavior change being considered, reflects the individual's current stage. A precontemplator is more aware of the cons than the pros of the behavior, a contemplator is aware of the pros and cons of change but is ambivalent, and someone in the preparation stage focuses more on the pros than the cons. Self-efficacy, the individual's belief in being able to perform the new behavior, is low in the precontemplation and contemplation stages and increases as the individual prepares and takes action; an individual in the termination stage has the highest level of self-efficacy (Palmeira et al., 2007).

In a study that raised questions about the theoretical significance of the first three stages of change, Resnicow and colleagues (2003) examined the relationship between the stage of change assessed at baseline and the behavioral and psychosocial outcomes one year later in a sample of African-American adults who participated in the Eat for Life Trial, a church-based intervention intended to increase fruit and vegetable intake. There were 14 churches and subjects were classified as being in precontemplation (n=105), contemplation (n=19), preparation (n=353), action (n=105), and maintenance (n=236). They reported

that 85% of precontemplators moved ahead one stage, whereas only 33% of individuals who were in the preparation stage moved ahead and 15% of them regressed. This result was surprising because according to the transtheoretical model, precontemplators should have demonstrated less behavior change than the individuals in the preparation stage. They concluded that the first three stages of change are not useful for predicting change in increasing fruit and vegetable intake and suggested that the time frames of 30 days and six months are less meaningful for dietary change than for smoking cessation, an addictive behavior whose ultimate goal is abstinence. They recommended not using stage-based tailoring for each of the first three stages and instead combining them into one 'preaction' stage (Resnicow et al., 2003).

Another study demonstrated that the act of enrolling in a weight management program does not guarantee that individuals are in the preparation or action stages. Krummel and colleagues (2004) evaluated factors related to the transtheoretical model in behaviors relevant to weight management. Subjects were enrolled in a weight management program called the Mothers' Overweight Management Study (MOMS) and recruited from a population of adult women who had given birth to a child within the past two years and were participants in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) (Krummel, Semmens, Boury, Gordon, and Larkin 2004). Researchers assessed the subjects' responses to statements about their performance of four weight management behaviors in the context of the time frames specified by the transtheoretical model: weight loss, choosing not to eat high-fat foods, eating

fiber-rich foods, and exercising 3 times per week. They used previously validated instruments to assess decisional balance, psychosocial characteristics, and depressive symptoms. Results showed that 17% - 30% of the participants were in the precontemplation and contemplation stages, which was a higher proportion than expected, and only 55% of the participants were in the action stage, which was far less than anticipated given that the participants were enrolled in a weight-management program. They concluded that women may not have sufficient weight-management behavior skills and that enrollment in a weight-management program is not necessarily an indicator of readiness to change (Krummel et al., 2004).

One of the constructs of the transtheoretical model, consciousness-raising, is particularly conducive to influence by the mass media. Renger, Steinfelt, and Lazarus (2002) reported positive results from a community-based television and worksite media campaign which had the goal of raising consciousness among physically inactive adults aged 30-64 in Yuma, Arizona about the benefits of regular physical activity. The media messages, in the form of 30-second television public service announcements, comic strips in worksite newsletters, and worksite posters were designed to increase self-efficacy and focused on benefits and barriers. Researchers used telephone interviews and written surveys at schools and businesses to evaluate the impact of the intervention in the community. They found that the intervention resulted in actual behavior change and increased the level of physical activity among the targeted group of Yuma residents. They acknowledge that this finding contrasts with existing evidence

that consciousness-raising is insufficient to cause behavior change and suggested that the local community focus of the tailored media messages may have contributed to the effectiveness at producing behavior change. There was no control group in this study, but the rest of Arizona reported increased numbers of sedentary individuals while the number of sedentary people decreased in Yuma (Renger et al., 2002).

Applying the transtheoretical model to initiating regular physical activity has been effective for reaching people in the contemplative stage. Reger and colleagues (2002) created a physical activity intervention targeted at sedentary adults aged 50 to 65 that successfully increased the proportion of the group that met the standard for regular moderate-intensity walking by 23% and facilitated progression to the next transtheoretical model stage (Reger, Cooper, Booth-Butterfield, Smith, Bauman, Wootan, Middlestadt, Marcus, and Greer, 2002). The eight-week media-based campaign utilized multiple channels to distribute the message to walk at least 30 minutes at least five days per week. They designed a mass media campaign involving paid advertising in local newspapers, radio, and television and an interactive website and launched public relations activities at community sites that generated television and radio coverage. They trained local health professionals to give presentations about walking and physical activity in the community. To assess the impact of the intervention, researchers conducted interviews of individuals walking at five sites for two hours daily for a week both prior to the intervention and after the intervention. They also collected data using a telephone survey questionnaire before and after the intervention. They used a

non-intervention group in a similar community for comparison as well. They concluded that the campaign had a positive effect on the desired behavior change of initiating walking and produced positive changes in perceived control and intention (Reger et al., 2002).

While encouraging an at-risk population to move into the action stage is extremely difficult using traditional action-oriented behavior interventions, a stage-based intervention should be more successful (Prochaska, Redding, and Evers, 2005); causing dietary change, however, involves many barriers. Findings from a randomized crossover intervention targeted at recipients of Maryland's WIC 5-A-Day Promotion Program, which was designed using principles of the transtheoretical model, indicated success at meeting the goal of increasing fruit and vegetable servings by half a serving per day among intervention participants; mean daily consumption increased by  $0.56 \pm 0.11$  servings in the intervention group and by  $0.13 \pm 0.07$  in the control group ( $P = .002$ ) (Havas, 1998). The goal of half a serving was considered realistic according to community nutrition intervention standards. The multi-faceted program included nutrition education sessions led by peer educators, printed materials such as a photonovella and a booklet of recipes by participants, and direct mail. Results showed, however, that the intervention generated movement in the stages of change only among Whites and participants with a high school education. While all of the peer educators were Black and had a high school or general equivalency diploma, these characteristics did not help to motivate Black participants and participants with

less education. This obstacle is an opportunity for further research on how the intervention can be adapted to meet the needs of more participants. (Havas, 1998).

Similar to media communication encouraging physical activity for sedentary individuals, media messages about weight loss may resonate with people in various stages of change who need to eliminate lifestyle behaviors that cause excessive weight gain. Well-designed media messages may influence precontemplators to become contemplators, contemplators to progress to the preparation stage and for individuals in the preparation stage to advance to the action stage. For example, contemplators demonstrating ambivalence and a lack of commitment to act in the near future may be inspired by media messages about the benefits of avoiding foods high in saturated fat. While the behavior of eating high-fat foods is not conceptually equal to smoking, this particular behavior has the potential to be extinguished in much the same way by applying the time frames of 30 days and six months to the behavior change and substituting the goal of consuming these foods rarely instead of setting a goal of abstinence.

### **Hope Theory**

The field of health psychology offers many opportunities to deepen the understanding of how hope may be leveraged to improve health outcomes. Research findings have found connections between hope and psychological, physiological, cognitive, and behavioral benefits (Drahos, 2004). Within the context of clinical practice in Western medicine, researchers have been exploring the association between patients' hopes about their own treatment outcomes, and



their resulting attitudes and behaviors (Leung, Silvius, Pimlott, Dalziel, and Drummond, 2009).

While hope can uplift, it can also endanger; patients who are unrealistically hopeful about their condition may forgo beneficial curative or palliative treatments (Schneiderman, 2005). Marketers of diet products are frequently accused of being in the “hope business” by abusing consumers’ hopes for transforming their lives via weight loss (Drahos, 2004). Public hope can be manipulated to the detriment of millions of people, as in the case of the World Trade Organization’s 1993 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This international trade agreement regarding intellectual property laws enabled large overseas pharmaceutical companies to take out patents on drugs in developing countries, thereby preventing the developing country’s own pharmaceutical industry from producing cheaper generic versions. Developing countries signed TRIPS because they hoped, unrealistically, that they would benefit from the patent laws as exporters of international patents someday; at the time, however, only the multinationals profited from the arrangement. A better solution that would have served their own interests would have been to create a coalition of developing countries that would resist the trade sanctions being placed on them by developed countries (chiefly, the United States). In South Africa, TRIPS effectively removed access to affordable AIDS antiretroviral medications for the poor that would have prevented the transmission of HIV between mothers and babies (Drahos, 2004).

Psychiatrists and psychologists began to study hope in the late 1950s as they began exploring the construct ‘positive expectations for goal attainment’ (Snyder, 2000). Hope has a multitude of definitions: “a cognitive attitude, an emotion, a disposition, and even a process or activity” (McGeer, 2004). In one cognitive approach to hope, Leung and colleagues (2009) distinguished between hopes and expectations; they defined expectations as an estimation of the most likely outcomes, and characterized hopes as an estimation of the most desired outcomes, without regard for the probability of the event’s occurrence (Leung et al., 2009).

According to Snyder’s classic model, hope is “a positive motivational state that is based on an interactively derived sense of successful (a) agency (goal-directed energy), and (b) pathways (planning to meet goals)” (Snyder, 2002). This theory focuses on cognitive processes involved in experiencing hope; rather than viewing hope itself as the emotion, the individual experiences emotional responses as a result of the unattainment or attainment of the goal (Snyder, 2000).

There are three components: goals, agentic thinking, and pathways thinking. A goal can be short-term or long-term, specific or vague, but a goal must be perceived as valuable enough to justify being an object of focus (Snyder, 2002). There must be some possibility, and some degree of uncertainty, of achieving the goal; an unattainable goal would not inspire hope and a goal that is certain to happen effortlessly would not inspire any motivational thought (Snyder, 2000). Agency, the perceived ability to execute the steps to achieve the goal, is the motivational element of hope (Snyder, 2002). When barriers arise, agentic

thinking enables the individual to stay motivated to create solutions to bypass those barriers (Snyder, 2000). Pathways thinking consists of strategizing how to get from point A to point B and creating connections between one's actions in the past, present, and future that are relevant to the individual's goals (Snyder, 2002). Successful pathways thinking creates alternative routes when encountering obstacles (Snyder, 2000). Agentic thinking and pathways thinking are interactive and iterative cognitive processes that lead to the goal being attained or not attained (Snyder, 2000).

These cognitive processes, ideally, happen quickly. High-hope individuals have high agentic thinking and high pathways thinking; when they foresee a challenge, they are quick to take charge and find a way to overcome the challenge (Snyder, 2002). Conversely, low-hope individuals have low agentic thinking and low pathways thinking; they are slow to realize their capability to take action and slow to generate any solutions to the problem (Snyder, 2002). Mixed-hope individuals could have low agentic thinking and high pathways thinking or high agentic thinking and low pathways thinking (Snyder, 2002).

In McGeer's (2004) view, hope is a process, though it is also integrated with the construct of agency. Hope is a necessary component of human agency, since hope is oriented toward the future and the actions that may be taken in the present in order to affect the future. Learning to hope is inseparable from learning about one's own agency as an individual, which is a process that starts at birth and continues throughout childhood. In a process that McGeer calls "parental scaffolding," an individual's parents reflect and reiterate his or her own potential

back to him or her. Later, agency-building continues as peers, rather than parents, perform 'peer scaffolding' by reflecting and reiterating the individual's capabilities back to him or her, as the individual does for them reciprocally. Likewise, successful hoping has a social dimension, because only by empowering others with one's own hope can one also be empowered by their hope (McGeer, 2004).

According to McGeer (2004), hope can be wishful, willful, or responsive. Wishful hope is characterized by a low belief in one's agency and an overdependence on external forces to insure the attainment of a goal. An individual who wants to lose weight only by taking a weight loss medication and not making any other changes related to behavior or environment would be a wishful hoper, for example. Willful hope involves having an unrealistically high belief in one's agency and allowing the goal to consume one's identity, even to the extent of sacrificing relationships with other people (McGeer, 2004). The optimal type of hope is responsive hope, which includes a realistic view of one's own agency and of the external forces that affect the attainment of a goal as well as the reciprocal empowering of others that generates empowerment back toward the individual (McGeer, 2004).

Viewing hope as an emotion is useful when exploring hope as an ubiquitous element of marketing campaigns for many products and services, such as stock market products, lottery tickets, weight loss products, self-help books, cosmetic surgical procedures, and visits with physicians and therapists for the purpose of resolving illnesses (MacInnis and de Mello, 2005). Marketers in a

variety of industries purposely appeal to the consumer's desire to feel hopeful. Monsanto, for example, uses the slogan "Food, Health, Hope" to sell its biotechnology products internationally (Drahos, 2004). Consumers tend to be susceptible to buying dangerous or ineffective weight-loss products because they are eager to believe in the promises presented in advertisements about the possibilities of achieving their goals through buying the product, which is the main focus; consumers do not stop to consider the lack of scientific evidence about the safety or efficacy of the product (MacInnis and de Mello, 2005). Companies design marketing campaigns that stimulate the emotion of hope, or a "yearning" for an outcome that is congruent with the consumer's existing goals and that can be supplied by the product or service being sold. One marketing principle is to enhance the perceived importance of the product by connecting it with the attainment of the consumer's ultimate goals; an effective marketing message for a weight loss product could be "Losing weight makes you healthier, increases your self esteem, and gains you respect and admiration from others" (MacInnis and de Mello, 2005).

The United States, as an overweight society, is vulnerable to promises of hope from the weight loss industry. To judge weight loss products, consumers need evidence about them to be gathered by parties that do not have a financial interest in the products under scrutiny. Drahos (2004) asserts that social structures that provide the opportunities for a variety of groups to investigate public hope are more conducive to finding the truth about public hope. Pharmaceutical

companies, therefore, should not be the sole sponsors of pre-market and post-market trials of weight-loss drugs since their profit-driven interests can affect how evidence is gathered with respect to the hypothesis (Drahos, 2004).

In the case of South Africa, in response to the Acquired Immune Deficiency Syndrome (AIDS) pandemic and the limited access to medicine caused by complying with international patent laws, the government passed a bill that gave the health minister some power in regulating access to the medicine supply (Drahos, 2004). The U.S. pressured South Africa strongly to repeal the bill and dozens of U.S. pharmaceutical companies began litigation processes against South Africa. Activists and non-governmental organizations conducted a global campaign that revealed the damage in other developing countries that resulted from supporting the pharmaceutical companies' interests in upholding patent law, leading to limited access to medicines. Pharmaceutical companies withdrew from the litigation because the 'access to medicines' campaign raised widespread criticism about the economics of the patents, the drugs, the research, and the actual risks being assumed by the private sector when the research was mainly being done in the public sector. The 'access to medicines' campaign achieved further reductions in the prices of AIDS antiretroviral treatments. The contributions of the activities and NGOs, as additional voices of truth, counteracted the exploitation of public hope (Drahos, 2004).

There are many possible ways to channel the communal sense of hope to motivate individuals to achieve better health for them and for future generations: changing public policies regarding access to nutritious foods for people of all

income levels, removing corporate interests from the process of creating federal diet planning recommendations to make room for evidence-based practices, training journalists how to present scientific evidence about nutrition topics for the lay public, and educating consumers about how to process health and nutrition information presented in the mass media. Through public health marketing campaigns that create links between specific nutrition habits and individual health goals, hope can be used to inspire, instead of to betray.

APPENDIX B  
CODEBOOK



Framing Weight-loss Drugs  
Newspaper Content Analysis Codebook  
Department of Nutrition  
Arizona State University

In this content analysis project, the goal is to document the media frames used to present the weight-loss drugs Xenical and Alli in articles in major U.S. newspapers during the time periods starting from each weight-loss drug's date of approval by the U.S. Food and Drug Administration and ending six months after the date the weight-loss drug was released and made available to the public.

The primary selection criteria for articles will be the coverage of the weight-loss drugs Xenical or Alli or their generic name, orlistat. News articles, feature articles, science/health articles, and business articles will be included. Corrections and quotations articles that mention the weight-loss drug in passing will be excluded. Coverage of the weight-loss drug will need to occupy at least 2 full paragraphs to be included in the content analysis. Articles from non-U.S. newspapers will be excluded. Duplicative articles will be included. The minimum length of articles must be 200 words in order to qualify for this study.

Text-analysis software will be utilized to tabulate key words into frequency tables. These tables will be used to create media frames.

**ARTICLENUMBER:** As an article is selected for coding, it must be assigned an article number. Articles should be numbered as integers beginning with 1.

**DUPLICATIVE:** Enter the code that indicates whether or not the article is a duplicative article (e.g. an AP story or an article that was previously published in another newspaper).

To determine whether an article is duplicative or not, look at the "Author" field that appears below the newspaper name and above the text of the article. An article is a duplicative article if Associated Press, Reuters, or other newswire service appears there, or if there is another publication's name after the writer's name that differs from the newspaper in which the article is printed. Also, look at the first line of the article or in the "Dateline" field below the article for the article's city of origin. If the city of origin of the article differs from the newspaper's city of origin, the article is a duplicative article.

Code:

1 = Yes

2 = No

999 = Unknown

Examples of duplicative articles:

Author: Reuters News Service

Author: The Associated Press

Author: John Hendren, Associated Press writer

Author: Knight-Ridder Newspapers (implies that the article has been published in other newspapers besides this one)

Author: From Our Press Services

Author: Marlene Cimon, Marilynn Marchione of the Journal Sentinel staff contributed to this report, Los Angeles Times (article is from the Milwaukee Journal-Sentinel)

Author: Marlene, Cimon, Los Angeles Times (article is from the Pittsburgh Post-Gazette)

Examples of non-duplicative articles:

Author: Record Searchlight (article is from Redding Record Searchlight)

Author: D'Ann Mabray Shippy, Karen Brooks, Star-Telegram Writer (article is from Fort Worth Star-Telegram)

Examples of unknown duplicative status:

“NEW YORK – Weight conscious Americans...” (The city of origin of the article is New York, and the newspaper is the Contra Costa Times in Walnut Creek, CA, but the newspaper may have its own staff writer in New York)

**ARTICLETITLE:** Enter the title of the article as it appears on the print-out from the LexisNexis® database. Do not correct any spelling or grammatical errors from LexisNexis®.

Enter into SPSS as a string variable.

**NEWSPAPER:** Enter the name of the newspaper as it appears on the print-out from the LexisNexis® database. Do not correct any spelling or grammatical errors from LexisNexis®.

Enter into SPSS as a string variable.

**RANK:** Enter the rank of the newspaper on the 2008 list of the Top 100 Daily Newspapers in the U.S. by Circulation in BurrellesLuce.

Code "0" to indicate a newspaper that was not on the list.

Enter into SPSS as a string variable.

**PAGENUMBER:** Enter the page number of the newspaper in which the article appears. The page number should be coded using both letters and numbers, if applicable. Use capital letters, e.g. enter “A1” whether the page number appears as “a1” or “A1”. If the page number is listed as “PD2”, enter it as “PD2”.

Enter into SPSS as a string variable.

**WORDCOUNT:** If the entire article is about the weight-loss drug, enter the word count of the article as it appears in the “Length” field in the search results screen of the LexisNexis® database. If the article contains multiple news segments and only one of them is about the weight-loss drug, then copy and paste the segment about the weight-loss drug from LexisNexis® into Word and use the word count function to get the word count

This is a numerical variable.

**MONTH:** Enter the number that corresponds to the month of publication (e.g. for July 16, 2007, code 7). Code:

- 1 = January
- 2 = February
- 3 = March
- 4 = April
- 5 = May
- 6 = June
- 7 = July
- 8 = August
- 9 = September
- 10 = October
- 11 = November
- 12 = December

**DATE:** Enter the date of publication as a two-digit number (e.g. for July 16, 2007, code 16).

**YEAR:** Enter the year of publication as a four-digit number. (e.g. for July 16, 2007, code 2007).

DAY: Enter the number that corresponds to the day of the week on which the article was published, which should be indicated in LexisNexis.

If the article does not indicate the day of the week of its publication, refer to the website

<http://www.timeanddate.com/calendar/>

Code:

- 1 = Sunday
- 2 = Monday
- 3 = Tuesday
- 4 = Wednesday
- 5 = Thursday
- 6 = Friday
- 7 = Saturday

DRUGCODE: Enter numerical code for the weight-loss drug. Code:

- 1 = Xenical
- 2 = Alli
- 9 = Meridia

RELEASE: Enter numerical code that corresponds to the timing of the article's publication in relation to the date the weight-loss drug was released.

The release date for Meridia was March 2, 1998.

The release date for Xenical was April 26, 1999.

The release date for Alli was June 15, 2007.

Code:

- 1 = Pre-release
- 2 = Post-release

PERSONALSTMT Indicate whether or not the article mentions at least one personal statement, defined as an attribution or quote by an individual lay person (e.g. "person on the street").

To qualify as a personal statement, the quote must be from a lay person who does not have a title nor a role as a representative of an established (e.g. an obesity advocacy group). The statement may appear in quotation marks or as a paraphrased statement. The content of the statement does not have to be about the weight-loss drug specifically.

Code:

1 = Yes

2 = No

Examples of personal statements:

“It took the edge off my appetite, gave me a feeling of fullness...” said Katie Philips, a participant in clinical trials of the drug.

“In the two weeks since she’s been taking Meridia, she’s cut her food intake by half. ‘(The drug) just tells you not to eat anymore,’”

“‘When you get to the point where you can’t fit into anything and you’re not mobile, you’re just desperate,’ said Ms. Hammond, who weighs over 300.”

PROFSTMT1

Indicate whether or not the article mentions at least one attribution or quote from an individual physician. The statement may appear in quotation marks or as a paraphrased statement. Code:

1 = Yes

2 = No

The salutation “Dr.” is not sufficient to indicate the individual is a physician; it may, but does not have to, appear before the individual’s name.

Examples of descriptions or titles that would indicate a statement from a physician:

“medical director”

“internist”

“cardiologist”

“psychiatrist”

“physician”

“MD” (doctor of medicine)

“medical resident”

“resident”

“medical intern”

“intern”

“DO” (doctor of osteopathy)

“...said cardiologist and researcher John A. Osborne”

Do not assume that the individual is a doctor because he or she is affiliated with a medical institution such as a hospital or a medical school.

Examples of descriptions or titles that would NOT indicate a statement from a physician:

“medical student”

“chiropractor”

“naturopath”

“holistic healer”

“homeopath”

“psychotherapist”

“psychologist”

“PhD”

“Dr. Jane Smith” (without an additional description qualifying her as a physician such as “surgeon” or other type of doctor)

“...said the FDA’s Dr. James Bilstad”

“Dr. John Foreyt of the Baylor College of Medicine”

“Dr. Robert Eckel of the University of Colorado Health Sciences Center, vice chairman of the AHA’s nutrition committee”

PROFSTMT2

Indicate whether or not the article mentions at least one attribution or quote from an individual registered dietitian, nutritionist, or dietitian. The statement may appear in quotation marks or as a paraphrased statement. Code:

1 = Yes

2 = No

PROFSTMT3

Indicate whether or not the article mentions at least one attribution or quote from an individual scientist. The statement may appear in quotation marks or as a paraphrased statement. Code:

1 = Yes

2 = No

The individual must be described as being actively engaged in research. Do not assume that the individual is a scientist because he or she is affiliated with the FDA, a university, a research institute, or a medical institution such as a hospital or a medical school.

Examples of descriptions or titles that would indicate a statement from a scientist:

“leader of one of the studies”

“involved with clinical trials”

“principal investigator”

“...said cardiologist and researcher John A. Osborne”  
A professor engaged in research, not necessarily affiliated with the same research study

Examples of descriptions or titles that would NOT indicate a statement from a scientist:

“Dr. Jane Smith”

“...said the FDA’s Dr. James Bilstad”

“Dr. John Foreyt of the Baylor College of Medicine”

“Dr. Robert Eckel of the University of Colorado Health Sciences Center, vice chairman of the AHA’s nutrition committee”

PROFSTMT4

Indicate whether or not the article mentions at least one attribution or quote from an individual pharmacist. The statement may appear in quotation marks or as a paraphrased statement.

Code:

1 = Yes

2 = No

PROFSTMT5

Indicate whether or not the article mentions at least one attribution or quote from an individual psychotherapist. The statement may appear in quotation marks or as a paraphrased statement.

Code:

1 = Yes

2 = No

Examples of descriptions or titles that would indicate a statement from a psychotherapist:

“psychotherapist”

“counselor”

“psychologist”

“social worker”

“Weight Watchers leader”

INDUSTRYSTMT

Indicate whether or not the article mentions at least one attribution or quote from the manufacturer’s spokesperson. The industry statement could be a quote from the manufacturer’s spokesperson, from printed material (e.g. a brochure about the weight-loss drug) produced by the manufacturer, or a statement (e.g. press release,

advertisement, television commercial) released by the manufacturer. The statement may appear in quotation marks or as a paraphrased statement.

Code:

1 = Yes

2 = No

Examples of industry statements:

“Meridia, the drug so anxiously awaited that dieters honored it with dozens of Internet sites before it was approved, is expected to be in most pharmacies by mid-March, Knoll said Thursday”

“Knoll intends to work closely with doctors and patients...”

FDAROLE

Indicate whether or not the article mentions the regulatory role of the FDA.

Code:

1 = Yes

2 = No

Examples of indicators of the FDA’s regulatory role:

“The FDA approved the drug”

“The FDA urged doctors to use caution in prescribing Meridia...”

““This drug should not be used for those who want to lose simply a few pounds, “warned Dr. James Bilstad, FDA’s metabolic drug chief.

BMISTDS

Indicate whether or not the article mentions BMI standards for the use of this drug. A relationship between height and weight may be stated rather than specific Body Mass Index scores. Code:

1 = Yes

2 = No

Examples of BMI standards:

“The drug should be used only by people who run the risk of serous health problems because of obesity, such as a patient who stands 5 feet 5 inches and weights 180 pounds”

“And it is only for the seriously obese, as measured by a body mass index – the relationship of weight to height – of



30 or greater, such as someone who is 5 feet, 6 inches and weighs 185 pounds.”

**SIDEEFFECTS** Indicate whether or not the article mentions side effects for the use of this drug. Code:

1 = Yes

2 = No

**WTLOSS** Indicate whether or not the article mentions a track record of success or a specific promise or prediction about the amount of weight loss either in the number of pounds, inches, or a percentage of body weight.

A promise of weight loss must be described as a quantifiable amount of weight, either in lbs., inches, or percentage of body weight lost. Qualitative descriptions (e.g. “modest weight loss” do not count as a promise of weight loss.

Code:

1 = Yes

2 = No

**MECHANISM** Indicate whether or not the article states the mechanism by which the drug works.  
The mechanism by which the drug works must be explicitly stated (e.g. “appetite suppressant”). A description of the drug’s mechanism as merely similar or different from another drug’s mechanism does not qualify (e.g. “works differently from other diet drugs”).

Code:

1 = Yes

2 = No

**CONTRAININD** Indicate whether or not the article mentions who should not use the drug.

In order to code “yes” for contraindications, the article must state at least one condition or disease state that is not compatible with usage of the drug. Examples of contraindications include pregnancy, liver disease, hypertension, and cardiovascular disease. If the article does not state who should not take the drug, then code “no”.

Code:

1 = Yes

2 = No

DIETRXS

Indicate whether or not the article includes recommendations for dietary changes with the use of this drug. There must be a stated connection between the use of the drug and at least one dietary change.

Code:

1 = Yes

2 = No

Examples of recommendations for dietary changes:

“Knoll Pharmaceutical’s sibutramine, to be sold under the brand name Meridia, appears to cause a modest weight reduction – usually about 5 percent – when taken together with diet and exercise.”

Examples that DO NOT qualify as recommendations for dietary changes:

“Many doctors say that like Weight Watchers and other diet centers, they, too, are helping former diet-drug patients shed pounds the old-fashioned way: by exercising and eating right.”

PHYSRXS

Indicate whether or not the article includes recommendations for changes in physical activity with the use of this drug. Code:

1 = Yes

2 = No

Examples of recommendations for changes in physical activity:

“Knoll Pharmaceutical’s sibutramine, to be sold under the brand name Meridia, appears to cause a modest weight reduction – usually about 5 percent – when taken together with diet and exercise.”

COUNRXS

Indicate whether or not the article includes recommendations for person-to-person psychological or

nutritional counseling with the use of this drug. Counseling may be performed by a psychologist, psychotherapist, social worker, Weight Watchers leader, nutritionist, or dietitian.

Code:

1 = Yes

2 = No

Examples of counseling recommendations:

“cognitive behavioral therapy”

Other approaches to psychotherapy

Examples that do NOT qualify as counseling recommendations:

“behavior modification program”

“behavior modification plan”

## COST

Indicate whether or not the article mentions the cost of the drug. The cost of ancillary treatments may be included in this amount. Global sales information does not qualify as cost. Code:

1 = Yes

2 = No

Examples of mentions of cost:

“The new drug, plus vitamins and supplements and behavior modification counseling, costs her \$200 a month.”

## RULES

1. Page number should be coded using both letters and numbers, if applicable.
2. The pre- and post- release variable should use the release dates as follows:
  - a. The release date for Meridia was March 2, 1998. (The FDA approval date was November 22, 1997.<sup>1</sup>)
  - b. The release date for Xenical was April 26, 1999. (The FDA approval date was April 23, 1999.<sup>2</sup>)

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<sup>1</sup> U.S. Food and Drug Administration Center for Drug Evaluation and Research. Accessed 18 July 2008.

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=SearchDrugDetails>

<sup>2</sup> U.S. Food and Drug Administration Center for Drug Evaluation and Research. Accessed 18 July 2008.

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=SearchDrugDetails>

- c. The release date for Alli was June 14, 2007. (The FDA approval date was February 7, 2007.<sup>3</sup>)
3. To qualify as a personal statement, the quote must be from a lay person who does not have a title nor a role as a representative of an established (e.g. an obesity advocacy group).
  4. The industry statement could be a quote from the manufacturer's spokesperson, from printed material (e.g. a brochure about the weight-loss drug) produced by the manufacturer, or a statement (e.g. press release, advertisement, television commercial) released by the manufacturer.
  5. An attribution statement by a layperson, health professional or by a representative of the industry can be a statement in quotation marks or a paraphrased statement.
  6. A promise of weight loss must be described as a quantifiable amount of weight, either in lbs., inches, or percentage of body weight lost. Qualitative descriptions (e.g. "modest weight loss" do not count as a promise of weight loss.
  7. The mechanism by which the drug works must be explicitly stated (e.g. "appetite suppressant"). A description of the drug's mechanism as merely similar or different from another drug's mechanism do not qualify (e.g. "works differently from other diet drugs").
  8. In order to code "yes" for contraindications, the article must state at least one condition or disease state that is not compatible with usage of the drug. Examples of contraindications include pregnancy, liver disease, hypertension, and cardiovascular disease. If the article does not state who should not take the drug, then code "no".
  9. Cost is defined as the cost of the drug to an individual consumer. Global sales information about the drug does not count as cost.
  10. Missing or unknown values will be indicated using the code "999"

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<sup>3</sup> U.S. Food and Drug Administration Center for Drug Evaluation and Research. Accessed 18 July 2008.

<http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.DrugDetails>