

ABSTRACT

Title of dissertation: WHERE DOES NEWS ABOUT PRESCRIPTION DRUGS COME FROM?: EXPLORING HOW ORGANIZATIONS BUILT AND FRAMED THE NATIONAL NEWS MEDIA AGENDA FOR HORMONE THERAPY FROM 1995 TO 2011

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This longitudinal study explored how health and medical organizations used public relations techniques to influence news content about postmenopausal hormone therapy (HT) from 1995 to 2011. A theoretical framework that combined agenda building, information subsidies, and framing guided the study (Zoch & Molleda, 2006). Quantitative content analyses were conducted on 675 press releases about HT distributed through *PR Newswire* and *EurekAlert!*, and 429 news stories about HT in the *Associated Press Newswire (AP)*, *The New York Times*, *The Washington Post*, *Los Angeles Times*, and *The Wall Street Journal*. Supplemental qualitative content analyses of organizational websites, annual reports, and scientific publications explored financial relationships and potential collaborations between ten organizations that emerged as the most successful agenda builders.

Six types of health and medical organizations produced press releases about HT: pharmaceutical companies, academic/medical institutions, nonprofit health advocacy organizations, medical/scientific journal publishers, U.S. government agencies, and other

for-profit organizations. A positive, statistically significant relationship was found between the quantity of press releases and news stories over time ($r = .55, p < .001$). Findings also supported the transference of specific objects, such as brand-name HT products, and attributes, such as risks and benefits, from the public relations to the news media agenda. Academic/medical institutions and nonprofit health advocacy organizations were significantly more likely than pharmaceutical companies to identify non-FDA approved, “off-label” benefits. Wyeth Pharmaceuticals, manufacturer of leading HT brands *Premarin* and *Prempro*, financially subsidized most of the top-ten, agenda-building organizations, including four academic/medical institutions and two non-profit health advocacy organizations that were frequently cited in news stories. Additionally, a substantial degree of synergy was found between these organizations in terms of how they framed menopause and HT over the study period.

This study supported and extended the theoretical framework used by offering insights into how organizations may collaborate through funding arrangements and third-party communication techniques to influence news content in a health and medical context. The findings also contributed a new and important dimension to scholarship on pharmaceutical promotion of prescription drugs, which has neglected the role of public relations and focused almost exclusively on more overt, paid-promotional efforts like direct-to-consumer advertising.

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NEWS MEDIA AGENDA FOR HORMONE THERAPY FROM 1995 TO 2011

by

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Chapter I: Introduction

Recent years have brought numerous cases of prescription drugs that became blockbuster sensations, only to be suddenly withdrawn from the market or the subject of consumer alerts due to serious risks and side effects. For example, anti-inflammatory *Vioxx*, taken by an estimated two million Americans, was taken off the market in 2004 when it became clear that the risks of heart attack and stroke outweighed any of its benefits (Batt, 2005; Rubin, 2004). In 2002, several pharmaceutical manufacturers were forced to add warning labels to antidepressants about the potential risk of suicidality in children and adolescents taking antidepressants. Although only one product, *Prozac*, had ever been approved by the U.S. Food & Drug Administration (FDA) for use in children and adolescents, physicians routinely prescribed other brands to this population group, a practice commonly referred to as “off-label” prescribing.

That same year, the National Heart Lung & Blood Institute (NHLBI), part of the U.S. National Institutes of Health (NIH), released findings from its Women’s Health Initiative (WHI) trial, indicating that postmenopausal women taking estrogen-plus-progestin hormone therapy were at increased risk for breast cancer, heart disease, blood clots, and stroke, which was followed by another announcement by the Institute in 2004, indicating that women taking estrogen-only hormone therapy were at risk for stroke and serious blood clots (U. S. Department of Health & Human Services, National Heart, Lung, and Blood Institute [USDHHS NHLBI], 2005). These announcements shocked women, their physicians, and the medical community at large because hormone therapy was frequently prescribed off-label to *prevent* heart disease (Katz, 2003; Roussouw, 1996; Utian & Schiff, 1994).

Although the reasons behind these types of cases are multiple and complex, some claim that aggressive pharmaceutical industry promotion of prescription drugs plays an important role by stimulating unnecessary prescribing and/or overuse of newer and more expensive, brand-name drugs despite their less solid track records of safety (Auton, 2004; Brownfield, Bernhardt, Phan, Williams, & Parker, 2004; Fugh-Berman, Alladin, & Chow, 2006; Mackowiak & Gagnon, 1985; Royne & Myers, 2008). Spending on promotion of prescription drugs increased from \$11.4 billion in 1996 to \$29.9 billion in 2005 (Donohue, Cevasco, & Rosenthal, 2007). Promotional dollars typically support a range of activities, including, but not limited to, sales visits to physicians known as “detailing,” which often includes distribution of free drug samples and small rapport-building gifts, medical journal advertising, and advertising directed to consumers, commonly referred to as direct-to-consumer advertising (DTCA).

To date, research has primarily focused on the role overtly promotional sources of information such as detailing, medical journal advertising, and DTCA play in stimulating prescription drug demand by influencing the decision-making processes of consumers and/or physicians (Donohue & Berndt, 2004; FDA, 2004; Gonul et al., 2001; Iizuka & Jin, 2006; Mizik & Jacobson, 2004; Rizzo, 1999; Rosenthal, Berndt, Donohue, Epstein, & Frank, 2003; Wang, Ausiello, & Stafford, 1999; Zachry et al., 2002). News media, however, may also play a key role in influencing prescription drug use, by disseminating information about the uses, benefits, and risks of prescription drugs in a manner similar to other sources of information. The U.S. news media are leading sources of health information for consumers, healthcare providers, and policymakers (Martinson & Hindman, 2005; Pew Project for Excellence in Journalism, 2010; Phillips, Kanter,

Bednarczyk, & Tastad, 1991; Schwartz & Woloshin, 2004; Viswanath et al., 2008), and news coverage has been associated with population-level changes in a variety of health behaviors (Hornik, 2002), including health care utilization (Grilli, Ramsay, & Minozzi, 2002). Paid advertising and marketing efforts are regulated by the FDA to make sure only FDA-approved products and indications are promoted accurately with a “fair balance of efficacy and risk information” (Sheehan, 2003, p. 160). Information distributed by health and medical organizations through news media, however, is not subject to FDA regulations (Leffler, 1981; Morris & Griffin, 1992; Sheehan, 2003). For this reason, news media content about prescription drugs may provide a non-FDA regulated outlet for information not easily disseminated by other means, such as promotion of off-label indications.

A substantial portion of health news content is influenced by the public relations activities of health and medical organizations, such as pharmaceutical companies, government agencies, universities, medical schools, medical professional societies, trade associations, and health advocacy groups (Gandy, 1982; IOM, 2009). It is estimated that anywhere from 25% to 50% of all news content in the United States is public relations-generated (Cameron, Sallot, & Curtin, 1997; Sallot & Johnson, 2006) by organizations and other actors attempting to influence the decisions of stakeholders and publics who consume the news in ways that are favorable to their strategic objectives (Cameron, Sallot, & Curtin, 1997; Sallot & Johnson, 2006; Zoch & Molleda, 2006).

The sources typically relied on by science and health journalists include not only government and institutional experts, but also scientists, physicians, and pharmaceutical representatives (Cho, 2006; Friedman, 1986b; Gandy, 1982; Gans, 1979; Tanner, 2004;

Wallington et al., 2007). Specifically, common sources of information for news about health and medicine are: scientific journals and conferences; press releases distributed by organizations, such as universities, government agencies, and pharmaceutical companies; news wire services and other news media outlets; and individual spokespersons, such as scientists, physicians, and government officials who work for a variety of health and medical organizations (Corbett & Mori, 1999; Dunwoody, 1986; Entwistle, 1995; Gandy, 1982; Gans, 1979; Nelkin, 1995; Rogers et al., 1991; Semir et al., 1998; Shoemaker & Reese, 1996; Van Trigt et al., 1994; Walters & Walters, 1992; Wilkes, 1997).

Some public relations scholars have emphasized the need for a greater understanding of the role organizations play in influencing the news media agenda, and through what processes these efforts might exert societal-level influence by changing the attitudes, beliefs, and behaviors of publics (Cameron et al., 1997; Kioussis, Mitrook, Wu, & Seltzer, 2006; Kioussis, Popescu, & Mitrook, 2007; Zoch & Molleda, 2006). The news media agenda refers to the salience or importance placed on issues or topics by news media, which is typically measured by the amount of coverage or prominence afforded to issues or topics by news media over a specific time period (Dearing & Rogers, 1996; McCombs & Shaw, 1972). News media attention can confer status to an issue or topic, draw public attention to it, and increase public perceptions of its importance (Lazarsfeld & Merton, 1948, 1964, as cited in Dearing & Rogers, 1996; McCombs & Shaw, 1972). Getting issues or topics of strategic interest onto the news media agenda and controlling the content of that news coverage can lead to desirable outcomes for organizations.

Although little research has looked specifically at the quality of prescription drug news, a substantial literature exists about the quality of science, health, and medical news

more generally. Common problems cited include news stories that exaggerate the incidence or prevalence of diseases or conditions, sensationalize new research findings, provide inaccurate and unbalanced information about the benefits and risks of medical products, and fail to disclose the financial conflicts of interest of experts and organizations that serve as news sources (Nelkin, 1995; Schwitzer et al., 2005; Schwitzer, 2008). Traditional explanations for these problems have focused on the way journalists work or the constraints of their news organizations (Gans, 1979; Nelkin, 1995; Tuchman, 1972), neglecting the role of organizations that produce, finance, and disseminate sources of information to journalists (Gandy, 1982; Manning, 2001; Seale, 2002; Shoemaker & Reese, 1996; Tankard, 2001).

Several scholars have advocated approaches to understanding news content that include not just factors internal to the news organization, but factors external to it as well, such as the role organizations and other actors play when they attempt to use news media to meet their own political and economic interests (Gandy, 1982; Manning, 2001; Seale, 2002; Shoemaker & Reese, 1996). Little research, however, has looked systematically at what types of health and medical organizations produce sources of information about prescription drug news; what their resources and goals are; how they act individually, and perhaps jointly with other organizations, to influence news content; and how these processes might influence the quality of news about prescription drugs.

Zoch and Molleda (2006) proposed a theoretical framework to discover how organizations conduct media relations to actively build and frame the news media agenda through various public relations techniques. They combined three existing theoretical areas: agenda building, framing, and information subsidies. Agenda building explores

how individuals and organizations “build” the news media agenda for a public issue through various activities (McCombs, 1992; Zoch & Molleda, 2006). Information subsidies are materials that public relations practitioners produce or make readily available to journalists to build the news media agenda, such as press releases and video news releases (VNRs) or individual experts or spokespersons (Gandy, 1982). Framing refers to the way information is selectively included, highlighted, or omitted in news stories (Entman, 1993), and how different news frames can alter audience perceptions, attributions, and decisions (Iyenger, 1991). Zoch and Molleda (2006) suggested that organizations attempt to influence the decisions of stakeholders and publics who consume the news by framing information subsidies in ways that are favorable to their strategic objectives.

This dissertation research used Zoch and Molleda’s (2006) theoretical framework to explore how the public relations efforts of a variety of health and medical organizations, such as pharmaceutical companies, government agencies, universities, medical schools, medical professional societies, trade associations, and health advocacy organizations, influence the news that is available to publics to make decisions about prescription drugs. Specifically, the purpose of this study was to apply agenda building, information subsidies, and framing theories to a content analysis of organizational materials and news to analyze how health and medical organizations built and framed the news media agenda for postmenopausal hormone therapy from 1995 to 2011.

Hormone Therapy (HT) as Context

HT was selected as the context to test the theoretical framework. This selection was made because substantial controversies have arisen over how the benefits and risks

of HT have been portrayed in news media over time, and what possible role organizations played in promoting these portrayals (Felgran & Hettinger, 2002; Fugh-Berman & Pearson, 2002; MacLennan et al., 2004; Moynihan et al., 2002; Pines, 2008; Zuckerman, 2002). Although estrogen and estrogen-plus-progestin HT formulations were only ever approved by the FDA for the indications of vasomotor symptoms (hot flashes), vulvar and vaginal atrophy, and postmenopausal osteoporosis (USDHHS FDA, 2011b), many women and their clinicians believed that hormone therapy could prevent a host of other conditions, such as cardiovascular disease, memory loss, and aging of the skin (Fugh-Berman & Pearson, 2002; Utian & Schiff, 1994), turning leading HT brands, *Premarin* (estrogen-only) and *Prempro* (estrogen-plus-progestin), into blockbuster drugs in the 1990s.

Striking differences in temporal trends of HT prescription use have been observed in response to the NHLBI's WHI trials, which demonstrated that HT use was associated with substantial risks and provided no cardiovascular disease benefit. HT use increased steadily prior to the 2002 WHI announcement about the risks of estrogen-plus-progestin therapy and decreased steadily after, with further reductions occurring after the 2004 announcement about the risks of estrogen-only HT (Austin et al. 2003; Haas et al., 2004; Hersh et al. 2004; Roumie et al., 2004). Women have also reported that news media played a role in their decision to discontinue their hormone therapies (see Barber et al., 2004; Bastian, Breslau, Davis, & Moser, 2005; Ettinger et al., 2003; Huston, Jackowski, & Kirking, 2009; MacLennan et al., 2004; McIntosh & Blalock, 2005). Despite indications that HT-related news coverage may have played a role in driving or decreasing HT prescription rates at different points in time, no systematic, longitudinal

studies have been conducted to examine the quantity and quality of news coverage prior to, during, or after the WHI announcements. The up-and-down patterns of HT prescription use over time, combined with the controversies that have arisen over how the benefits and risks of HT have been portrayed in news media, make HT a productive and compelling context for this study.

Summary of Method

This study used content analysis to examine how health and medical organizations used information subsidies to build and frame the news media agenda for HT from 1995 to 2011. The public relations agenda of organizations was measured through press releases about HT distributed through *PR Newswire* and *EurekAlert!*. The news media agenda was measured via HT stories in the *Associated Press Newswire (AP)* and four, top-circulating, U.S. newspapers: *The New York Times*, *The Washington Post*, *Los Angeles Times*, and *The Wall Street Journal*.

Quantitative content analysis procedures were used to describe the over-time relationship between the public relations and news media agendas in terms of the quantity and quality of HT coverage and to understand how a variety of health and medical organizations actively built and framed the news media agenda for HT over the study time period. Supplemental qualitative content analysis procedures were applied to a subset of the data to provide a more nuanced and contextual understanding of the agenda-building and framing activities of organizations that emerged from the quantitative content analysis as successful agenda builders, as evidenced by frequent mentions of these organizations in press releases and news stories. Additional archival/document research was conducted as necessary to understand the financial relationships and

collaborations that existed between organizations that emerged as successful agenda builders.

Significance of Study

This research contributed to public relations scholarship by exploring how agenda building, information subsidies, and framing theories worked together in the context of HT. Public relations scholars have stressed the need to understand how organizations use information subsidies to build and frame the news media agenda (see Zoch & Molleda, 2006). To date, most work on information subsidies has been conducted from the perspectives of journalists and news organizations rather than from the perspectives of organizations that produce, fund, and disseminate information subsidies (Cameron et al., 1997). By focusing instead on the health and medical organizations that distributed information subsidies, this study contributed insights into how organizations influence the quantity and quality of news media content in ways that align with their strategic interests, and the potential ramifications of these processes on the marketplace of ideas and information available to publics to inform decision making.

This application of this theoretical framework to a health context also provided a deeper understanding of commonly cited problems related to the accuracy and quality of health and medical journalism. Past research has identified common sources of health and medical information used by journalists, but has not gone further to investigate the organizations and organized interests that produce, fund, and disseminate these sources of information. Comparisons of the content of press releases and news stories provided an opportunity to assess whether quality problems originated from journalists themselves or

the organizations that produced information subsidies, leading to practical recommendations to improve the quality of health and medical news.

Finally, this study contributed to the literature on prescription drug promotion. To date, research has primarily focused on the role overtly promotional, FDA-regulated sources of information, such as detailing, medical journal advertising, and DTCA play in stimulating prescription drug demand (Donohue & Berndt 2004; Gonul et al., 2001; Iizuka & Jin, 2006; Mizik & Jacobson, 2004; Rizzo, 1999; Rosenthal et al., 2003; Wang, Ausiello, & Stafford, 1999). Data from this study indicated that another type of prescription drug promotion occurs in the form of news stories created through the media relations activities of a variety of health and medical organizations that frame information about the uses, benefits, and risks of prescription drugs in ways that align with their strategic interests.

Summary of Dissertation

This dissertation is organized into five chapters. Chapter one introduced and provided background and context for the study. Chapter two reviews the theoretical and empirical literature that informed the conceptualization of the study. Conceptual models used to guide the research questions and data analyses are presented at the end of chapter two, along with a summary of the study's research questions. Chapter three outlines the study methodology in detail. Chapter four presents the study's detailed results. Chapter five discusses the theoretical and practical implications of the study. Study limitations and suggestions for future research are also discussed.

Chapter II: Literature Review

This chapter reviews the theoretical and empirical literature that informed the conceptualization of the study. This chapter blends together research from three primary perspectives: mass communication scholarship, strategic communication scholarship, and critical scholarship to understand how health and medical organizations may use news media to communicate strategically about prescription drugs. Specific areas of literature reviewed relate to the role prescription drug news may play in consumer and physician decision making; the theoretical framework guiding the study, which includes agenda building, information subsidies, and framing; the major types of organizations that produce information subsidies about health, medicine, and prescription drugs; financial conflicts of interest between health and medical organizations; sources of information used by journalists to produce health, medicine, and prescription drug news; and the quality of health, medicine, and prescription drug news and information subsidies. Existing research about HT, the quality of HT-related news, and the types of organizations that may have been involved in building and framing the news media agenda for HT are also reviewed.

Conceptual models used to guide the development of the research questions and data analyses, along with a summary of the study's research questions, are presented after the review of the literature. The conceptual models were informed by the interactions and linkages between the different areas of literatures reviewed, which resulted in a set of research questions that was driven by multiple theoretical perspectives.

Potential Role of Prescription Drug News in Health Decision Making

Prescription drug use is a complex behavior due to the “intermediary role” physicians play (Gonul, Carter, Petrova, & Srinivasan, 2001, p. 79). Unlike the consumption of other products, it is the physician who decides if a product is needed and what specific product should be selected, even though it is the consumer who actually purchases and uses the drug (Gonul, et al., 2001). Prescription drug use is a product of decision making by physicians and consumers and interactions between both parties. The consumer must present to the physician to receive a diagnosis; the physician must prescribe the drug; and the consumer must comply by filling the prescription and taking the drug (Deshpande, Menon, Perri & Zinkhan, 2004; Ledford et al., 2010; USDHHS FDA, 2004).

The information environment about a prescription drug can influence the decision-making processes of physicians and consumers, resulting in increases or decreases in prescription drug use. Although many intrapersonal and interpersonal factors influence physicians’ prescribing practices and consumers’ prescription drug use, considerable focus has been placed on pharmaceutical industry promotions targeted to physicians and consumers. Three major promotional sources of information have received the most attention in the literature in terms of their potential to stimulate prescription drug demand: sales visits to physicians known as “detailing,” which often include free product samples and small rapport-building gifts; medical journal advertising; and direct-to-consumer advertising (DTCA), which refers to promotional efforts that directly target the general public through lay media (Cline & Young, 2004; Fugh-Berman, Alladin, & Chow, 2006; Morris & Griffin, 1992).

In marketing terms, prescription drug use can be thought of in terms of primary demand and selective demand. Primary demand refers to the size of the overall market for a therapeutic class of drugs (for example, all HT brands available for menopause). Selective demand refers to the market share for a particular drug within its therapeutic class (for example, *Prempro*) (Mackowiak & Gagnon, 1985). Research has indicated that DTCA increases primary demand by driving consumers to physicians through help-seeking behaviors (Donohue & Berndt, 2004; Iizuka & Jin, 2006; Rosenthal, Berndt, Donohue, Epstein, & Frank, 2003; Zachry et al., 2002), and perhaps selective demand by encouraging consumers to request specific brand-name drugs from their physicians (An, 2007; Desphande et al., 2004; USDHHS FDA, 2004). Physician-targeted promotional activities, such as detailing and medical journal advertising, tend to influence selective demand, or brand choice (Donohue & Berndt 2004; Gonul et al., 2001; Iizuka & Jin, 2006; Mizik & Jacobson, 2004; Rizzo, 1999; Rosenthal et al., 2003; Wang, Ausiello, & Stafford, 1999).

Medical professional journals have also received significant attention for the role they play in influencing prescribing patterns. Physicians have reported relying heavily on peer-reviewed scientific literature to make prescribing decisions (Avorn, Chen, & Hartley, 1982), and publication of new evidence in scientific journals, particularly from large clinical trials, has been associated with increases and decreases in physician prescribing, depending upon the positive or negative nature of the findings (Col et al., 1996; Lamas et al., 1992; Majumdar et al. 2003; Majumdar et al., 2004; Stafford et al., 2004). Medical professional journal articles are used heavily in sales visits to physicians by pharmaceutical representatives (Entwistle, 1995; Fugh-Berman, 2005; Nelkin, 1995;

Sismondo, 2007; Wilkes, 1997). Information from scientific publications also reaches both physicians and consumers indirectly through news media, as medical journals are the most frequent sources of information that journalists rely on for health and medical stories (Entwistle, 1995; Nelkin, 1995; Van Trigt et al., 1994; Wilkes, 1997).

The influence of news media on prescription drugs use patterns, however, has received little attention. This is surprising given that U. S. news media are leading sources of health information for consumers, health care providers, and policymakers (Martinson & Hindman, 2005; Pew Project for Excellence in Journalism, 2010; Phillips et al, 1991; Schwartz & Woloshin, 2004; Viswanath et al., 2008). Information about medical treatments and devices is typically produced by scientific experts, and news media play an important role in translating this information to other non-specialist publics (Manning, 2001; Nelkin, 1995; Viswanath et al., 2006; Viswanath et al., 2008; Wilson, Robertson, McElduff, Jones, & Henry, 2010). News coverage can disseminate information about medical treatments directly to consumer publics, through key influencers such as physicians, or by stimulating policy actions that change the social, political, and economic context in which individuals make choices (Grilli et al., 2002; Hornik, 2002; Viswanath, et al., 2006).

In addition to being frequently cited as an important source of health information, news coverage has been associated with population-level changes in health behaviors (Hornik, 2002). Studies have demonstrated concomitant variation over time between news coverage of adverse events and behavioral changes in a variety of areas, such as IUD removal during pregnancy (Cates, Grimes, Ory, & Tyler, 1977) tobacco use, (Pierce & Gilpin, 2001), calcium channel blocker use (CCBs) (MacLure et al., 1998), and

discontinuation of aspirin for children with flu-like symptoms (Soumerai et al., 1992). Increased health screening behaviors have also been detected after highly-publicized celebrity events, such as Magic Johnson's announcement that he was HIV-positive (Casey & Allen, 2003) and Katie Couric's efforts to raise awareness of colon cancer screening on the *Today Show* (Cram et al., 2003). Time series-based analyses have also identified news coverage as a temporally prior and significant predictor of behavior change in areas such as mammography screening (Yanovitzky & Blitz, 2000), youth binge drinking (Yanovitzky & Stryker, 2001), marijuana use (Stryker, 2003), cocaine use (Fan & Holway, 1994), high-risk sexual behaviors among gay and bisexual men (Fan, 2002), and drunk driving (Yanovitzky, 2002).

News coverage may also play a role in stimulating primary and/or selective demand for prescription drugs. News coverage may raise awareness of health conditions, leading to increased help-seeking behaviors, or diffuse information about the uses, benefits, and risks of specific drugs in a manner similar to that of more extensively studied promotional sources of information. As first amendment-protected speech, prescription drug information transmitted through news media and medical journals is not subject to FDA regulations that prohibit promotion of off-label indications or require accurate and balanced information about risks and benefits, as are detailing, medical journal advertising, and DTCA (Leffler, 1981; Morris & Griffin, 1992; Sheehan, 2003). For this reason, news media might disseminate information about prescription drugs that is quite different from FDA-regulated sources of information. Like medical professional journals, news media coverage may increase or decrease prescription drug use by

spreading awareness of health conditions, or about the benefits and risks of specific prescription drugs, to consumers and physicians.

A substantial amount of news coverage is generated by the media relations activities of organizations attempting to influence the decisions of stakeholders and publics who consume the news in ways that are favorable to their strategic objectives (Cameron, Sallot, & Curtin, 1997; Sallot & Johnson, 2006; Zoch & Molleda, 2006). For this reason, another major, but infrequently mentioned or studied, form of prescription drug promotion and other commentary about prescription drugs may occur in the form of news stories created as a result of information subsidies provided to news media by organizations. This study took the initial step of examining how health and medical organizations, such as pharmaceutical companies, government agencies, universities, medical schools, medical professional societies, trade associations, and health advocacy groups, used information subsidies to stimulate coverage about prescription drugs that furthered their strategic interests. How these processes shaped the quantity and quality of news coverage was also be explored. The task of linking resulting news coverage to potential outcomes, such as prescription drug use, was reserved for a later project.

Theoretical Framework

Organizations conduct media relations to influence the news media agenda for specific issues or topics that intersect with their strategic goals. The news media agenda refers to the salience or importance placed on issues or topics by news media and is typically operationalized by the amount of coverage or prominence afforded to issues or topics over a specific time period (Dearing & Rogers, 1996; McCombs & Shaw, 1972). News media attention can confer status to an issue or topic, draw public attention to it,

and increase public perceptions of its importance (Lazarsfeld & Merton, 1948, 1964, as cited in Dearing & Rogers, 1996; McCombs & Shaw, 1972). Getting on the news media agenda and controlling the content of that coverage can serve organizations' strategic interests in various ways by helping them to promote products, build reputation, distribute financial news to shareholders and investors, manage crises, and engage in issues management to promote favorable and avoid unfavorable public policy actions, such as legislation or regulation (Heath, 1990; Heath & Cousino, 1990; Lattimore, Baskin, Heiman, & Toth, 2007).

Zoch and Molleda (2006) proposed a theoretical framework to discover how organizations actively build and frame the news media agenda through public relations techniques by combining three existing theoretical areas: agenda building, framing, and information subsidies. Agenda-building theory explores how individuals and organizations "build" the news media agenda for a public issue through various activities (McCombs, 1992; Zoch & Molleda, 2006). Information subsidies are sources of information or materials that public relations practitioners produce or make readily available to journalists to build the news media agenda, such as press releases and video news releases (VNRs) or individual experts or spokespersons (Gandy, 1982). Framing refers to the way information is selectively included, highlighted, or omitted in news stories (Entman, 1993), and how different news frames can alter audience perceptions, attributions, and decisions (Iyenger, 1991). Zoch and Molleda (2006) suggested that organizations attempt to influence the decisions of stakeholders and publics who consume the news by framing information subsidies in ways that are favorable to their strategic objectives. This study used Zoch and Molleda's (2006) theoretical framework to

understand how a variety of health and medical organizations used information subsidies to build and frame the news media agenda for HT.

Agenda building. The term agenda building refers to scholarship that explores how the news media agenda is set in terms of its priorities and focus on issues and topics (Cameron et al., 1997; McCombs 1992; Shoemaker & Reese, 1996; Zoch & Molleda, 2006). Agenda-building research emerged from the broader area of agenda-setting scholarship. McCombs and Shaw (1972) first used the theoretical term agenda setting to describe news media's role in determining what issues undecided voters in Chapel Hill, North Carolina, thought were most important during the 1968 Presidential election. They found that the news media agenda, as operationalized through content analysis procedures to rank order the amount of news coverage dedicated to different issues, and the public agenda, as operationalized by survey research to determine how the public ranked issues in terms of their relative importance, were highly correlated. Hundreds of agenda-setting studies have been conducted since McCombs and Shaw's (1972) seminal study documenting positive rank-order correlations between the amount of coverage dedicated to various issues by news media and the public's relative rankings of the importance they assign to those issues (Dearing & Rogers, 1996; McQuail, 2005).

Dearing and Rogers (1996) divided the scholarly work on agenda setting into three categories based on the primary dependent variable of interest: media agenda-setting research, which focuses on how the news media agenda is set; policy agenda-setting research, which focuses on how the policy agenda is set; and public agenda-setting research, which focuses on how the public agenda is set. Many scholars have argued that more studies are needed that conceptualize news media as a dependent

variable and explore in-depth who or what sets the news media agenda from an agenda-building perspective (Cameron et al., 1997; Dearing & Rogers, 1996; Manning, 2001; McCombs 1992; Shoemaker & Reese, 1996; Zoch & Molleda, 2006).

Explorations of how the news media agenda is set have found that “real-world indicators” of “objective reality,” such as national statistics that measure the extent of problems, such as crime, women’s rights, race relations, HIV/AIDS infection rates, rates of illicit drug use, or the number of deaths attributed to breast cancer play little role in setting the news media or public agendas (Corbett & Mori, 1999; Dearing & Rogers, 1996; Funkhouser, 1973; Gozenbach, 1996; Rogers et al., 1991). Instead, scholars have found that the agendas of a variety of political actors and publics and the news media and policy agendas all interact with one another through a complex back-and-forth process of reciprocal influence (Cobb & Elder, 1972; Corbett & Mori, 1999; Gozenbach, 1996; Kiouisis et al., 2007; Lang & Lang, 1981; Schneider, 1977; Walters & Gray, 1996). Actors that seek to exhibit influence over the agenda-building process include individuals, groups, and organizations, which often play a key role in stimulating initial news media attention to an issue and sustaining that attention.

Although public relations scholars have stressed the need to understand the role organizations play in building the news media agenda (Kiouisis et al., 2007; Zoch & Molleda, 2006), little research exists that systematically explores how organizations build the news media agenda for health and medical issues. While not identifying their studies as part of the agenda-building tradition, some scholars have highlighted the role that debates and controversies between organizations play in driving and sustaining health-related news coverage over long periods of time, which in turn, might lead to population-

level behavioral changes. For example, debates between major organizational players – the CDC, FDA, Public Citizen's Health Research Group (HRG), and a pharmaceutical industry-based group called the Committee for the Care of Children – about the validity of the epidemiological evidence linking aspirin to Reye's syndrome and whether product labeling and public education should be mandatory were credited with stimulating extensive news media coverage of Reye's syndrome from the early 1980s until 1986. Peaks in coverage over time were associated with substantial reductions in incidence rates of Reye's syndrome, which just about ceased to exist by the time labeling changes were made in 1986 (Soumerai, Ross-Degnan, & Kahn, 1992). Similarly, Pierce and Gilpin (2001) described how the news media agenda for tobacco from 1950 to 1983 was driven by debates between major players in the public health community, medical community, and tobacco industry about the epidemiological evidence linking tobacco to cancer. They also found substantial associations between peaks in news coverage and national smoking cessation rates.

The agenda-building perspective focuses on the role individuals, groups, and organizations play in stimulating news media attention to an issue or problem. Public relations scholars are particularly interested in the role organizations play in building the news media agenda (Kioussis et al., 2007; Zoch & Molleda, 2006). To date, little research exists that systematically explores what types of organizations build the news media agenda for health and medical issues and through what processes they gain and sustain media attention.

Information subsidies. To gain access to and influence the content of news media, organizations and organized interests often provide journalists with packaged,

ready-to-use information, such as press releases, video news releases, fact sheets, public opinion polls, memoranda, white papers, scientific research articles, and access to a variety of scientific experts and spokespersons (Gandy, 1982; Turk, 1985, 1986; Turk & Franklin, 1987). Gandy (1982) described these prepackaged resources as “information subsidies” because organizations pay the cost of producing the information, which in turn reduces the burden on journalists to gather news. Turk (1985) further distinguished the concept by using the term “proactive subsidies” to refer to subsidies initiated by practitioners, such as press releases, and “reactive subsidies” to refer to subsidies used to respond to journalist-initiated inquiries (p. 12).

Organizations use information subsidies to get their viewpoints covered by news media and often hope to influence the opinions, attitudes, and decisions of individuals who consume the news (Turk, 1985, 1986). By strategically trying to control access to information through the production and distribution of information subsidies, organized interests can succeed in “changing the stock of information” on which decisions are made (Gandy, 1982, p. 13). Because substantial economic resources are required to produce information subsidies, organized interests with more economic and political power tend to supply sources of information for journalists more often (Gandy, 1982; Gans, 1979; Manning, 2001; Shoemaker & Reese, 1996).

News media are frequently targeted by organizations with information subsidies because publicity gained through news is free, unlike other forms of paid-media like advertising. Information delivered via news is also often regarded as more objective than information delivered directly by an organization or actor presumed to have an interest or stake in the information, a phenomenon referred to as third-party endorsement (Gandy,

1982; Lattimore et al., 2007; Toth, 2009). Organizations provide journalists with a “direct information subsidy,” but the ultimate targets of the subsidized information, such as the consumers or policymakers the organization is trying to influence the attitudes, beliefs, behaviors, decisions or actions of, receive an “indirect subsidy” when the information is passed along as news (Gandy, 1982, p. 62).

Information subsidies make it difficult for end-users of news to fully understand the interests and motivations of the organizations or actors behind the information they receive. Newspapers sometimes print material from press releases verbatim and rarely credit the organizations or individuals that produced these information subsidies (Cameron, Sallot & Curtin 1997; Curtin, 1999). Journalists themselves may not always be certain about the interests behind the subsidies they receive. While organizations often issue information subsidies directly to journalists, they also do so indirectly through a variety of third-party techniques. Third-party techniques have not been clearly defined in the literature, but generally refer to getting other experts, organizations, or coalitions that are perceived as more disinterested in an issue, and therefore, more credible to journalists and publics, to deliver a message (Palenchar & Fitzpatrick, 2009; Rampton & Stauber, 2002).

The use of information subsidies by journalists is significant and likely has a substantial influence on the content received by news consumers. While estimates vary based on the methodological approaches taken, it is estimated that anywhere from 25% to 50% of news content in the United States is public relations-generated (Cameron et al., 1997; Turk, 1985, 1986; Sallot & Johnson, 2006). For example, a study based on 418

journalists from 1991 to 2004 found that 44% of news in the U.S. is generated by public relations practitioners (Sallot & Johnson, 2006).

To date, most research on information subsidies has been conducted from the perspectives of news organizations and journalists rather than the perspectives of the organizations that produce subsidies (Cameron et al., 1997). Research has explored if characteristics, such as the size of a news organization, are related to frequency of information subsidy use, or what features make a press release more apt to be used by journalists (Berkowitz, 1990; Cameron et al, 1997; Gans, 1979; Martin & Singletary, 1981; Morton, 1986; Tuchman, 1978; Walters & Walters, 1992; Walters, Walters, & Starr, 1994). For example, Walters and Walters (1992) found that journalists were more likely to use press releases issued by a state agency when the releases conveyed timely material and were picked up by a wire service.

Public relations scholars have stressed the need to understand the role organizations play in building and framing the news media agenda for various issues and through what processes these efforts may exert societal-level influence by changing the attitudes, beliefs, and behaviors of publics (Cameron et al., 1997; Zoch & Molleda, 2006). Little work exists that attempts to use information subsidies to trace the influence of organized interests on the news media agenda, or to understand the ramifications of these processes on the marketplace of ideas and information available to publics (Cameron et al., 1997). Research that analyzes records of information subsidies and corresponding news coverage from this perspective can begin to bridge this gap in the research.

Framing. A key component of producing information subsidies involves framing the content from the perspective of the organization or organized interests involved (Zoch & Molleda, 2006). Framing refers to the way information is selectively included, highlighted, or omitted, either consciously or unconsciously, to guide interpretation (Entman, 1993). The concept of framing is often attributed to the work of Goffman (1974) who described frames as “schemata of interpretation” that guide understanding or sense making (as cited in Zoch & Molleda, 2006, p. 281). A substantial literature exists on framing across disciplines, including mass communication scholarship (for e.g., Entman, 1993; Gitlin, 1980; Iyengar, 1991; McCombs, 1992; Scheufele, 1999; Weaver, 2007) and public relations scholarship (e.g., Hallahan, 1999; Kiousis et al., 2006; Kiousis et al., 2007; Zoch & Molleda, 2006).

While framing has been the subject of substantial scholarship, conceptual definitions of framing have varied considerably (Entman, 1993). Scheufele (1999) sought to clarify conceptual definitions of framing by dividing the literature into a four-cell typology formed by two dimensions: whether the frame under consideration is a media frame or an audience frame and whether the frame is conceptualized as an independent or dependent variable. This study and this literature review section is concerned with news media frames as dependent variables, by focusing on what is known about how organizations attempt to strategically frame information for news media (Hallahan 1999; Zoch & Molleda, 2006). At the same time, it should be noted that while organizations engage in frame-building activities to influence the content of news media, the process of framing the news is a complex one that is subject to resistance by journalists and publics who receive the news (Scheufele & Tewksbury, 2007). Factors found to influence how

journalists ultimately frame the news, include not just the frames they receive from organized interests, but their own ideological and political values, professional norms, organizational routines, competition among news outlets, interactions with other journalists, and attempts by competing organizations, individuals, and publics to frame an issue (see Scheufele, 1999; Scheufele, 2000; Scheufele & Tewksbury, 2007).

Hallahan (1999) argued that framing is central to public relations, referring to public relations professionals as “frame strategists,” (p. 224) who “construct social reality” in ways that will help their organizations and clients attain their goals (p. 206). Hallahan (1999) discussed several types of frames that public relations professionals create for a variety of situations. The frames most relevant to this inquiry related to prescription drug news that will be explored are: news frames, which package stories in terms of cultural themes that resonate with audiences to gain news attention (Gamson & Modigliani, 1987, as cited in Hallahan, 1999; Hallahan 1999; Wallack et al., 1993; Zoch & Molleda, 2006); causal explanation and treatment recommendation frames, which define issues or problems in terms of their causes and what constitutes appropriate treatments or solutions (Entman, 1993, Iyengar, 1991); and attribute frames, which highlight some aspects of people, issues, or objects and downplay or ignore others (Kiousis et al. 2006, 2007; McCombs 1992; McCombs & Ghanem, 2001). The following sections describe how these types of frames can be used to understand how organized interests might attempt to frame prescription drugs news.

News frames/framing for access. An important part of the agenda-building process is stimulating and sustaining news coverage. Public relations professionals typically package press releases in ways that put “complex or abstract ideas in familiar,

culturally resonating terms” to increase the likelihood of journalists using their materials and passing them on to audiences (Hallahan, 1999, p. 221; Zoch & Molleda, 2006). In their work on media advocacy, Wallack et al. (1993) described this type of framing as “framing for access” to news media (p. 79). This type of framing corresponds most closely to Gamson and Modigliani’s (1987) description of news frames as “media packages that feature a central organizing idea for events and employ various symbolic or framing devices that support the main idea of the story” (as cited in Hallahan, 1999, p. 222).

To successfully frame information subsidies for access, public relations professionals must understand journalistic norms and values about what makes a good news story (Manning, 2001; Tuchman, 1978). Scholars across a variety of disciplines have suggested that several types of news frames or angles tend to recur and might stimulate coverage of health topics, such as controversy; community events, fundraisers, or connections to historical events, milestones, seasons, or holidays; a human interest, personal story, or local angle; an ironic, dramatic, or unusual story or event; injustice; celebrity involvement; new scientific breakthroughs; the use of numbers or statistics to convey that a problem or issue is of large proportion or magnitude; or how business interests, such as stock prices, are affected by regulation, licensing, lawsuits, or competition (Atkin, Smith, McFeters, & Ferguson, 2008; Cameron et al., 1997; Hilgartner & Bosk, 1988; Johnson & Hufbauer, 1985; Lang & Lang, 1981; Moriarty, Jensen & Stryker, 2008; Nelkin, 1995; Seale, 2002; Tuchman, 1978; Wallack, Dorfman, Jernigan, & Themba, 1993).

Causal explanations and treatment recommendations. While news frames put an issue on the news media agenda, other frames within a story serve to define issues or problems in terms of their causes, who should take responsibility, and what constitutes appropriate solutions and treatments. The relevant conceptual definitions of framing in this area focus on frames that guide audience attributions and evaluations. Iyengar (1991) described these types of frames as “contextual cues” that lead to perceptions of “causal responsibility” and “treatment responsibility” (p. 8). Entman (1993) described how these types of frames “promote a particular problem definition, causal interpretation, moral evaluation and/or treatment recommendation” (p. 55). While this definition of framing has been used to understand how different frames lead audience members to attribute responsibility and solutions for issues like crime, poverty, and unemployment (Iyengar, 1991), this type of framing can be extended to understand the framing of health issues and conditions as well.

According to some medical sociologists, diseases and illnesses are socially constructed through definitional processes (for e.g., see Brown, 1995; Bury, 1986). Diagnosis plays a central role in the process of social construction because it defines illness experiences within the biomedical model of institutionalized medicine (Brown, 1995). Balint (1957) described diagnosis as the process by which an "unorganized illness," which is made-up of various unconnected complaints and symptoms, is turned into an "organized illness," which is interpretable and treatable. Illness experiences range from those that are generally accepted by the medical establishment and society, and to which a biomedical definition has been applied, to those generally not accepted, for which no biomedical definition has been applied (Brown, 1995).

In addition to defining and legitimizing the illness experience, definitions of disease and illness also shape treatment options. Diagnoses provide physicians and their patients with a framework to understand a problem within by suggesting the underlying cause of the problem, and in turn, what constitutes viable treatment options (Brown, 1995; Dardennes et al., 2001). In terms of the framing literature, this could be explained as a process by which different disease or illness frames lead to different causal attributions and treatment recommendations (Entman, 1993; Iyengar, 1991). For example, in the area of mental health, the biomedical model of psychiatry has led to greater use of medications as treatment choices rather than other types of therapeutic interventions, such as counseling or support groups (Brown, 1995). Other scholars have also noted that biomedical diagnoses often discourage self-help or alternative healing approaches in favor of technological interventions (Entwistle, 1995; Zoller, 2005).

Attribute frames. In addition to framing diseases and conditions in terms of their causation and what constitutes appropriate treatment, framing can play a role in highlighting or downplaying specific attributes of a treatment. An attribute is “a property, characteristic, or quality that describes an object” (Kioussis et al., 2007, p. 151). In addition to bringing attention to a medication through repeated coverage in the news, framing processes can also structure how people think about that medication by including, omitting, highlighting, or downplaying benefit and risk attributes, and perhaps shifting decisions about the overall risk-benefit profile of a treatment. Attribute frames have been explored in the mass communication literature (e.g., McCombs, 1992; McCombs & Ghanem, 2001) and the public relations literature (e.g., Kioussis et al., 2006; Kioussis et al., 2007).

The framing of attributes is referred to by some mass communication and public relations scholars as second-level agenda setting, which has been used as a way to link agenda-setting theory to framing. Traditional agenda setting, or first-level agenda setting, posits that news media attention to objects or issues can determine *if* people think about an object or issue by making it more salient in their minds. Second-level agenda setting posits that news media attention can also influence *how* people think about a topic by selecting and/or emphasizing certain attributes and ignoring or downplaying others (McCombs, 1992; McCombs & Ghanem, 2001).

To date, the framing literature in the mass communication and public relations fields has focused on studies of attributes associated with issues, political candidates, and organizations (Hester & Gibson, 2003; Kioussis et al., 2007; McCombs, Llamas, & Lopez-Escobar, 2000). Two different types of attributes have been studied, substantive attributes and affective attributes (McCombs & Ghanem, 2001). Substantive attributes are specific factors that might be associated with a candidate in a news story, such as the candidate's integrity or qualifications. Affective attributes refer to the valence of those substantive attributes, for example, a candidate's integrity can be portrayed in a positive, negative, or neutral manner (McCombs, Llamas, & Lopez-Escobar, 2000).

Minimal work exists that systematically looks at the framing of diseases and conditions and their treatments by different organizations. Organizations may frame information subsidies about health issues in specific ways to gain access to news media, promote their preferred definition of a health condition or illness and what constitutes appropriate treatment, and accentuate or downplay the attributes of treatments in terms of their benefits and risks.

Empirical support for theoretical framework. Zoch and Molleda (2006) argued that multi-stage research processes are needed to fully understand the contributions organizations make to publics' perceptions, attitudes, and behaviors through media relations activities. They recommended examining information subsidies for specific frames that can be quantified and tracking those frames to see if and how they transfer onto the news media agenda, along with outcomes measured further out in time to measure public understandings of the viewpoints framed by organizations. Scheufele (2000) has argued for similar types of process research that begin with agenda-building processes to explore how various actors frame information, how those actors pass those frames through mass media, and how those frames might lead to audience frames.

Only a few public relations scholars have begun to explore whether attributes highlighted in press releases translate to attribute salience on the news media agenda, and in turn, to the salience of those attributes in the public's mind or to other tangible outcomes. In a study focused on 28 large companies, Kioussis et al. (2007) explored relationships between corporate attributes highlighted in press releases obtained through *PR Newswire*, news articles in *The New York Times* and *The Wall Street Journal*, public opinion about corporate reputation, and financial performance data. Similarly designed studies were conducted to explore the relationships between press releases posted on Speaker of the House Nancy Pelosi's website, news articles in the *New York Times*, and Congressional policymaking in 2007 (Kioussis et al., 2009), and to explore the relationships between candidate news releases, newspaper content, and public perceptions of issue salience and substantive and affective candidate images during the 2002 Florida gubernatorial general-election period (Kioussis et al., 2006). All three studies

found positive correlations between object or issue salience in the public relations and news media agendas. Substantial support was also obtained to support the transfer of attribute salience from public relations agendas to news media agendas. Mixed support was found for links between news coverage and public opinion and corporate performance data, and no support was found for the link between the news media agenda and Congressional policymaking.

Little research explores how organizations influence the news media agenda for prescription drug news, and how those efforts might influence the quality of that news. Only one study could be found by Anderson (2001) that compared press releases distributed via *PR Newswire* by Merck and Searle on their competing anti-inflammatory arthritis drugs, *Vioxx* and *Celebrex*, to news coverage in high-circulation, U.S. daily newspapers from 1998 to 2000. A qualitative, thematic analysis revealed that both pharmaceutical companies successfully influenced the news media agenda in terms of topics discussed. Major topical themes included comparisons of the drugs to older anti-inflammatories like ibuprofen and aspirin in terms of their gastrointestinal side effects, the costs of these newer drugs compared to existing alternatives, and the specific advantages of *Vioxx* vs. *Celebrex*. Although pharmaceutical companies successfully influenced the news media agenda in terms of topical frames, resulting newspaper articles tended to be more neutral overall in tone and to cite a greater variety of sources than presented in press releases, including physicians, industry analysts, and insurance-company spokespersons. While insightful, this study, however, did not examine the press releases of any other health and medical organizations that also likely tried to influence the news media agenda for these drugs.

The research on agenda building and information subsidies led to the following research questions to determine the role the public relations agenda of organizations played in setting the news media agenda, and what types of issues and stories stimulated the most news media attention. As will be discussed further in the Method chapter the public relations agenda was operationalized as the number of press releases distributed about HT over the study time period; the news media agenda was operationalized as the number of print news stories over the same time period.

RQ1: What was the relationship between the quantity of press releases about hormone therapy (HT) distributed by organizations via *PR Newswire* and *EurekAlert!* and the quantity of news stories about HT in *AP Newswire* and four, top-circulating U.S. newspapers from 1995-2011.

RQ1a: How many press releases about HT appeared between 1995-2011?

RQ1b: How many news stories about HT appeared between 1995-2011?

RQ1c: Was the amount of press releases positively correlated with the amount of newspaper stories over time?

RQ1d: What overall story frames or themes were associated with peaks in press release and news story activity?

The framing literature led to the following research questions to measure the transference of organizations' viewpoints from the public relations to the news media agenda about the substantive attributes of HT. Each research question was posed separately for each body of text, press releases (RQ2 sequence of questions) and news stories (RQ3 sequence of questions) for the purpose of generating univariate data first in

the Results section (see summary of research questions at the end of this chapter). For brevity, only the research questions that compared the two sequences are listed below.

RQ4: How did the press releases and news stories compare in terms of content from 1995-2011?

RQ4a: How did press releases and news stories compare in terms of the types of organizations mentioned and types of individuals quoted?

RQ4b: How did press releases and news stories compare in terms of benefits and risks associated with HT and risk and benefit presentation (qualitative vs. quantitative; relative vs. absolute terms)?

RQ4c: How did press releases and news stories compare in terms of mentioning specific brand-name HT products?

Sources of Health, Medicine, & Prescription Drug News

News sources refer not only individuals, but to material sources of information as well. Gans (1979) described news sources as “the actors who journalists observe or interview, including interviewees who appear on the air or who are quoted in articles, and those who only supply background information or story suggestions”(Gans, 1979, p. 80). Scientific journals and conferences, press releases, wire services, other newspapers, spokespersons, and personal networks of scientific contacts are all common sources of information for stories about health and medicine (Dunwoody, 1986; Gandy, 1982; Nelkin, 1995; Rogers et al., 1991; Semir et al., 1998; Van Trigt et al., 1994).

Many of the common sources of information used by journalists are produced, financed, or made available by organizations or organized interests that seek to shape the information environment about health and medicine in ways that align with their strategic

goals. These sources of information can also be thought of as information subsidies, as they reduce the burden on journalists to gather news (Gandy, 1982). Organizations and organized interests with the economic resources to produce commonly-used information subsidies for news stories about health and medicine may be in positions of power to influence a substantial amount of news content (Gandy, 1982; Manning, 2001).

Common information subsidies. Previous research has found that journalists typically rely on government, scientific, and medical institutions for information about health and medicine (Cho, 2006; Friedman, 1986b; Gandy, 1982; Gans, 1979; Tanner, 2004; Wallington et al., 2007). Medical professional journals are the most frequent sources of information that journalists rely on for information about health and medicine (Entwistle, 1995; Nelkin, 1995; Van Trigt et al., 1994; Wilkes, 1997). One study found that 35% of journal articles published in the *New England Journal of Medicine (NEJM)* and the *Journal of the American Medical Association (JAMA)* received coverage in top-circulating, U.S. newspapers (Burns, Moskowitz, Osband, & Kazis, 1995). Several scholars have also found that the number of articles published on a health topic or issue is highly correlated with the number of articles published in newspapers on the same health topic or issue (Cates et al., 1977; Corbett & Mori, 1999; Rogers et al., 1991; Soumerai et al.; Van Trigt et al. 1995). A study that specifically focused on medications found that the same medications that were discussed most frequently in the medical professional literature were also the ones discussed most frequently in newspapers (Van Trigt et al., 1995).

Medical journals also exert considerable control over the flow of scientific information (Wilkes, 1997). Many scientific journals have a policy, known as the

Ingelfinger Rule, of not publishing research if it was previously published anywhere else, including the press, which protects the revenue stream of the journals and keeps journalists highly dependent on journals for new research (Association of British Science Writers, 2011; Nelkin, 1995; Wilkes, 1997). With the advent of electronic publishing, some journals allow researchers to submit drafts of not yet published papers to preprint databases, such as arxiv.org or eprints.org, for consumption by the scholarly community (Harnard, 2000), but policies vary considerably by publishers and journal. For example, *JAMA* and *The Lancet* limit preprint publication to preliminary findings in the form of an abstract only (*JAMA*, 2013; *The Lancet*, 2011); NEJM allows authors who present at scientific meetings to post an audio recording and selected slides to the Internet; and *Science* will allow a manuscript to be posted to a not-for-profit preprint server like arxiv.org, but to no other places on the Internet (Science, 2013). In addition, most science and medical journals, including the four journals mentioned above, still have embargo policies in place and distribute advance copies of articles to journalists with embargos that specify release dates (Kiernan, 2006; Nelkin, 1995).

Journalists also depend on press releases as sources of information for news. In addition to medical professional journals, which are cited as the most important source of information, journalists have cited press releases from universities, hospitals, government institutions, and the pharmaceutical industry as important sources, although some have expressed reservations about the credibility of information distributed by pharmaceutical companies (Van Trigt et al., 1994). A study that compared press releases distributed by major scientific journals to U.S. and European newspapers found that across all newspapers, 84% of news stories referred to journal articles that were the subject of press

releases, and only 16% of news articles referred to journal articles that were not the subject of a press release (Semir et al., 1998). Entwistle (1995) achieved similar results, finding that 86% of British newspaper articles that referred to studies in the *British Medical Journal (BMJ)* and the *Lancet* were also the subject of journal press releases.

Other news outlets and wire services are also important sources of information. *The New York Times* and *The Washington Post* often set the agenda of health topics covered by other newspaper and television news outlets (Corbett & Mori, 1999; Gans, 1979; Rogers et al., 1991; Shoemaker & Reese, 1996). Wire services, such as the *Associated Press (AP)*, are also important agenda setters, particularly for specialized topics like health (Nelkin, 1995). Stories covered by wire services are more likely to get coverage (Walters & Walters, 1992) and are often reproduced exactly as written in daily papers throughout the United States (Gandy, 1982), particularly in the case of local and regional papers with smaller staffs (Nelkin, 1995). The reliance on wire services and other media outlets leads to a situation where health and medical news looks similar throughout the U.S.

Individuals also serve as sources of information for journalists, who often cite individuals and their quotes as evidence or support in news stories. Individuals frequently cited in news stories about science, health, and medicine are most often scientific or clinical experts who are perceived as highly authoritative and credible, such as research scientists and physicians (Atkin et al., 2008; Dunwoody, 1986; Nelkin, 1995; O'Leary, 1986). Other sources that tend to be cited somewhat often, but less frequently, include patients or "person on the street" sources who are directly or indirectly affected by a health condition or problem, patient advocates, and celebrities (Atkin et al., 2008; Nelson

& Signorielli, 2007, p. 3; Seale, 2002). In their content analysis of breast cancer news coverage by top U.S. newspaper, magazine, and television stations, Atkin et al. (2008) found that researchers or physicians were cited in (63%) of all stories. More than a third cited patients, patient advocates, or family members, and 11% cited celebrities.

Most individuals who serve as sources, particularly scientific experts, are rarely “self-employed” and work for organizations (Dunwoody, 1986, p. 4). Organizations often make individuals readily available to journalists as spokespersons as a type of information subsidy (Gandy 1982; Sweet & Brown, 2008). Content analysis studies suggest that individuals, particularly experts, are rarely cited without their organizational affiliations. Atkin et al.’s (2008) content analysis of breast cancer news coverage found that 75% of experts cited were associated in the text with an organization, and 90% of references to organizations cited or named an individual expert. Scientists consulted as sources are most often those that are highly established in their fields and tend to work for government institutions and universities rather than private industry because of journalists’ skepticism of the public relations agendas of industry scientists and experts (Dunwoody, 1986).

Previous research has found that the types of organizations cited in health and medical news include government agencies and academic research institutions, foundations and medical societies, pharmaceutical companies and other corporations, and health advocacy and consumer groups (Atkin et al., 2008; Manning, 2001; Moriarty et al., 2008; Nelkin, 1995; Nelson & Signorielli, 2007; Seale, 2002). For example, Atkin et al. (2008) found that organizations cited in breast cancer news stories were medical research centers or practices (52%), breast cancer foundations and societies (26%), federal

agencies, such as the National Institutes of Health, Centers for Disease Control & Prevention, and the Environmental Protection Agency (20%), and pharmaceutical companies and other corporations (15%). Another 29% of stories cited medical journals. Moriarty et al. (2008) found in their content analysis of cancer news coverage in 44 top-circulating, U.S. newspapers in 2003 that large academic research centers were cited most frequently (29.7%), followed by medical journals (12.3%). Large organizations like the American Cancer Society (9.5%), the National Cancer Institute (4.5%), and pharmaceutical companies (5.2%) were also cited by journalists.

Types of organizations that produce information subsidies. Much of the research on sources of health, medicine, and prescription drug news has focused on identifying commonly used information subsidies, such as medical journal articles and press releases, or describing the types of individuals and organizations that are cited in news stories. Relatively unexplored in the literature is the role organizations play in shaping health and medical news through the production and dissemination of information subsidies, how they frame these subsidies to achieve their goals, and how these processes influence the quality of health and medical news. Several scholars have advocated approaches to understanding news content that include not just factors internal to the news organization, but factors external to it as well, such as the role organizations and other actors play when they attempt to use news media to meet their own political and economic interests (Gandy, 1982; Manning, 2001; Seale, 2002 Shoemaker & Reese; 1996).

This inquiry is particularly important because of widespread concern about the role of organized interests and conflicts of interest in medicine across a wide variety of

areas. Conflicts of interest are defined as “circumstances that create a risk that professional judgments or actions regarding a primary interest will be unduly influenced by a secondary interest” (IOM, 2009, p. 6). Most definitions of conflict of interest stress the potential for biased judgment, not necessarily that any kind of bias actually exists or will occur (Batt, 2005). A conflict of interest can be personal or financial, but financial is easiest to identify and the type of conflict that often generates the most concern (Batt, 2005; Cook et al. 2007; IOM, 2009).

In 2009 the Institute of Medicine (IOM) convened an expert panel to write a report on conflicts of interest in medicine due to growing concerns among the public and throughout Congress about highly publicized instances of undisclosed financial ties between industry and organizations involved in medical research, practice, and education. Conflicts of interest documented in the IOM report were numerous, including but not limited to, failures of academic researchers and physicians to disclose industry support on medical journal articles; instances of academic researchers who played little-to-no role in study design, data analysis, or writing, taking authorship credit on scientific publications for honoraria payments; pro-industry publication biases in the medical literature; industry sponsorship of medical professional societies that write clinical practice guidelines; and a growing concern about pharmaceutical company support of patient- and disease-specific health advocacy groups.

The IOM report (2009) indicated that although both individual-level and organizational-level financial conflicts of interest were commonplace, more attention has been paid to individual-level conflicts, such as physicians receiving pharmaceutical industry payments, than organizational-level conflicts, such as medical schools, medical

professional societies, or patient advocacy groups receiving industry funding. While many of the types of organizations mentioned had conflict of interest policies or codes for relationships with industry, the IOM concluded that the policies were often not specific enough or enforced in any way to effectively manage potential conflicts. Among its many recommendations, the IOM called for the U.S. Congress “to create a national program that requires pharmaceutical, medical device, and biotechnology companies and their foundations to publicly report payments to physicians, researchers, health care institutions, professional societies, patient advocacy and disease-specific groups, providers of continuing medical education, and foundations created by any of these entities” in the interest of greater disclosure and transparency (IOM, 2009, p. 9).

Growing evidence suggests that the pharmaceutical industry might make substantial use of what could be considered third-party techniques when they fund the production of information subsidies through a variety of partnerships and collaborations with other organizations, such as academic research institutions and medical schools, medical professional societies, and patient advocacy and disease-specific groups. From an information subsidies perspective, many of these types of organizations conduct substantial media relations activities. It is unclear how proactive these organizations are in disclosing financial conflicts when working with news media. Third-party techniques that operate through funding support might be a way for industry to build the news media agenda through academic and other nonprofit organizations. Nonprofit organizations are often perceived by journalists as more credible sources of information than for-profit organizations, and news editors are more likely to accept subsidies from nonprofit

organizations that they perceive to be working in the public interest than any other organization type (Berkowitz & Adams, 1990; Curtin, 1999; Qui, 2006).

Little research has looked systematically at what types of health and medical organizations produce information subsidies about prescription drug news; what their resources and goals are; and how they act individually, and perhaps jointly with other organizations, to influence news content. The following descriptive categories represent different types of health- and medical-oriented organizations and organized interests that might play a significant role in influencing prescription drug news, along with some basic information about their resources and goals, what is known about the types of subsidies they produce, and how they have collaborated with other organizations in the past to produce information related to prescription drugs. Some categories have examples of specific organizations to be illustrative, but this does not mean that many other relevant organizations do not exist within these categories.

Industry. Manufacturers of prescription drugs engage in research and development to bring new products to market and engage in substantial public relations and marketing activities to promote new products, maintain loyalty for existing products, ensure a favorable regulatory environment, and inspire shareholder and investor confidence. Prescription drug spending is one of the fastest growing components of total national health care spending. In the United States in 2008, \$234.1 billion was spent on prescription drugs compared to \$40.3 billion in 1990 (Kaiser Family Foundation, 2010). As large corporate entities, pharmaceutical manufacturers have considerable public relations resources including internal public relations teams, contracts with outside public relations agencies and consultants, and their own experts and scientists to validate their

claims (Fugh-Berman, 2005; Manning, 2001; Nelkin, 1995). In addition to direct attempts to influence news media, pharmaceutical companies may engage in third-party techniques through their funding of many other organizations, such as universities and academic medical centers, medical professional societies and associations, and a variety of nonprofit patient- and disease-advocacy groups.

The pharmaceutical industry is the largest producer of medical information about prescription drugs; it exerts considerable control over information about the scientific evidence base through its financial control of clinical research. Industry funds approximately 57% to 61% of all biomedical research in the United States, and 70% of all clinical drug trials (Moses & Martin, 2001, as cited in DeAngelis, Fontanarosa, & Flanagan, 2001; IOM, 2009). About 70% of pharmaceutical support goes to contract research organizations (CROs) that manage clinical trials for their clients; the other 30% goes to academic researchers (Sismondo, 2007).

This economic advantage provides pharmaceutical companies with substantial control over what studies get funded, and if, and how, the findings are published in the scientific literature. Publications in prestigious, peer-reviewed scientific and medical professional journals are a “valuable commodity” for pharmaceutical companies (Wilkes, 1997, p. 14). Biomedical journals are top sources of information for journalists and are the primary way that scientists, health care providers, and the public learn about new medical research findings (Fugh-Berman, 2005; Wilkes, 1997; Wilkes & Kravitz, 1995). Journal articles are used in sales visits to physicians and to convince regulators of drug efficacy and safety (Entwistle, 1995; Fugh-Berman, 2005; Nelkin, 1995; Sismondo, 2007; Wilkes, 1997). As with news media, medical journals are protected by the first

amendment and may also serve as a valuable, non-FDA regulated marketing tool (Sweet, 2003).

Concerns about the integrity of the medical professional literature have been raised by many concerned about industry control of the scientific literature and potential conflicts of interest between scientific investigators and industry sponsors (Collier & Iheanacho, 2002). Past research has found that manufacturer-sponsored studies are more likely to report favorable results about drug products and to publish studies with negative results later after prescribing patterns have been established (Bodenheimer 2000; Collier & Iheanacho, 2002; Healy & Cattell, 2003). One of the most controversial practices is the practice of ghostwriting. Ghostwriting is when an individual makes a substantial contribution to a manuscript, usually in the form of research and writing, without attribution or disclosure (Bodenheimer, 2000; Gøtzsche et al. 2007; Gøtzsche et al., 2009; Ross, Hill, Egilman, & Krumholz, 2008). Ghostwriters often work for contract research organizations (CROs) or medical education and communication companies (MECCs) hired by pharmaceutical companies to produce, place, and track journal articles. In the most extreme cases, ghostwriters produce manuscripts and high-profile academics are recruited after-the-fact to author the publications, sometimes collecting honoraria payments (Fugh-Berman, 2005; Healy & Cattell, 2003; Sismondo, 2007).

Ghostwriting is difficult to detect and most knowledge about this practice has been made available through litigation. Cases of ghostwriting have been discovered through litigation for several high-profile drugs, including Wyeth's hormone therapy drugs *Premarin* and *Prempro*, Merck's anti-inflammatory *Vioxx* (Berenson, 2005; Ross et al., 2008; Saul, 2008; Sismondo, 2007), Pfizer's antidepressant *Zoloft* (Healy & Cattell,

2003) and seizure-control drug *Neurontin*, also manufactured by Pfizer (Steinman, Bero, Chren, & Landefeld, 2006).

Academic/medical institutions. A large portion of biomedical research and discoveries related to drug products happen at universities, particularly those with medical schools and affiliations with large teaching hospitals. Universities and medical centers benefit from positive publicity in the news media about faculty research, as publicity builds institutional reputation, which attracts high quality faculty, physicians, and students, and can bring more patients to medical centers (Gandy, 1982; Nelkin, 1995). Academics rely on peer-reviewed publications for promotion and tenure, and news media attention can enhance their professional reputations and ability to secure grant funding (Wilkes, 1997). Although individual scientists will sometimes promote themselves, most often their institutions promote their work. Most major research institutions have public relations departments with substantial resources (Nelkin, 1995).

Public support of science has been declining, making academics and research institutions more reliant on industry sources of support (IOM, 2009). A 2006 national survey of department chairs in medical schools and teaching hospitals found that 67% of departments had financial relationships with industry (Campbell et al., 2007, as cited in IOM, 2009). In terms of individual-level arrangements, 60% of department chairs had relationships with industry, which ranged from paid consultancies and speaking opportunities to service on scientific advisory boards (Bero, 2008, as cited in IOM, 2009).

Links between academia and industry have often been controversial due to concerns about economic interests reducing academic investigators' ability to fully

control their research programs and projects (IOM, 2009; Martinson, Anderson, & deVries, 2005). Through grant and contract funding opportunities, industry exerts a powerful role by deciding what studies are worthy of funding and hand-selecting investigators. Although university-industry contracts vary, academics sometimes must allow industry sponsors to be involved in designing study protocols and analyzing and interpreting data, and in some cases, investigators are not given full access to study data and statistical analyses are performed by company statisticians (Fugh-Berman, 2005; Healy & Cattell, 2003; IOM, 2009; Sismondo, 2007; Wager, 2007). Investigators are also sometimes forced to delay publication of important results when the information reported would result in the release of trade secrets on pending industry patents (IOM, 2009).

Government agencies. Several agencies within the U.S. Public Health Service are engaged in medical research, health policymaking, and education and outreach efforts. Government agencies may enjoy a distinct advantage in the communication marketplace of ideas related to prescription drug efficacy and safety, as research has found that journalists perceive government officials and scientists as credible sources and rely on them heavily for health and medical news (Gandy, 1982; Manning, 2001; Nelkin, 1995). Two government agencies heavily involved in prescription drug science, regulation, and education are the National Institutes of Health (NIH) and the Food & Drug Administration (FDA).

As institutions supported by tax dollars, the NIH and FDA use media relations to fulfill their missions of service to the public, manage their reputations, and demonstrate value and visibility to maintain public funding (Gandy, 1982). The NIH has an extensive communication operation, which includes public affairs offices at all agency institutes

and centers, and the FDA positions public affairs staff throughout the country to provide information at the local level. Both agencies engage in a wide range of public relations activities, including releasing medical research findings to the public, issuing safety alerts to consumers and health care professionals as necessary, and initiating a variety of health education and community outreach campaigns. In addition to internal staff, these federal agencies often contract with public relations agencies and consultancies for education and outreach efforts (U.S. Department of Health & Human Services, National Institutes of Health [USDHHS, NIH], 2010c).

National Institutes of Health. The National Institutes of Health (NIH) is a federal, medical research agency. Part of the United States Public Health Service, it is comprised of 27 institutes and centers in different disease areas. The “NIH’s mission is to seek fundamental knowledge about the nature and behavior of living systems and the application of that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability” (USDHHS NIH, 2010a). The NIH, funded by tax dollars through appropriations authorized by Congress, spends more than \$31.2 billion annually on medical research, making it the second largest funder of biomedical research, after the pharmaceutical industry, which invests more than twice that amount (Moses & Martin, 2001, as cited in DeAngelis et al. 2001, p. 90). About 80% of NIH funding goes to universities, academic medical centers, and other research institutions in the United States and around the world in the form of extramural grants. Another 10% goes to NIH employee scientists, often called intramural scientists, at the NIH clinical center campus in Bethesda, Maryland (USDHHS NIH, 2010b).

As a tax-supported agency, NIH is answerable to the public for its research programs and actions. Historically, a range of consumer groups have launched initiatives to pressure the agency to alter its funding priorities. Due to growing concerns about the potential for government-funded investigators to have financial ties to industry, the U.S. Public Health Service (PHS) began requiring all research institutions that receive PHS funding to disclose financial conflicts of interests between investigators and industry when applying for grants and to develop conflict of interest policies. The IOM panel on conflict of interest in medicine concluded, however, that these requirements are often not properly overseen or enforced (IOM, 2009). For example, in 2004, national newspapers publicized an account of scientists in NIH's own intramural research program that failed to disclose financial relationships with industry, which triggered an NIH investigation (IOM, 2009).

Food & Drug Administration. The Food & Drug Administration (FDA) is a regulatory consumer protection agency with authority over food and drug products. The agency works to ensure the safety and efficacy of all prescription and over-the-counter drugs by reviewing clinical data and approving drugs for market, inspecting manufacturing facilities, monitoring drugs on the market for adverse events, and reviewing all product labeling and advertising for truthfulness and accuracy. A range of educational and regulatory techniques are used by the agency when industry is in violation of the law, including issuing warning letters to manufacturers, requesting mandatory product labeling changes, issuing public health safety advisories to health care providers and consumers, and asking manufacturers to remove products from the market

when they pose an immediate threat to public health or accumulating evidence suggests the risks of their use significantly outweigh the benefits (USDHHS FDA, 2011a).

The fiscal year 2010 budget for the FDA was \$3.2 billion, which included \$2.35 billion in Congressional tax dollar-funded appropriations, and \$828 million in industry-user fees for regulated products. Of these industry-user fees, \$578 million came from manufactures of prescription drugs when submitting drug approval applications (USDHHS FDA, 2009). The FDA began collecting user fees from the pharmaceutical industry through the Prescription Drug User Fee Act of 1992, which allowed the agency to expand staff and approve drug applications more quickly (Meier, Garman, & Kaiser, 2003). This arrangement, however, is controversial and critics worry about potential conflicts of interest in the drug approval process due to this substantial industry support (Kaufman, 2002).

The FDA's Division of Drug Marketing, Advertising, and Communications oversees all promotional labeling and advertising of prescription drugs to health care providers and consumers to ensure that "prescription drug information is truthful, balanced and accurately communicated" (USDHHS FDA, 2010). FDA guidelines require a "fair balance of efficacy and risk information in all communications" (Sheehan, 2003, p. 160). The FDA conducts the bulk of its review process when reviewing a new product's labeling, and at times will require what is commonly referred to as a "black box" warning, which requires the manufacturer to highlight serious adverse side effects in text surrounded by a black box to get the attention of health care providers and consumers. When reviewing advertising and other regulated promotional materials, the

FDA reviews claims made to make sure they conform to the FDA-approved product labeling (Calfee, 2002; Morris & Griffin, 1992).

As a regulatory agency, FDA must manage relationships with a variety of publics, including but not limited to, industry, Congress, the President, the federal courts, state agencies, and a variety of trade associations, lobbyists, and scientific and consumer groups that seek to influence the agency, often through testimony on proposed regulations (Meier, Garman, & Kaiser, 2003).

Professional societies and trade associations. Often active in the debate about prescription drugs and other medical treatments are numerous nonprofit medical professional societies and trade associations. There are many professional societies at the national and state levels that represent the interests of physicians, specific medical specialties, and other allied health professionals. For example, the American Medical Association (AMA) represents physicians across the nation, the American Congress of Obstetricians and Gynecologists represents obstetrics and gynecology specialists, and the Massachusetts Medical Society represents physicians practicing in the state of Massachusetts only. Other types of trade organizations typically represent industry. For example, The Pharmaceutical Research and Manufacturers of America (PhRMA) represents just about all the nation's leading pharmaceutical and biotechnology companies. Professional societies and trade associations play a key role in advocating for legislation and public policies that are favorable to their memberships. Medical societies also tend to engage in a range of other activities, such as providing continuing education for their members, sponsoring medical conferences, publishing peer-reviewed medical journals, and leading a variety of clinician and patient education efforts.

Referred to as “business leagues” or 501c(6) organizations per the IRS classification system, professional societies and trade associations are nonprofit, tax-exempt organizations. While exempt from federal taxes on revenues, they cannot receive tax-deductible contributions from individual or corporate donors as 501c(3) public charities can (Boris, & Steuerle, 2006). 501c(6) organizations are permitted to engage in unlimited lobbying to influence federal, state, and local legislation related to the organization’s common business interests without jeopardizing its tax-exempt status. Lobbying can include grassroots lobbying activities to influence public opinion and mobilize support or direct lobbying activities to influence legislation. They can also engage in political campaigns to support or oppose candidates for public office, but this cannot be the organization’s “primary activity,” or it risks losing tax-exempt status, and monies spent on political election activities may be taxed (U.S. Department of Treasury, IRS [USDT IRS], 2010b). A large portion of the budgets of professional societies and trade associations are paid by members in the form of dues. Medical societies typically earn additional revenue through sponsorship of continuing education and conferences and journal subscriptions and advertising fees (IOM, 2009).

Some concerns have been raised about pharmaceutical support of medical professional societies. The pharmaceutical and medical products industries contribute substantially to these organizations’ operating budgets through continuing education and conference support, advertising in medical journals, and a variety of research and recognition awards (Beder et al., 2003; IOM, 2009). Overall, it is estimated that approximately 30% to 50% of medical society budgets come from industry sources (IOM, 2009), raising concerns about conflicts of interest, particularly in the areas of

clinical practice guidelines and editorial control of peer-reviewed journals. Clinical practice guidelines are often developed by medical societies and distributed to members to guide their treatment practices and approaches to various diseases and conditions (IOM, 2009), and more than one-third of leading medical journals are published by medical societies (Wilkes & Kravitz, 1995).

Assessing the extent of potential conflicts of interest between industry and professional societies and trade organization is a difficult task. 501c(6) organizations are not required to report information about the actual sources of the funds they receive when they report financial information via IRS Form 990, the form required of all nonprofit, tax-exempt organizations (Boris, & Steuerle, 2006). While many organizations transparently list corporate donors in their annual report or other publications, or announce corporate support of specific activities, the actual amount of funding is often not reported (IOM, 2009).

Health advocacy organizations. A large number of nonprofit patient and consumer advocacy groups play an active role in communication about health issues. Some represent constituencies, such as women, and others are disease-specific in orientation. These organizations are diverse in their nature, size, and resources, ranging from large, well-funded organizations like the American Heart Association to small community-level organizations with names rarely recognized outside of their respective communities. These organizations engage in a range of activities, including fundraising, patient counseling and support, education campaigns, and public policy advocacy (Batt, 2005; Lofgran, 2004). Some well-funded organizations have public relations departments that rival large corporations (Nelkin, 1995; Manning, 2001); others make do with little-

to-no resources. Many employ media advocacy techniques, such as holding press conferences, issuing press releases, and using celebrities, community events, and protests to build the news media agenda for their cause (Shoemaker & Reese, 1996; Wallack et al., 1993).

Most patient and disease-specific advocacy groups are IRS-category 501c(3) organizations, which are commonly referred to as “public charities” or “charitable organizations,” and comprise the largest number of nonprofit organizations in the United States (Boris & Steuerle, 2006; USDT IRS, 2010a). To qualify as a public charity, an organization must be “engaged in educational, religious, scientific, or other forms of charitable behavior” (Boris & Steuerle, 2006, p. 67). Public charities have the most generous exemption rules. In addition to their revenues being tax exempt, 501c(3) organizations can receive tax-deductible donations from individuals and corporations. Unlike 501c(6) professional societies and trade organizations; however, the lobbying and political activities of public charities are more restricted. Although 501c(3) organizations cannot engage in any direct or indirect activity related to the election of political candidates for public office, they can engage in mission-related grassroots and direct lobbying, as long as these activities do not comprise a “substantial part” of the organization’s overall activities (USDT IRS, 2010a).

Pharmaceutical company-patient advocacy group partnerships are now common in the U.S., Canada, Europe, Australia, and New Zealand (Batt, 2005; Beder et al., 2003; Lofgran, 2004). Although pharmaceutical companies had long viewed consumer groups as antagonists, this began to change in the 1980s when pharmaceutical companies recognized the value of partnering with AIDS activists to fight for faster federal approval

of drugs to treat HIV/AIDS and for federal money for AIDS research (Batt, 2005; Burton & Rowell, 2003a). Industry typically targets financial support to these organizations in areas of disease awareness campaigns, education, and advocacy, often providing funds for specific projects like outreach events and conferences or development of brochures and other materials (Batt, 2005; Moynihan et al., 2002). In addition, pharmaceutical company representatives sometimes serve on the boards of directors or other advisory boards of these organizations (Zones & Fugh-Berman, 1999).

Tracing the amount of industry funding received by a nonprofit health advocacy group is difficult. Like 501c(6) organizations, 501c(3) organizations are not required to disclose the names of organizations or individuals that make contributions to their organizations to the IRS. While the Federal Lobbying Disclosure Act of 1995 requires 501c(3) organizations to report sources of funding for federal lobbying activities, organizations are not required to do so unless lobbying is the “primary activity” of the organization (Fitzpatrick & Palenchar, 2006; USDT IRS, 2010a). As in the case of medical professional societies and trade organizations, many patient and consumer advocacy groups opt to disclose information in their annual reports and other materials in the interest of transparency. Often, however, it is difficult, and sometimes impossible, to ascertain the amount of funding received or to link funding sources back to specific initiatives.

In a rare investigation of six patient-advocacy organizations in 2006—the American Diabetes Association, the National Alliance on Mental Illness (NAMI), Children and Adults with Attention Deficit/Hyperactivity Disorder (CHADD), the Arthritis Foundation, the National Gaucher Foundation, and the National Organization

for Rare Disorders—the *Philadelphia Inquirer* reported that the groups received at least \$29 million from major drug companies that marketed drugs to their constituencies, such as Eli Lilly, Merck, and Pfizer, but “disclosed limited or no details about the ties” when “commenting or lobbying about donors’ drugs” (Ginsberg, 2006, p. A01). Support from pharmaceutical companies also came in the form of management consulting arrangements; for example, an Eli Lilly & Company executive reportedly worked closely with the American Diabetes Association “to chart its growth strategy and write its slogan”(Ginsberg, 2006, p. A01).

Substantial controversy exists over whether industry support of patient and consumer advocacy groups is a conflict of interest and should be disclosed, particularly within the nonprofit community itself. Some argue these partnerships violate the organization’s primary responsibility to its constituents; others argue that taking industry funding is a legitimate way for nonprofits to raise much-needed funds and for pharmaceutical companies to “give back” to their communities (see Batt, 2005; Beder et al., 2003; Burton & Rowell, 2003a; Ginsberg, 2006; Lofgran, 2004). Differences of opinion are evident in the varied funding policies of these groups: some accept no industry money; some will not accept money from companies that sell products directly to their constituencies; some will accept monies from those that target their constituencies, but will not publicize brand names; and some have no restrictions (Burton & Rowell, 2003b; Zones & Fugh-Berman, 1999).

Coalitions. Coalitions are not actual organizations, but organized interests which are often made up of a variety of public- and private-sector organizations. “Coalitions are temporary constructs of individuals, groups, and organizations that ban together and

advocate for an intended purpose” and seek to influence public opinion and/or policymaking (Fitzpatrick & Palenchar, 2006, p. 205). Coalitions often produce joint media relations materials (Yoon, 2005) and once in place are often reactivated as areas of mutual interest continue to arise (Bridges, 2004; Crable & Vibbert, 1985). Coalitions are perhaps the most poorly understood type of organized interest that participates in the public policy process.

Coalitions derive their credibility from the perception that they represent a large and diverse group of constituents typical of grassroots movements, but coalitions vary significantly in their funding bases, ranging from legitimate coalitions to illegitimate front groups (Batt, 2005). According to Fitzpatrick and Palenchar (2006), legitimate coalitions are transparent about their mission, sources of funding, and membership. Front groups are typically funded by a small number of individuals or an organization, and intentionally try to deceive publics by pretending they represent large constituencies. Front groups are often given “noble sounding” names, such as “Citizens for [Something Good]” (Fitzpatrick & Palenchar, 2006, p. 204). The front group phenomenon has often been called, “Astroturf lobbying,” in reference to grassroots lobbying that is false (Bodensteiner, 1997, p. 32). Often times the only way to distinguish a legitimate coalition from a front group is to analyze the group’s funding sources. Coalitions have multiple and numerous funding sources; front groups are often funded by a single source (Bodensteiner, 1997). Depending on how they are constructed, coalitions are often not subject to federal lobbying disclosure rules that require disclosure of their funding sources (Bodensteiner, 1997; Fitzpatrick & Palenchar, 2006).

Little scholarly research overall has focused on front groups, and what does exist are typically case studies or anecdotal news media reports. The cases of front groups that have been uncovered are usually industry-driven efforts. For example, front groups have been used by the tobacco, gas, oil, utility, gaming, and pharmaceutical industries (Bodensteiner, 1997; Fitzpatrick & Palenchar, 2006). The tobacco industry used front groups to oppose federal anti-tobacco legislation in the name of smokers' rights (Appollino & Bero, 2007), the health insurance industry used front group efforts to oppose Clinton-era health care reform (Bodensteiner, 1997), and an AARP investigation revealed that coalitions of senior citizen groups to oppose prescription drug policy changes were funded primarily by the pharmaceutical industry (Batt, 2005).

Information subsidies and disclosure. Organizations produce a variety of information subsidies. Some information subsidies are provided in a more direct manner, in which the organization or organizations involved in their production are clear; others in a more indirect manner using a range of third-party techniques, with varying degrees of transparency.

Understanding the organizations and interests that produce, fund, or disseminate a message is important, particularly in this health care climate in which conflicts of interest are common, making “the borders between research, education, and promotion more porous than is commonly recognized” (Steinman et al., 2006, p. 290). Some have claimed that the involvement of the pharmaceutical industry in the production and dissemination of health communication directly, and through financial relationships with a variety of other organizations, has led to a situation in which, “the social construction of disease is being replaced by the corporate construction of disease” (Moynihan, Heath, & Henry,

2002, p. 886). Critics argue that diseases are now created by organizations seeking to create a market for or increase demand for a drug through public relations campaigns that often involve multiple players (Burton & Rowell, 2003a; Moynihan, Heath, & Henry, 2002; Sweet, 2003). For example, Moynihan, Heath, and Henry (2002) used the examples of irritable bowel syndrome, male baldness, social phobia, and hormone therapy to describe “disease awareness campaigns” sponsored by “informal alliances” of pharmaceutical companies, physicians, and consumer groups, stating:

A key strategy of the alliances is to target the news media with stories designed to create fears about the condition or disease and draw attention to the latest treatment. Company sponsored advisory boards supply the ‘independent experts’ for these stories, consumer groups provide the ‘victims,’ and public relations companies provide media outlets with the positive spin about the latest ‘breakthrough’ medications (Moynihan, Heath, & Henry, 2002, p. 886).

While collaborations between industry, academia, government, and the nonprofit sector undoubtedly lead to positive scientific discoveries and public education initiatives, they can also bias the information available to publics for decision making in favor of the agendas of groups with more economic and political power. The medical and lay presses have no legal requirement to present fair and balanced information (Batt, 2005), and organizations may strategically use these outlets to build an agenda that promotes not only products, but the diseases or conditions those products are intended to treat. Because promotional messages are not always evident when delivered through third parties, individuals may process these messages less cautiously than messages delivered directly by a commercial source of information (Bodensteiner, 1997; Fitzpatrick & Palenchar,

2006; Lofgran, 2004; Steinman et al., 2006), exerting a negative effect on informed decision making.

Just about all entities that participate in the circle of prescription drug development and communication, including government, medical schools and universities, and a variety of professional societies and trade associations that represent medical professionals, medical writers, industry, and journalists have voluntary codes of conduct or conflict of interest policies to encourage their members to police themselves and avoid questionable practices, such as ghostwriting, off-label promotion, and front group-style advocacy efforts. These policies sometimes fail, however, because they lack adequate supervision and enforcement (IOM, 2009; Wager, 2007).

A recurring theme in the scholarly work on conflict of interest in medicine is the need for full disclosure of all potential conflicts to maintain the integrity of and public confidence in medical science (Cook et al., 2007; Gøtzsche et al., 2007; Gøtzsche et al., 2009; Hamilton & Royer, 2003; IOM, 2009; Woolley et al., 2006). Disclosures of conflicts of interest are made in the spirit of highlighting the potential for conflicts, but do not mean that actual conflicts actually exist, or that if conflicts do exist they can be eliminated through disclosure (DeAngelis et al., 2001). Public disclosure is primarily a deterrent and serves as a way to empower consumers with an understanding of the potential motivations of the organizations and individuals behind the information they receive (IOM, 2009).

Some have argued that more responsibility should be placed on organizations to be more proactive about disclosing funding sources when working with news media (Batt, 2005; Bodensteiner, 1997). With regard to the medical professional literature, some

journals, like *JAMA*, are moving toward publication policies that require more transparency about study financing and the role of study sponsors in study design, data collection, analysis, and manuscript preparation (DeAngelis et al., 2001; DeAngelis & Fontanarosa, 2008; Gøtzsche et al., 2009). In addition to *JAMA*, *NEJM* and *The Lancet* require authors to complete and sign detailed conflict of interest disclosure forms. A study of conflict of interest policies on the websites of 256 high-impact medical journals, found that while 89% of journals had conflict of interest policies requesting that authors submit information about any relevant conflicts, only 54% required authors to complete and sign disclosure statements (Blum, Freeman, Dart, & Cooper, 2009).

There is a lack of literature to ascertain how proactive health and medical organizations are about their funding sources when issuing press releases and working with news media. Certainly, the use of front groups and other outward acts of deception clearly violate public relations codes of ethics as outlined by the Public Relations Society of America and the International Public Relations Association (Bodensteiner 1997; Fitzpatrick & Palenchar, 2006; Palenchar & Fitzpatrick, 2009). In the interest of transparency and reputation, organizations should proactively disclose information about potential financial conflicts of interest when a range of other strategies, such as third-party techniques, are used as well.

The literature on disclosure of pharmaceutical industry funding of other health and medical organizations generated the following research question, which was first posed separately for each body of text, press releases (RQ2d) and news stories (RQ3d) in the summary of research questions and the end of this chapter for the purpose of

generating univariate descriptions first in the Results chapter. For brevity, only the comparison question is listed below:

RQ4d: How did press releases and news stories compare in terms of mentioning pharmaceutical industry-related financial conflicts of interest?

The literature related to lack of disclosure in funding arrangements and third-party communication strategies indicated a need to trace funding relationships between organizations. For this reason, the most successful agenda builders that emerged from the study were identified and supplemental archival/document research was conducted to look for financial disclosures on materials produced by those organizations, such as scientific publications, websites, and annual reports. Additional qualitative analyses were also applied to the subset of press releases and news stories that mentioned these organizations to identify potential third-party communication strategies and collaborations and to provide a more nuanced and contextual understanding of how the organizations constructed and defined menopause and any proposed treatment recommendations. The research questions below were used to guide these inquiries:

RQ5: What specific organizations emerged as successful agenda builders as evidenced by frequent mentions of these organizations in both press releases and news stories?

RQ6a: What are the profiles of the most successful agenda-building organizations in terms of organization type, mission and goals, memberships, and financial support? Were any potential conflicts of interest evident through archival analysis of these organizations' websites or materials, such as annual reports, or financial disclosures available on scientific articles or elsewhere? Were these conflicts of

interest disclosed in press releases produced by these organizations or that mentioned these organizations or in news stories that mentioned these organizations?

RQ6b: Did these organizations tend to collaborate with other organizations to produce joint press releases as evidenced by the press release source and contact fields? Did mentions of these organizations tend to frequently be associated with mentions of other organizations in the text of press releases? How did these patterns of organizational associations compare to the patterns of associations found in news stories that mentioned these same organizations?

RQ6c: How did these organizations construct and define menopause, and how did these definitions relate to proposed treatment recommendations in press releases that were produced by these organizations or that mentioned these organizations? How did these definitions and treatment recommendations compare to those used in news stories that mentioned these same organizations?

Health, Medicine, & Prescription Drug News

A substantial literature has documented significant problems related to the accuracy and quality of science, health, and medical news (see for e.g., Friedman 1986a, 1986b; Nelkin, 1995; PLOS Editors, 2008; Schwitzer, 2008; Seale, 2002). Traditional explanations for problematic news content have often focused solely on journalists and news organizations. For example, some have cited journalists' lack of training in health and scientific methods (Friedman, 1986a; Nelkin, 1995; Schwitzer et al., 2005; Tanner, 2004; Voss, 2002; Wilson et al., 2010) or reliance on routine storytelling frames that conform to newsroom norms, values, and routines (Gans, 1979; Seale, 2002; Tuchman,

1972). Others have faulted the U.S. commercial media system, which results in the need for news organizations to please advertisers, considerable competition, and constant deadline pressures (Friedman, 1986b; Manning, 2001; PLOS Editors, 2008; Shoemaker & Reese, 1996).

While insightful, the above explanations neglect the role organizations and other actors play in shaping the quality of news content (Gandy, 1982; Manning, 2001; Seale, 2002; Shoemaker & Reese, 1996; Tankard, 2001). Exploring the role organizations and other organized interests play is particularly important given journalists' heavy reliance on sources for health and medical news (Cho, 2006; Corbett & Mori, 1999; Gandy, 1982, Gans, 1979; Manning, 2001; Tanner, 2004; Wallington et al., 2007) and concerns about conflicts of interest in medicine, which involve organizations that produce, disseminate, and provide access to commonly used sources of information about health and medicine (IOM, 2009). Little research exists that systematically compares information subsidies to news content to see if problematic content originates from journalists themselves or the sources of information provided to journalists. This section reviews research on frequently cited problems associated with health and medical news, followed by the literature that is available on the quality of information subsidies produced by health and medical organizations.

Quality of news. Although only a few content analyses have been conducted to assess the quality of prescription drug news, a substantial literature exists on the quality of science, health, and medical journalism more generally. Many scholars have written about problems related to the accuracy and quality of science, health, and medical news (for e.g., see Friedman 1986a, 1986b; Nelkin, 1995; PLOS Editors, 2008; Schwitzer,

2008; Seale, 2002). The concerns highlighted in the literature that pertain to health and medical news are numerous, but for the purpose of this review will be collapsed into the following four major areas of concern: disease mongering or medicalization; sensationalism or lack of appropriate context; lack of balanced and accurate information related to benefits and risks; and limited sourcing and source disclosure.

Disease mongering/medicalization. Medicalization refers to the application of biomedical diagnoses and definitions to states of health that some consider normal states of the human experience, rather than disease or illness (Brown, 1995). Disease mongering is a term used to refer to what are thought to be intentional attempts to medicalize natural states of health into diseases or conditions in need of treatment, or to exaggerate the true incidence of diseases or conditions to “expand markets for those who sell and deliver treatments” (Moynihan et al., 2002; p. 886; Schwitzer, 2008). Another element of what some refer to as disease mongering is treating “surrogate end points,” which are risk factors, not clinical manifestations of disease, as actual diseases, a problem that has become more common with the increased focus on preventive medicine (Schwitzer, 2008, p. e95).

Claims about disease mongering have been made for many different health conditions. For example, some have argued that conditions, such as social phobia, male balding, and irritable bowel syndrome, represent normal states of physical and mental health rather than medical problems that require treatment (Moynihan et al., 2002). Historically, many women’s group have also claimed that normal biological changes experienced by women, such as childbirth, breast feeding, and menstruation, have been medicalized and have challenged the necessity of medical and technological intervention

in these areas (Boston Women's Health Book Collective, 2006; Chrisler & Levy, 1990; Kalbfleisch & Bonnell, 1996; Kalbfleisch, Bonnell & Harris, 1996; Seale, 2002).

Despite these claims, only a few empirical studies have been conducted to document these problems in a systematic manner. In a content analysis of 500 news stories from the top-50 most widely circulated U.S. newspapers and *AP Newswire*; three weekly news magazines, *Time*, *Newsweek*, and *U.S. News & World Report*; and network newscasts on ABC, CBS, and NBC, Schwitzer (2008) found that almost one-third (30%) of articles that made claims about a healthcare product or procedure engaged in some type of disease mongering by medicalizing a natural state as disease, reporting benefits based only on surrogate end points, or exaggerating the prevalence of a health condition. News coverage may also inaccurately attribute symptoms to various conditions. For example, a content analysis of print media coverage of premenstrual syndrome found that a range of symptoms were attributed to the syndrome that had never been supported in the scientific literature (Chrisler & Levy, 1990).

Sensationalism and lack of context. Sensationalism is a common criticism of news stories about scientific and medical developments that are often presented as miraculous breakthroughs, technological scare stories, or the latest controversy (Antilla, 2005; Atkin et al. 2008; Nelkin, 1995; Seale, 2002). For example, Atkin et al. (2008) noted that breast cancer news stories tended to present news about new medical research findings or drugs as “breakthroughs” or potential “cures” (p. 15). Another common science story focuses on conflict by reporting opposing opinions and positions, as found by Nelkin (1995) in her case studies of news coverage of dioxin, artificial sweeteners, and biotech products. Although based on journalistic norms of balance and objectivity,

these types of conflict stories provide little in-depth analysis of the technical information required for informed decision making (Nelkin, 1995). For example, in the case of climate change, news coverage that focused on balancing news reports with the viewpoints of opposing sides provided a distorted picture of the underlying body of scientific evidence that clearly supported climate change (Antilla, 2005).

Sensationalized news stories typically report new developments as isolated stories that are devoid of any context or in-depth reporting and analysis (Antilla, 2005; Nelkin, 1995; Schwitzer et al., 2005; Seale, 2002). News reports often fail to contribute to effective decision making by reporting on individual study findings as opposed to the accumulation of findings in a specific area (Parrott & Condit, 1996), or analyses of how treatments compare to other available alternatives in terms of clinical benefits and risks (Schwitzer et al., 2008). A content analysis of top-circulating, U.S. news outlets also found that only 38% of stories about medical procedures and treatments discussed alternative options or financial costs of different treatments (Schwitzer, 2008).

Balance and accuracy about benefits and risks. Concerns related to a lack of balanced or accurate benefit and risk information in news stories about medical treatments are common, with complaints related to presentations that directly omit critical benefit or risk information, attribute a benefit or risk inappropriately, fail in accurately conveying the magnitude or probability of a risk or benefit, or fail to mention the quality of the scientific evidence behind risk and benefit estimates (Roche & Muskavitch, 2003; Schwartz & Woloshin, 2004; Schwitzer, 2008; Wilson et al., 2010).

Scholars have noted that news stories often present a distorted picture of the overall benefit and risk profiles of prescription drugs (Barry & Busch, 2010; Nelkin,

1995; Schwartz & Woloshin, 2002; Seale, 2002). For example, after findings about breast cancer drug tamoxifen were released from the Breast Cancer Control and Detection Program in 1998, almost all stories (91%) reported on the increased risk of uterine cancer and only 44% reported on the increased risk of pulmonary embolism, even though the risk of experiencing pulmonary embolism was much higher than uterine cancer and the cause of all deaths reported in the tamoxifen trials (Schwartz & Woloshin, 2002). Seale (2002) noted that coverage of the contraceptive implant, *Norplant*, was overwhelmingly favorable around the time of product launch and then became almost completely negative when the side effect of heavy menstrual bleeding became news in the mid-nineties. A similar pattern was observed for antidepressant *Prozac*, widely acclaimed as a wonder drug by the news media, until a period of negative news coverage that primarily focused on claims related to suicidal and violent behavior exhibited by some patients who took *Prozac* (Nelkin, 1995). News coverage of antidepressant *Paxil* also turned almost entirely negative after the FDA released safety advisories and product labeling changes to warn physicians and consumers about an increased risk of suicidality in children taking the drug; only 4% of 167 print, broadcast, and cable news stories published after the FDA action suggested that the benefits of *Paxil* may still outweigh the risks in some cases (Barry & Busch, 2010).

According to risk communication experts, in addition to portraying a balanced portrayal of a treatment's benefits and risks, how benefits and risks are communicated in terms of their magnitude is also important. A consistent finding in the risk communication literature is that individuals, including the general public and many who are considered experts, such as physicians, have substantial difficulty interpreting

numerical information and particularly risk estimates that convey the probability of an outcome or event occurring (Rothman & Kiviniemi, 1999; Skubisz, Reimer, & Hoffrage, 2009; Weinstein et al., 2004; Yamagishi, 1997). Current research suggests that benefit and risk information should be presented quantitatively in absolute terms whenever possible (Schwartz & Woloshin, 2004; Schwitzer, 2008), or through a combination of qualitative and quantitative information (Arkin, 1999; Ratzan, 1999), but not through qualitative information only because interpretations of words vary significantly (Holtgrave, Tinsley, & Kay, 1995; Weinstein et al., 2004). Quantitative information should always be reported with the most “contextual precision” possible by reporting both numerator and denominator information; where the numerator conveys the incidence or likely incidence of an event and the denominator conveys the population for which the effect is likely to occur (Roche & Muskavitch, 2003, p. 354), also called the “reference class” (Skubisz et al., 2009, p. 179).

Medical research findings are often communicated in absolute and relative risk terms. “*Absolute risk* is simply the risk that an individual will get a certain disease over a defined time period. *Relative risk* is the ratio of the chance of disease in individuals exposed to a risk factor compared to the risk of disease in individuals without exposure” (Jeffery, 1989, p. 1196). Some representations, like relative risk, typically do not specify the reference class or supply base rate information regarding the reference class (Skubisz et al., 2009, p. 185). Relative risk figures are often reported in news stories and can make findings sound more dramatic (Boston Women’s Health Book Collective, 2006). For example, as described below for consumers in *Our Bodies Ourselves: Menopause*, if a news story uses relative risk to report that a medication results in a 50 percent decrease in

getting a disease, actual disease reduction might be more limited than the 50 percent terminology suggests based on the absolute risk of getting the disease in the first place.

If the relative risk for developing a disease is cut in half by taking a certain drug, but only one in 100,000 women who do not take the medicine develop the disease each year, only 1 in 200,000 women per year would avoid developing the disease if the whole group took the medicine—and all of the other women would be at risk of developing its unwanted ‘side’ effects (p. 27).

Existing evidence indicates that news stories may convey the magnitude of benefits and risks poorly. Stories often include qualitative-only presentations of risks and benefits, and when quantitative information is reported, it often has a low degree of contextual precision (Moynihan et al., 2000; Roche & Muskavitch, 2003; Schwartz & Woloshin, 2002; Switzer, 2008). In Switzer’s (2008) content analysis of news coverage of medical products and treatments, only 28% of articles quantified benefits, 33% quantified harms, and 35% addressed the quality of the scientific evidence behind reported findings. Schwartz and Woloshin (2002) found that almost two-thirds (60%) of tamoxifen news stories that quantified the benefits of taking tamoxifen did so by reporting relative risk reduction figures without the base rate. For example, stories reported that the tamoxifen group had 49% fewer cases of breast cancer, but neglected to report that the breast cancer rate in the control group without tamoxifen was 67 annual cases per 10,000 women.

Limited sourcing and disclosure. When citing sources of information within health and medical stories, journalists often do not identify financial conflicts of interest that might influence the motivations and opinions of the organizations or actors that

supplied the information. The financial conflicts of interest of individuals who serve as sources of information are rarely reported, and information on conflicts of interest at the level of the organization are reported even less frequently (Appollino & Bero, 2007; Barry & Busch, 2010; Cassels et al., 2003; Moynihan et al., 2000).

In a content analysis of 1,152 top news stories published in national and regional U.S. newspapers and by wire services in 2004 and 2005 in areas of basic science, engineering, and clinical research, Cook, Boyd, Grossmann, and Bero (2007) found that 38% of stories provided information on funding agencies or organizations, and only 11% included information about investigators' financial ties, such as stock ownership, consulting fees, or honoraria. Moynihan et al. (2000) found that information available about financial ties in the scientific literature were disclosed only 39% of the time in corresponding news stories about three drugs in large-circulation national and regional newspapers, ABC, NBC, CBS, and CNN. A study of news coverage about the association between antidepressant use and suicidality found that none of the analyzed news stories included any information indicating whether reports asked the experts they interviewed if they had any pharmaceutical industry conflicts of interest (Barry & Busch, 2010).

Quality of information subsidies provided to news media. Although substantial research has focused on inaccurate or exaggerated news media treatment of the benefits and risks of medical treatments, devices, and products, less research exists that goes one step back to see if these presentations come from the sources of information provided to journalists, or journalists themselves. Some studies have demonstrated patterns between the sources of information cited in news stories and the quality of those stories. Few

studies, however, have compared news content to the actual information subsidies provided to news media.

Several studies have demonstrated associations between the sources of information cited in health and medical news and the information or frames included in those stories or story tone (Kennedy & Bero, 1999; Moriarty et al., 2008; Wells, Marshall, Crawley, & Dickersin, 2001). For example, Moriarty et al. (2008) found that news stories about cancer clinical trials were mostly neutral to positive in nature, and positive stories were more likely to cite pharmaceutical companies and medical journals as sources of information. Kennedy and Bero (1999) found in their content analysis of newspaper and magazine coverage of passive smoking from 1981 to 1994 that articles were more likely to portray the risks of passive smoke as controversial when tobacco industry sources of information were cited, even after the danger of passive smoking had long been established in the scientific community.

Studying 627 news stories about genetic research from major daily newspapers in the U.S., Canada, Britain, and Australia, as well as 111 studies in 24 scientific and medical journals, Bubela and Caulfield (2004) found that 11% of newspaper articles had “moderately to highly exaggerated” claims in comparison to the scientific articles. Almost all of the newspaper articles (97%) and scientific journal articles (98%) discussed the likelihood of the benefits of the research, and only 15% of the newspaper articles and 5% of the scientific journal articles discussed any potential costs or risks. Woloshin and Schwartz (2002) found in a study of 127 press releases by nine top medical journals, obtained from journal websites and *EurekAlert!*, a wire service for medical and scientific press releases, that 65% of press releases quantified study results; 58% reported on

differences between groups via relative risk or odds ratio information, and of those, only about half gave corresponding base rate or denominator information. Only 23% mentioned any study limitations, and although 23 studies were industry-funded, only 22% of releases for those studies indicated that support.

Based on the above studies, some recommendations have been made to improve the quality of information subsidies and make it easier to investigate the organizations that produce, fund, and disseminate information subsidies about health and medicine. Woloshin and Schwartz (2002) suggested that press releases should all contain common components, such as a section that displays all statistics in absolute terms, a section for study limitations, and disclosures of any potential conflicts of interest. Moriarty et al. (2008), surprised that their content analysis of cancer news found such infrequent explicit mentions of pharmaceutical companies, suggested that future researchers look not just at explicit references in news stories to pharmaceutical companies, but other ways pharmaceutical companies more subtly influence news content through grants to research institutions and other organizations, or by examining statements of disclosure on medical journal articles.

The use of third-party strategies by organizations might make it difficult for journalists to uncover financial relationships, or less likely to investigate financial relationships when information subsidies are disseminated by government or other nonprofit organizations. Past research has indicated that news editors are more likely to accept subsidies from nonprofit organizations or organizations that they perceive to be working in the public interest than other organization types (Berkowitz & Adams, 1990; Curtin, 1999), and may be less likely to investigate them (Burton & Rowell, 2003a).

Investigating financial conflicts of interest is also difficult due to practices like ghostwriting and federal legislation and tax codes that do not require many organizations to report on their funding sources (see Bodenheimer, 2000; Bodensteiner, 1997; DeAngelis & Fontanarosa, 2008; Fitzpatrick & Palenchar, 2006). In the absence of common repositories for funding information, journalists must take considerable time to conduct investigative research if they want to “connect the dots” between messages and their funding sources (Batt, 2005; Fitzpatrick & Palenchar, 2006, p. 212; Schwitzer et al., 2005).

Because of the scientific and technical nature of health and medical information, it might be unrealistic in some cases to expect journalists to improve their reporting, if the sources of information they receive are biased and/or inaccurate. Placing the burden solely on journalists to uncover financial relationships that are not disclosed on source documents or to detect practices like ghostwriting through investigate reporting is impractical. Health and medical organizations that supply information to news media also need to take responsibility for the quality and transparency of the information disseminated. Research that compares the content of prescription drug news to the content of information subsidies produced by health and medical organizations about prescription drugs can yield new insights and recommendations to improve news coverage about health and medicine.

Hormone Therapy (HT)

Literature specifically related to HT has indicated that women rely on a variety of sources for information about HT, including news (Barber et al., 2004; Bastian, Breslau, Davis, & Moser, 2005; McIntosh & Blalock, 2005), and that patterns of HT use shifted

dramatically at times over the study period in response to new evidence about its benefits and risks (Austin et al. 2003; Haas et al., 2004; Hersh et al. 2004; Roumie et al., 2004).

Although little systematic research has been conducted to examine the quality of HT news, some have claimed that news coverage about HT may have inaccurately portrayed or exaggerated the benefits and risks of HT (Fugh-Berman & Pearson, 2002; Katz, 2003; Moynihan et al., 2002; Pines, 2008; Sweet, 2003), and that health and medical organizations, particularly pharmaceutical companies and organizations funded by them, played a role in promoting misperceptions (Felgran & Hettinger, 2002; Fugh-Berman & Scialli, 2006; Zones & Fugh-Berman, 1999; Zuckerman, 2002).

Women and HT. Menopause is clinically defined as the end of fertility, which is marked by the absence of menstrual period for 12 consecutive months (North American Menopause Society, 2010). The average age of menopause is 51, but the changes leading to menopause often begin gradually years before in the time period referred to as perimenopause. During the transition through perimenopause and into menopause, the ovaries shrink and produce less of the female reproductive hormones estrogen and progesterone. This reduced hormone production can lead to vasomotor symptoms, commonly referred to as “hot flashes” or “night sweats,” sleep disturbances, changes in mood, low libido, and vaginal dryness (USDHHS NHLBI, 2005). Women experience menopause differently, due to various factors related to socioeconomic status, health status, cultural factors, and social support, but evidence suggests that only about 15% of women experience problems severe enough to disrupt their daily lives (Boston Women’s Health Book Collective, 2006).

For women who experience problems, there are various ways to control symptoms, including prescription medications now most commonly referred to as hormone therapy (HT), but once referred to as hormone replacement therapy (HRT) and estrogen replacement therapy (ERT). Two different types of therapies exist. Estrogen-plus-progestin therapy is typically prescribed for women whose uterus is intact, and estrogen-only therapy for women whose uterus has been removed. Some women find non-prescription alternatives helpful in controlling symptoms, including a variety of vitamins and herbs, dietary changes and exercise, relaxation techniques, support groups, acupuncture and vaginal lubricants (Boston Women's Health Book Collective, 2006; Kalbfleisch & Bonnell, 1996).

Whatever decisions a woman makes about relieving symptoms should be based on a thorough understanding of the benefits and risks of each approach so she can make a decision that best suits her unique circumstances. Because all interventions have benefits and risks, the optimal decision is often the one that maximizes benefits while keeping risks to a minimum (Parrott & Condit, 1996). Literature on shared decision-making has indicated that individuals experience more satisfaction and better outcomes when they are empowered to participate in decisions about their health (for e.g., see Frosch & Kaplan, 1999; King, Eckman, & Moulton, 2011). To make informed decisions, consumers need information from a variety of sources and the skills to understand that information. "True empowerment comes from having independent information about diseases and their treatments, and tools to critically analyze a problem" (Batt, 2005, p. 12). Unfortunately, much of the information women often have access to is dominated by corporations interested in selling products (Boston Women's Health Book Collective, 2006).

Role of news in HT decision making. Previous research has found that the decision to take HT is highly complex, and a variety of factors play a role in women's decision-making processes, including: internal beliefs, feelings, and values related to menopause; experience and perceptions of menopausal symptoms; expected consequences of taking HT; influence of family members, friends and physicians; information in a variety of media, including advertising, news, magazines, pamphlets, and books; and cultural factors, such as ageism, sexism, and associated stereotypes (Boston Women's Health Book Collective, 2006; Buick et al., 2005; Fugh-Berman & Scialli, 2006; MacLennan, Taylor, & Wilson, 2004; Majumdar, Almasi, & Stafford, 2004; Wathen, 2006).

Although many external sources of information contribute to the complex decision of whether or not to take HT, news media are a significant source of information. More than 80% of middle-aged women have reported relying on mass media for health information (National Council on Aging Survey, as cited in Whiteman, Cui, Flaws, Langenberg, & Bush, 2001), and some women report relying on mass media more than medical professionals (Buick et al., 2005; MacLennan et al., 2004). In a 1997 study, 49% of women reported using magazines and newspapers as sources of information to help them decide about HT (Newton et al., 1997). Newspaper readership is high for women age 50 and older, particularly among women with high levels of education and income, who also happen to be more likely to use HT (Keating, Cleary, Rossi, Zaslavsky, & Ayanian, 1999). Substantial numbers of women who discontinued hormone therapy have also reported that news media coverage played an important role in their decision to stop their HT regimens (Barber et al., 2004; Bastian, Breslau, Davis, & Moser, 2005;

Ettinger et al., 2003; Huston, Jackowski, & Kirking, 2009; MacLennan et al., 2004; McIntosh & Blalock, 2005).

History and patterns of HT use. Estrogen was first approved to treat the symptoms associated with menopause in 1942 by the FDA (U.S. Department of Health & Human Services, Food and Drug Administration [USDHHS FDA], 2011b). Based on research to ascertain the ability of animal sex glands to maintain youth, Ayerst Laboratories manufactured the product from the urine of pregnant horses and named it *Premarin*, which was short for “PREgnant MAREs’s urINE” (Rothenberg, 2005). Although it took a couple decades to catch on, the use of estrogen therapy increased significantly in the 1960s and 1970s, but then dropped off sharply in the late 1970s and early 1980s when it was linked to an increased risk of uterine cancer. In the mid-to-late 1980s, sales began to increase again when it was discovered that adding progestin to estrogen could protect women from uterine cancer, leading to multi-pill regimens. Estrogen-only therapy continued to be prescribed for women without a uterus. In 1995, the FDA approved *Prempro*, the first one-pill-only formulation of estrogen-plus-progestin, manufactured by Wyeth-Ayerst (Boston Women’s Health Book Collective, 2006; Hersh, Stefanick, & Stafford, 2004; Katz, 2003).

Women began taking hormone therapy in unprecedented numbers throughout the 1990s, turning *Premarin* and *Prempro* into blockbuster drugs. An estimated 36 million annual prescriptions for hormones were filled in the United States in 1992, representing approximately 17% of women ages 50 to 74. By 2001, that number had jumped to 91 million annual prescriptions, with an estimated 42% of women age 50 to 74 taking hormones (Hersh et al., 2004). Although estrogen and estrogen-plus-progestin

formulations had only been approved by the FDA for the indications of vasomotor symptoms (hot flashes), vulvar and vaginal atrophy, and postmenopausal osteoporosis (USDHHS FDA, 2011b), many women and their clinicians believed hormone therapy could prevent a host of other conditions, such as cardiovascular disease, memory loss, and aging of the skin (Fugh-Berman & Pearson, 2002). Prevention of cardiovascular disease was perhaps the most common, unproven belief (Utian & Schiff, 1994). In 1990, the FDA denied a request by Wyeth to add a cardiovascular disease prevention indication to estrogen due to conflicting scientific evidence. Despite this fact, many physicians routinely prescribed estrogen off label for this reason (Katz, 2003; Roussouw, 1996).

In 1991, the Women's Health Initiative (WHI), one of the largest controlled, clinical prevention trials ever conducted in the United States, was launched by the National Heart, Lung, and Blood Institute (NHLBI) in conjunction with other agencies within the National Institutes of Health (NIH), including the Office of Women's Health. The trials, which involved 161,808 healthy, menopausal women between the ages of 50 to 79 across the nation, tested the effects of estrogen-plus-progestin (*Prempo*) and estrogen-only (*Premarin*) hormone therapy, low-fat diet, calcium, and vitamin D supplements on the prevention of heart disease, bone fractures, breast and colorectal cancer (Katz, 2003; USDHHS NHLBI, 2005).

On July 9, 2002, WHI investigators held a press conference to announce that the estrogen-plus progestin portion of the clinical trial had been stopped prematurely because the researchers found that women given *Prempo* experienced a higher risk of heart disease, blood clots, stroke, and breast cancer compared to those taking a placebo. In February, 2004, WHI investigators announced that they were stopping the estrogen-only

trial as well upon finding that women taking *Premarin* had an increased risk of stroke and venous thrombosis (deep vein blood clots) and had experienced no significant reductions in risk of coronary artery disease. Although *Prempro* and *Premarin* did result in reductions in vasomotor symptoms, atrophy-related symptoms of vaginal dryness, and osteoporotic bone fractures, investigators determined the risks outweighed these benefits (USDHHS NHLBI, 2005; WHI Investigators, 2002).

Several studies have indicated that extensive news coverage of the WHI findings in 2002, which documented substantial harms associated with estrogen-plus-progestin combination therapy, resulted in dramatic drops in HT prescription use. Evidence of striking differences in temporal trends of HT prescription use before and after the release of the WHI findings have been documented, with HT use increasing steadily prior to the release and decreasing steadily after the release (Austin et al. 2003; Haas et al., 2004; Hersh et al. 2004; Roumie et al., 2004). For example, Haas et al.'s (2004) analysis of an observational cohort of women, ages 50 to 74, from the San Francisco Mammography Registry documented an 18% per quarter decrease in HT use after the WHI announcement. An analysis of the Breast Cancer Surveillance Consortium cohort of 327,144 postmenopausal women across the U.S., ages 50 to 74, found that the prevalence of HT use declined from 45% to 27% among women who lived in areas where there was an average household exposure of at least three WHI-related newspaper articles compared to a decline of 43% to 31% among women who lived in areas exposed to one article or less (Haas et al., 2007).

Claims about quality of HT news. Despite the substantial news coverage that the WHI findings received, some studies indicate that women lacked specific knowledge

about the benefits and risks of HT, raising questions about the quality of news coverage that was received. For example, although 95.7% of 185 postmenopausal hormone therapy users in Minnesota were aware of the WHI findings when surveyed from August 2002 to January 2003, they showed less understanding of the study's specific results. Only 39.8% were aware of the reported breast cancer increase; 30% were aware of the increased risk for heart attack; and 26.7% were aware of multiple risks. Only 2.8% were aware that estrogen-plus-progestin was no longer thought to have overall health benefits or to prevent cardiovascular disease. Almost a third of women (31.8%) reported feeling "confused, scared, nervous, or worried about the results" (Barber et al., 2004, p. 978). Some studies also found that women taking estrogen-only were just as likely in some cases as women taking estrogen-plus-progestin to discontinue use after the 2002 WHI announcement, even though the 2002 announcement pertained only to the combination therapy (McIntosh & Blalock, 2005). It is likely, however, that some women understood the differences, but wanted to be cautious due to the estrogen in both products.

The difficult decision many women face about whether or not to take HT has not gone away. Women continue to report frustration about HT information that seems contradictory (Wathen, 2006) and express a desire for better information to make decisions about HT (Buick et al., 2005). Despite the focus on the role HT news coverage may have played in reducing HT prescription rates immediately after the 2002 WHI announcement, little systematic research has been conducted to understand the actual quality of HT news coverage prior to the WHI announcement, during the WHI announcements, or after. Prior to the 2002 announcement, approximately 42% of all American women between the ages of 50 to 74 were taking HT (Hersh et al., 2004).

Analyses of the quantity and quality of news coverage in the run-up to the announcement might provide some insights as to why this was the case. It is also important to understand the current news environment surrounding HT, particularly with the more recent emergence of new, lower-dose HT formulations on the market (Global Data, 2010).

Although little systematic research has been conducted to examine the amount and quality of HT news, claims have been made in editorials and other articles in the medical literature about the quality of HT news coverage (see for e.g., Fugh-Berman & Pearson, 2002; Katz, 2003; MacLennan et al., 2004; Moynihan et al., 2002; Pines, 2008). These claims are sometimes backed by systematic research, but more often backed by anecdotal evidence, and are similar to the four major areas of concern that have been raised about health and medicine more generally that were reviewed earlier: disease mongering/medicalization, sensationalism and lack of context, balance and accuracy about benefits and risks, and limited sourcing and source disclosure.

Media hype about menopause has been referred to as the “menoboom” in reference to the tendency of the media to try to exaggerate problems associated with menopause to appeal to aging women who are a large segment of the population (Kalbfleisch, Bonnell & Harris, 1996, p. p. 284), despite the fact that estimates suggest that only about 10 to 15 percent of women encounter menopausal symptoms that pose serious challenges to their everyday lives (Kalbfleisch et al., 1996). Menopause began to be understood within the medical establishment as an estrogen-deficiency disease beginning in the 1930s and 1940s. This view was further popularized in the 1960s when “estrogen replacement therapy” began to be promoted as a way for women to stay

youthful, attractive, and sexually active (Boston Women's Health Book Collective, 2006; Katz, 2003), and beginning in the 1980s, as a cure all, preventive measure that could prevent other diseases like osteoporosis and heart disease (Fugh-Berman & Pearson, 2002; Katz, 2003).

Popular media have often portrayed menopausal women as physically or mentally unwell and have rarely portrayed women experiencing menopause in positive ways (Kalbfleisch et al., 1996). This view of menopause as a medical condition in need of pharmacological treatment has been countered by some feminists and women's health advocates who view menopause as a natural development stage or claim that women are not adequately informed of non-prescription alternatives and coping strategies outside of the dominant medical model (Boston Women's Health Book Collective, 2006). Lack of communication about treatment options has been observed for other women's health issues, particularly in the area of reproductive health. For example, despite concerns voiced by women's health organizations that hysterectomy was an over-used procedure, particularly for uterine fibroids, U.S. newspaper stories that appeared from 1986 to 1992 reported superficially on new technologies related to hysterectomy, rarely offered critical analysis as to whether or not hysterectomies were always needed, and failed to place the long-term benefits and risks of hysterectomy in the context of other surgical and non-surgical alternative approaches (Sefcovic, 1996).

In the wake of the WHI findings, several scholar-physicians in the medical community claimed that news media presented a distorted picture of HT by emphasizing its benefits and excluding or downplaying its potential risks (Fugh-Berman & Pearson, 2002; Katz, 2003; Moynihan et al., 2002). For example, some claimed that news media

had inaccurately conveyed information about off-label uses of HT never approved by the FDA. Most controversial was the off-label use of HT for heart disease prevention, which was based entirely on associations found in observational studies or clinical trials that examined surrogate endpoints only rather than controlled clinical trials that assessed actual heart disease outcomes (Fugh-Berman & Pearson, 2002; Katz, 2003), with some alleging that this important fact was rarely communicated (Sweet, 2003). Moynihan et al. (2002) claimed that the perceptions of the osteoporosis prevention benefit of HT were often inflated through news reports that included relative risk reduction information only.

Conversely, others have argued that news media coverage of the WHI findings was alarmist and overemphasized and dramatized the risks of HT (Pines, 2008). A content analysis that compared scientific journals and print news media coverage about the HT-breast cancer link from January, 1, 1995, to June 30, 2000, found that news media were more likely to report on scientific studies that found a positive link between HT and breast cancer than those with null or negative findings (Whiteman et al., 2001). MacLennan et al. (2004) argued that frequent, relative risk-only presentations exaggerated the risk of breast cancer for estrogen-plus-progestin therapy.

Claims about sources of HT news. After the 2002 WHI findings, some accounts blamed journalists for not being critical enough of HT-related research and information due to aggressive pharmaceutical promotion and influence (Felgran & Hettinger, 2002; Zuckerman, 2002). Felgran and Hettinger (2002), two former editors of women's magazines, recounted in a *Columbia Journalism Review* article that "a handful of sources" had regularly "fed" women's magazines HT information that often promoted the off-label use of HT for heart disease prevention (p. 71). The two former editors argued

that journalists need to better identify sources with financial ties to pharmaceutical companies that often use press conferences and other non-FDA regulated avenues to promote off-label indications for drugs.

Documents that became public during litigation by women who developed breast cancer while taking HT highlighted the extent of pharmaceutical industry influence. An analysis of 1500 internal documents revealed that Wyeth Pharmaceuticals paid DesignWrite, a MECC, to produce more than 50 peer-reviewed articles in medical journals, including those reporting on clinical trials, and a variety of other materials, including journal supplements, scientific abstracts, and posters on *Premarin* and *Prempro* from 1996 to 2003. Numerous pieces of correspondence indicated that DesignWrite often wrote the publications and then recruited prestigious academic physicians, who played minimal roles, to author the publications with no attribution to DesignWrite writers. Comparisons of court documents to actual publications, found that Wyeth used ghostwriters to produce “dozens” of articles to “mitigate the perceived risks of breast cancer associated with HT, to defend the unsupported cardiovascular ‘benefits’ of HT, and to promote off-label, unproven uses of HT such as the prevention of dementia, Parkinson’s disease, vision problems, and wrinkles” (Fugh-Berman, 2010, p. 2).

Although many claims have focused on potential pharmaceutical industry influence on HT information, other types of organizations were also involved in communicating about HT, particularly government organizations. The Women’s Health Initiative (WHI) study, which demonstrated the risks of HT, was an NIH-funded collaboration between several NIH institutes and centers, including NHLBI and the Office of Women’s Health. The FDA was also at the center of many debates over HT.

For example, in 1990, women's health advocates successfully organized to prevent the FDA from approving Wyeth's application to get heart disease prevention on the list of approved indications for HT due to insufficient evidence (National Women's Health Network, 2006). In 2003, after the WHI study had documented the risks of HT, the FDA required that all labels on estrogen and estrogen-plus-progestin carry black-box warnings on possible adverse events and state clearly that the products are not approved for cardiovascular disease prevention (Katz, 2003).

Professional societies and health advocacy organizations may have also played a key role in framing HT treatment. For example, the American Congress of Obstetricians and Gynecologists, a 501c(6) organization that represents more than 52,000 dues-paying physicians, residents, and medical students practicing in the area of obstetrics and gynecology, and its educational subsidiary, the American College of Obstetricians and Gynecologists, a 501c(3) organization that publishes the journal, *Obstetrics & Gynecology* (ACOG, 2011), released various technical publications and clinical recommendations to guide physician practice in the 1990s, suggesting HT was effective for prevention of cardiovascular disease and senile dementia (Fugh-Berman & Scialli, 2006). The organization also became active in response to the WHI findings released in both 2002 and 2004, issuing public statements and creating its own Hormone Therapy Task Force to examine the WHI data. ACOG now recommends against the routine use of menopausal hormone products for chronic disease prevention, but supports its use for short-term treatment of the menopausal symptoms of hot flashes and vaginal dryness, and for osteoporosis prevention in some cases (ACOG, 2004).

Various nonprofit health advocacy and consumer groups also played a role in HT controversies, particularly groups associated with the women's health movement. Some have argued that industry funding might be related to the positions of various women's health groups on HT-related policy and treatment (Batt, 2005; Zones & Fugh-Berman, 1999). The women's health movement is a diverse one, comprised of "grassroots" organizations, which are run primarily by consumers and tend to challenge the status quo and offer women information on a range of treatment options, including complementary and alternative approaches, and "professionalized" organizations, which are run primarily by clinicians and researchers and tend to promote greater access for women to conventional treatments offered within the dominant medical model (Batt, 2005; Zones & Fugh-Berman, 1999). A study of 51 nonprofit women's health groups, found that grassroots groups were less likely to accept industry funding than more professionalized groups, particularly funding from corporations that directly targeted their constituents as customers (Zones & Fugh-Berman, 1999).

The WHI study came about through the advocacy actions of a coalition of several women's health groups. Spearheaded by the National Women's Health Network, a 501c(3) nonprofit organization that does not accept any support from pharmaceutical, medical device, or tobacco companies, the coalition pressured the NIH and Congress to conduct the large-scale trials (National Women's Health Network, 2006). The coalition was brought about by concerns about the relationships between HT and heart disease and breast cancer, combined with an interest in how diet was related to a variety of women's health outcomes, particularly the relationship between dietary fat and breast cancer (National Women's Health Network, 2006). Cynthia Pearson, Executive Director of the

National Women's Health Network, recounted in the network's newsletter that the coalition felt a need to fill what they perceived as a serious void in the research on the relationship between diet and women's health, which she attributed to the pharmaceutical industry's lack of interest in sponsoring trials that explored the efficacy of alternative interventions that do not make money (National Women's Health Network, 2006).

Other debates have also taken place with various women's health groups taking different issue positions. For example, in 1990 several advocacy groups that received contributions from Wyeth-Ayerst, including the American Medical Women's Association, the National Osteoporosis Foundation, and Business and Professional Women/USA, testified at an FDA hearing against allowing a generic form of estrogen on the market to compete with *Premarin*, claiming it contained an extra ingredient that might be dangerous even though the FDA initially considered the ingredient insignificant. The only group that supported the generic entry as a way of saving consumers money was the National Women's Health Network (Zones & Fugh-Berman, 1999). In another example, the executive director of the Society for Women's Health Research (SWHR), a 501c(3) charitable organization, spoke out strongly against the WHI findings when they were released, arguing that the findings were premature and exaggerated. News media later reported that Wyeth-Ayerst had funded the organization's black-tie gala in 2000 to celebrate "the coming of age" of midlife women, gave the society a \$250,000 check to celebrate the 60th anniversary of *Premarin*, and that individuals from Eli Lilly, Johnson & Johnson, Merck, Pfizer, and Wyeth served on the society's corporate advisory board (Burton & Rowell, 2003b; Mundy, as cited in Batt, 2005).

Conceptual Models

The following conceptual models, which are displayed as figures, were developed based on the theoretical and empirical literature reviewed in this chapter. These conceptual models were informed by the interactions and linkages between the literatures reviewed in the areas of mass communication, strategic communication, and critical scholarship. The interdisciplinary approach resulted in a set of research questions that was driven by multiple theoretical perspectives to understand how health and medical organizations use news media strategically to communicate about prescription drugs.

Based on the lack of empirical literature specifically investigating how organizations use information subsidies to build and shape the news media agenda for prescription drugs, all inquiries in this study were stated as research questions rather than hypotheses. Although there was not enough empirical literature to justify the advancement of hypotheses, the literature related to agenda building, information subsidies, framing, and health and medical issues more generally, suggested some initial, tentative expectations that guided the conceptual models. Three models were created: one overall conceptual model outlining the focus and scope of the study, and two more specific models to elaborate some of the expectations regarding the production and framing of information subsidies. These models were used to guide the research questions summarized below and the data analysis procedures outlined in the Method chapter.

Figure 1 below outlined the overall focus and scope of the study. This figure proposed that a variety of health and medical organizations would produce carefully-framed information subsidies to build the news media agenda about HT in ways that

furthered their strategic interests. These subsidies were conceptualized as having the potential to act like a form of prescription drug promotion, similar to DTCA, medical journal advertising, detailing and sampling, and medical/scientific journal articles. Based on agenda-building research, I expected the public relations agenda created by these organizations to influence the news media agenda through an interactive process of reciprocal, bi-directional influence. I assumed that the public relations agenda would influence the news media agenda through proactive information subsidies, and that the news media would sometimes influence the public relations agenda by stimulating reactive information subsidies in response to news coverage of issues with strategic value for health and medical organizations.

The process of effects for press releases was envisioned as an indirect one, in which the content of press releases would be diffused to physicians and consumers through news media. This study only explored the red boxes and arrows in Figure 1. The purpose was to explore how information subsidy production and distribution by a variety of health and medical organizations shaped the quantity and quality of news coverage. The link from news coverage to potential outcomes, such as prescription drug use, was not explored in this study. Although the current study did not attempt to link the quantity and quality of news coverage to HT prescription rates, it did yield data that can be used in the future to examine patterns of concomitant variation between news content and prescription rates over time.

Figure 1: Focus and Scope of Study

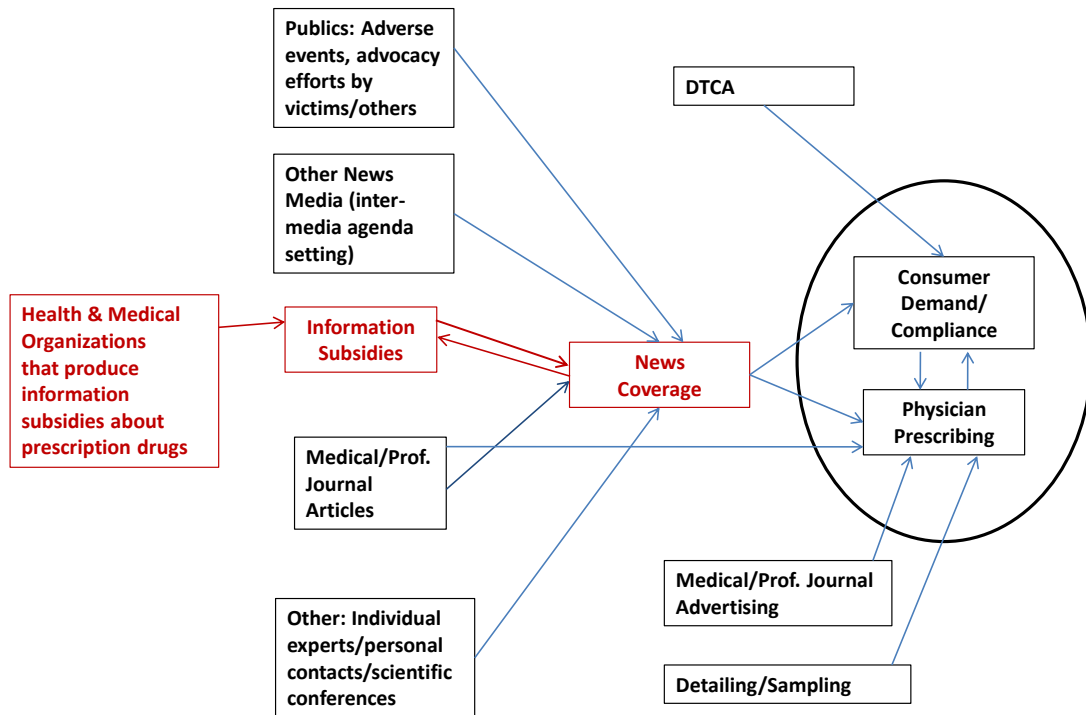
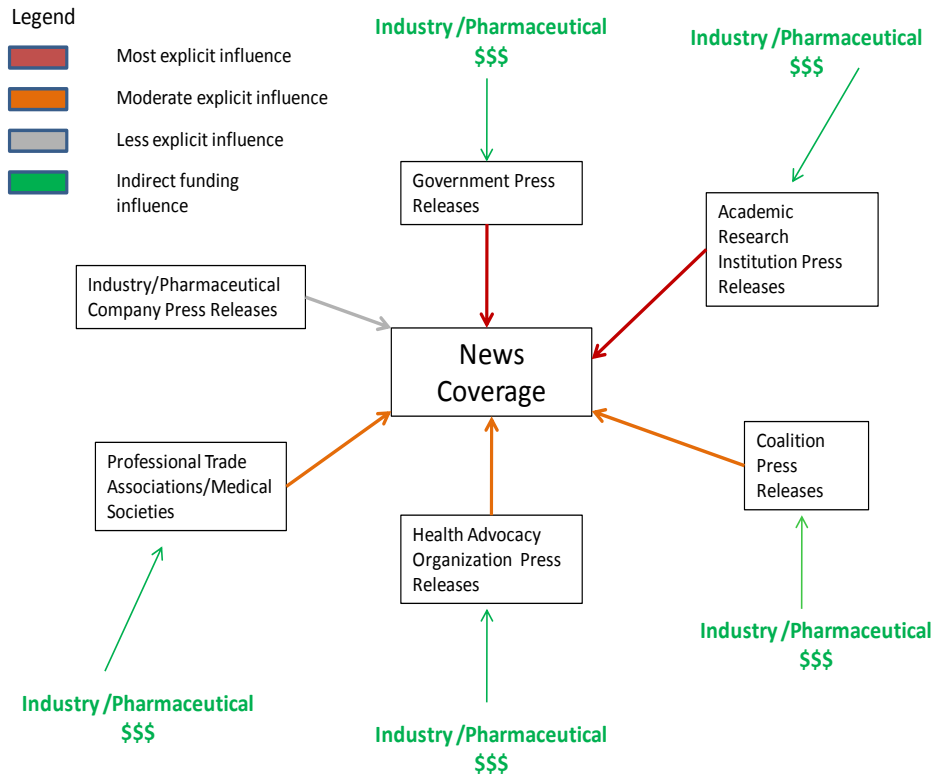


Figure 2 below proposed that some types of organizations would have more explicit influence and other types of organizations would have less explicit influence on the news media agenda. As demonstrated by the figure, I tentatively expected government and academic research organizations to have the most explicit influence on the news media agenda because they are perceived by many journalists as authoritative and credible sources. Because other nonprofit organizations perceived to be working in the public interest are also valued as sources of information by journalists, they were expected to have more success in explicitly building the news media agenda than industry/pharmaceutical companies, which were expected have less explicit influence. For these reasons, I expected government, academic, and nonprofit organizations to have

more success in terms of getting their organizations mentioned in news stories as a result of press releases.

Figure 2: Explicit vs. Inexplicit Influence on News Media Agenda

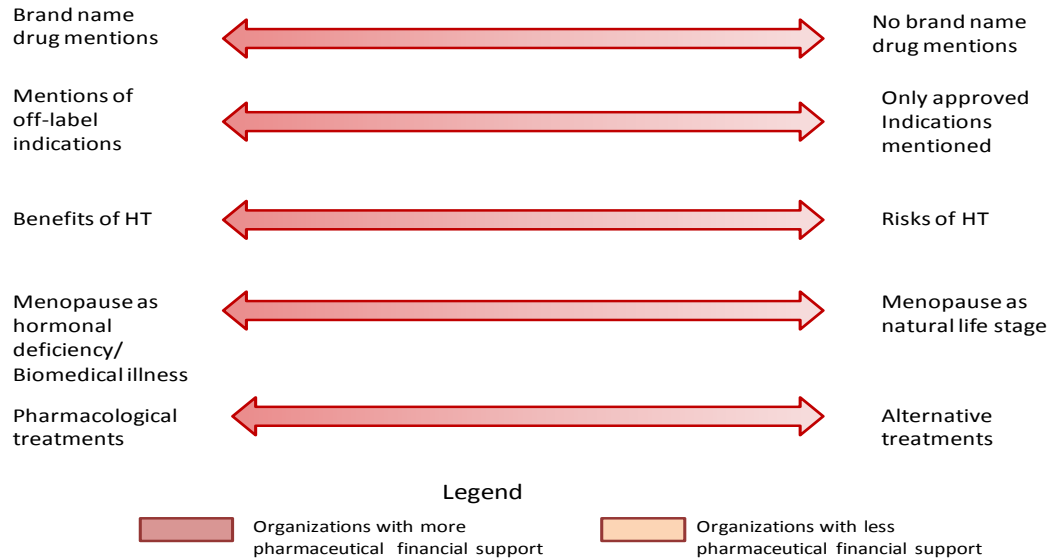


The remainder of the figure, based on literature related to conflict of interest in medicine, suggested that pharmaceutical companies would influence the news media less explicitly by funding the efforts of U.S. government agencies, academic/medical institutions, and nonprofit organizations with the potential to further their strategic interests. These organizations would in turn influence the news media directly through press releases about these funded efforts. Specifically, it was proposed that pharmaceutical companies may make use of third-party techniques by funding the

production of a variety of information sources, such as scientific research and publications, the results of which would then be delivered to news organizations by experts and organizations perceived as more credible and less profit motive-oriented. It was anticipated that collaborations between organizations through such funding mechanisms would be rarely disclosed in press releases and news stories.

Figure 3 tentatively proposed a relationship between the funding base of organizations and how they framed menopause, its proposed treatments, and more specifically, HT, in terms of its substantive attributes. Pharmaceutical companies and organizations that received pharmaceutical industry funding were expected to be more likely to distribute press releases that framed menopause as a biomedical illness or deficiency in need of pharmacological treatment and to frame the attributes of HT in more promotionally-oriented ways by mentioning the brand names of HT products, promoting off-label indications for HT, and emphasizing the benefits of HT. Organizations that received less or no pharmaceutical support were expected to frame menopause as more of a natural life stage, to address alternative, non-pharmacologically-based treatments, and to frame the attributes of HT in a less promotionally-oriented way by not mentioning brand names, sticking to FDA-approved indications for HT, and including more information about the potential risks of HT. If organizations were successful in their framing efforts, news content was expected to be similar to press release content on these dimensions.

Figure 3: Organizations & Quality of Content



As discussed in the Method chapter to follow, quantitative content analysis, along with some supplemental qualitative content analysis procedures were required to test specific research questions generated from these conceptual models. A summary of the study's research questions appears below:

Summary of Research Questions

(Note: RQ1-RQ5 questions were addressed with quantitative procedures, except RQ1d.)

RQ1: What was the relationship between the quantity of press releases about hormone therapy (HT) distributed by organizations via *PR Newswire* and *EurekAlert!* and the quantity of news stories about HT in *AP Newswire* and four, top-circulating U.S. newspapers from 1995 – 2011?

RQ1a: How many press releases about HT appeared between 1995-2011?

RQ1b: How many news stories about HT appeared between 1995-2011?

RQ1c: Was the amount of press releases positively correlated with the amount of newspaper stories over time?

RQ1d. What overall story frames or themes were associated with peaks in press release and news story activity?

RQ2: What was the content of press releases about hormone therapy (HT) distributed by organizations via *PR Newswire* and *EurekAlert!* from 1995-2011?

RQ2a: What types of organizations distributed press releases most often? What types of organizations were mentioned in press releases most often? What types of individuals were quoted most often? How did these factors vary by the types of organizations that produced press releases?

RQ2b: What benefits and risks were associated with HT? How were benefits and risks presented (qualitative vs. quantitative; relative vs. absolute terms). How did these factors vary by the types of organizations that produced press releases?

RQ2c: How often were specific brand-name HT products mentioned in press releases? How did brand-name mentions vary by the types of organizations that produced press releases?

RQ2d: How often were pharmaceutical industry-related financial conflicts of interest mentioned in press releases? How did identification of conflicts of interest vary by the types of organizations that produced press releases?

RQ3: What was the content of news stories about HT in *AP Newswire* and four, top-circulating U.S. newspapers from 1995 – 2011?

RQ3a: What types of organizations were mentioned in news stories most often?
What types of individuals were quoted most often?

RQ3b: What benefits and risks were associated with HT? How were benefits and risks presented (qualitative vs. quantitative; relative vs. absolute terms).

RQ3c: How often were specific brand-name HT products mentioned in news stories?

RQ3d: How often were pharmaceutical industry-related financial conflicts of interest mentioned in news stories?

RQ4: How did the press releases and news stories compare in terms of content from 1995-2011?

RQ4a: How did press releases and news stories compare in terms of the types of organizations mentioned and types of individuals quoted?

RQ4b: How did press releases and news stories compare in terms of benefits and risks associated with HT and risk and benefit presentation (qualitative vs. quantitative; relative vs. absolute terms)?

RQ4c: How did press releases and news stories compare in terms of mentioning specific brand-name HT products?

RQ4d: How did press releases and news stories compare in terms of mentioning pharmaceutical industry-related financial conflicts of interest?

RQ5: What specific organizations emerged as successful agenda builders as evidenced by frequent mentions of these organizations in both press releases and news stories?

(Note: RQ6 questions were answered with qualitative procedures.)

RQ6: How, if at all, did organizations that emerged as key agenda builders via the quantitative content analysis procedures (as determined by RQ5 above) collaborate with other organizations to build and frame the news media agenda?

RQ6a: What are the profiles of the most successful agenda-building organizations in terms of organization type, mission and goals, memberships, and financial support? Were any potential conflicts of interest evident through archival analysis of these organizations' websites or materials, such as annual reports, or financial disclosures available on scientific articles or elsewhere? Were these conflicts of interest disclosed in press releases produced by these organizations or that mentioned these organizations or in news stories that mentioned these organizations?

RQ6b: Did these organizations tend to collaborate with other organizations to produce joint press releases as evidenced by the press release source and contact fields? Did mentions of these organizations tend to frequently be associated with mentions of other organizations in the text of press releases? How did these

patterns of organizational associations compare to the patterns of associations found in news stories that mentioned these same organizations?

RQ6c: How did these organizations construct and define menopause, and how did these definitions relate to proposed treatment recommendations in press releases that were produced by these organizations or that mentioned these organizations? How did these definitions and treatment recommendations compare to those used in news stories that mentioned these same organizations?

Chapter III: Methodology

This study used content analysis to examine the public relations and news media agendas for hormone therapy (HT) from 1995-2011. The public relations agenda refers to the amount and content of information subsidies about HT that were provided by organizations to news media during this time period. The news media agenda refers to the amount and content of HT news coverage about HT during the same time period. These conceptualizations are similar to those found in the public relations and mass communication literatures (for e.g., see, Dearing & Rogers, 1996; Kiousis et al., 2006, 2007; Turk, 1985, 1986; McCombs & Shaw, 1972). The public relations agenda was measured through press releases about HT distributed through *PR Newswire* and *EurekAlert!*. The news media agenda was measured via HT news stories in the *Associated Press (AP) Newswire* and four, top-circulating, U.S. newspapers: *The New York Times*, *The Washington Post*, *Los Angeles Times*, and *The Wall Street Journal*. The rationale for these source selections are discussed in the sections to follow.

Quantitative content analysis procedures were applied to the entire dataset to understand how a variety of health- and medical-oriented organizations actively built and framed the news media agenda for HT over the study period. These procedures were used to examine the over-time relationship between the public relations and news media agendas in terms of the quantity of HT coverage and the quality of HT coverage, as demonstrated by co-occurrences of constructs of interest within and between the two agendas. Supplemental qualitative content analysis procedures were applied to a subset of the data to provide a more nuanced and contextual understanding of the agenda-building and framing activities of organizations that emerged from the quantitative analysis as

successful agenda builders. Supplemental analyses included qualitative, thematic analyses of press releases and news stories that contained references to the most frequently mentioned organizations as documented by the quantitative content analysis, along with additional archival/document research to understand the financial relationships and collaborations that may have existed between these organizations.

Content Analysis

Content analysis has been used extensively in mass communication research to analyze a variety of texts, such as news, advertising, entertainment programming, and political speeches (Krippendorff, 2004; Riffe, Lacy, & Fico, 2005). It has also been used in agenda-setting studies to determine the salience of various objects and frames in news stories (see Dearing & Rogers, 1996) and agenda-building studies to examine the transference of object salience and frames from press releases to news coverage (Andsager & Smiley, 1998; Dunn, 2009; Kioussis et al., 2006; Kioussis et al., 2007; Kioussis et al., 2009; Miller & Riechert 2001; Tedesco, 2001). Riffe et al. (2005) described news content as “the consequence of a variety of other antecedent conditions or processes that may have led to or shaped its construction” (p. 10), such as journalists’ interaction with sources (Riffe et al. 2005; Shoemaker & Reese, 1996). Content analysis is well suited to explore these interactions, as it is a nonobtrusive or nonreactive technique often used to study phenomena that are not easily observed by other means (Krippendorff, 2004; Riffe et al., 2005).

Many definitions of content analysis abound in the literature. Cartwright (1953) described content analysis as the “objective, systematic, and quantitative description of any symbolic behavior” (p. 424). Berelson (1952) limited content analysis not only to

quantitative analyses, but to analyses of “manifest content” only (p. 18). Manifest content refers to the “surface meaning of the text” and latent content refers to “the deeper layers of meaning embedded in the document” (Holsti, 1969, p. 12). Holsti (1969) and Krippendorff (2004) have advocated for more open definitions of content analysis, arguing that content analysis does not need to be quantitative or restricted to manifest content only. Holsti (1969) defined content analysis as “the application of scientific methods to documentary evidence” (p. 5). Krippendorff (2004) defined content analysis as “a research technique for making replicable and valid inferences from texts (or other meaningful matter) to the contexts of their use” (p. 18).

Holsti (1969) and Krippendorff (2004) argued that using quantitative versus qualitative distinctions to define content analysis results in a false dichotomy. All texts are inherently qualitative to begin with, and what differs between quantitative and qualitative approaches to content are merely differences in techniques for processing, reducing, and summarizing data. Restricting analyses to manifest content only is also rejected by these scholars because the notion of manifest content implies that meaning resides inside a text, but texts have no “reader-independent qualities;” humans give texts their meaning and texts can have multiple interpretations (Krippendorff, 2004, p. 22). Krippendorff (2004) identified the context for the meaning of a text for a content analysis study as the context that the researcher brings to the text based on research objectives that are grounded in theoretical and empirical literature. Holsti (1969) made a similar argument claiming that content analyses have “generality” in terms of having “theoretical relevance” (Holsti, 1969, p. 5).

Research Design

A longitudinal content analysis study was conducted because longitudinal, single-issue studies are best suited to understanding the temporal dynamics of agenda-setting processes (Dearing & Rogers, 1996; Trumbo, 1995), as this study attempted to do by examining how the agenda building and framing efforts of organizations influenced the news media agenda over time. Quantitative content analysis procedures were chosen as the primary analytic method because these procedures are well-suited to analyzing large amounts of content, making reproducible generalizations about the presence or absence of manifest content, and yielding data that can be submitted to statistical analysis to test for relationships between items (Holsti, 1969; Krippendorff, 2004; Riffe, Lacy, & Fico, 2005). Quantitative analysis procedures used alone do not allow for analysis of latent content or important nuances or context (Berg, 2006; Holsti, 1969; Krippendorff, 2004). For this reason, supplemental qualitative content analysis was performed on a subset of the data. The combination of these procedures strengthened the study by capitalizing on the strengths and mitigating the weaknesses of each.

The methodological goal was to examine press releases and news stories that were primarily about HT in terms of the universe of appropriate content that would provide answers to the research questions. Therefore, the unit of analysis was each press release or/and news story that was primarily about HT. What qualified as a press release or news story that was *primarily* about HT is discussed in the following sections.

Collecting a census of content. This study used a census as opposed to a sample. Studies that use a census analyze all relevant content in the defined population of interest. For this reason, this study examined a limited number of sources, but all the relevant

content in those sources, rather than sampling from a wider set of sources. The approach of using a census over time from a more limited number of sources that have been found to set the agenda for news coverage at the national level has been used by other scholars for longitudinal studies (e.g., Corbett & Mori, 1999; Hester & Gibson, 2003; Rogers, Dearing & Chang, 1991; Trumbo, 1995; Yanovitzky, 2002). Of key interest to this study was the quantity of coverage and variation in that quantity over time and the relationship between the public relations and news media agendas. Although some studies have employed sampling procedures for media outlets with constructed-week sampling methods, these methods introduce error to estimates of coverage variation over time and are fairly complex (Connolly-Ahern, Ahern, & Bortree, 2009). Various scholars have used censuses of news stories from major news sources, such as *The New York Times*, *The Washington Post*, *Los Angeles Times*, *USA Today*, and *AP Newswire*, to predict various national-level outcomes, such as cocaine use, mammography screening rates, safe sex behaviors, federal funding for HIV/AIDS research, and drunk driving legislation over time (Fan, 2002; Fan & Holway, 1994; Rogers et al., 1991; Stryker, 2003; Trumbo, 1995; Yanovitzky, 2002; Yanovitzky & Blitz, 2000; Yanovitzky & Stryker, 2001).

Selecting a census of appropriate content for this study required several steps. The following sections detail the steps taken and the rationale behind the choices made at each decision point. First, I describe the sources selected to measure the public relations and news media agendas, and the databases used to retrieve those sources. Second, I detail the iterative process used to arrive at a suitable search string for use on these databases. Third, I describe how I operationalized what qualified as a press release or news story that was *primarily* about HT.

Source selection and retrieval. The first step in collecting a census of appropriate content for this study involved selecting specific press releases distribution outlets and news sources to measure the public relations and news media agendas and establishing appropriate databases to retrieve the relevant content in these outlets.

Measuring the public relations agenda. Press releases were selected as measures of the public relations agenda. Although organizations produce many different types of information subsidies for news outlets, the press release is the most common type of publicity release (Lattimore et al., 2007). Press releases have been analyzed by other scholars to discover how political candidates, organizations, and other groups frame issues, and how those frames translate to the news media agenda (Andsager & Smiley 1998; Dunn, 2009; Kioussis et al., 2006; Kioussis et al., 2007; Kioussis et al., 2009; Miller & Riechert, 2001; Tedesco, 2001). Press releases are distributed by the types of organizations relevant to this study, including pharmaceutical companies, government agencies, universities, medical centers and hospitals, medical professional societies and trade organizations, medical journal publishers, foundations, and health advocacy groups.

Press releases were retrieved from two major wire and press release distribution services: *PR Newswire* and *EurekAlert!*. Previous content analysis studies have used *PR Newswire* and/or *EurekAlert!* to retrieve press releases distributed by organizations (Andsager & Smiley, 1998; Brechman et al., 2011; Brechman et al., 2009; Kioussis et al., 2007; Woloshin & Schwartz, 2002). *PR Newswire* distributes press releases to about 1,500 major media outlets (Lattimore et al., 2007). *PR Newswire* was chosen instead of a similar service, *Business Wire*, because *PR Newswire* has a more diverse clientele than *Business Wire*, which primarily distributes releases from corporations more narrowly

related to financial management and earnings. *PR Newswire*'s clientele includes a variety of organization types in the private, public, and nonprofit sectors, and distributes more releases in the categories of "Medicine and Health" and "Diseases and Disorders" (Connelly-Ahern et al. 2009, p. 865). *EurekAlert!* is a press release distribution service for science and medical news operated by the American Association for the Advancement of Science (AAAS). Universities, medical centers, medical journals, government agencies, nonprofit organizations, and corporations worldwide use *EurekAlert!* to distribute news about research developments in the areas of science, medicine, and technology.

All press releases were retrieved in full-text format through electronic, searchable databases. *PR Newswire* was searched via the LexisNexis database, and press releases were available for the entire study period. Press releases distributed by *EurekAlert!* were retrieved through an online archive available on the *EurekAlert!* website. *EurekAlert!* releases were only available back to January 1, 1996. For this reason, it was not possible to include press releases distributed through *EurekAlert!* for the first year of the study, 1995. This distribution service was still used, however, because its omission would have substantially reduced the scope of press releases available for this study in systematic ways. It became clear through preliminary searches on both databases that *EurekAlert!* is the distribution vehicle of choice for many academic research institutions and medical journals that do not release information via *PR Newswire*. Omitting this resource would have eliminated most of the press releases distributed by these types of organizations.

Measuring the news media agenda. The news media agenda was measured via news stories in the *Associated Press (AP) Newswire* and the following four, top-

circulating U.S. newspapers: *The New York Times*, *The Washington Post*, *Los Angeles Times*, and *The Wall Street Journal*. Newswire and newspaper stories were selected as measures of the news media agenda for several reasons related to: audience characteristics; the role these particular news sources play in setting the agenda for other news media outlets throughout the U.S.; content and geographical diversity; and their full-text accessibility via electronic, searchable databases for the entire study period, which is an important feature for a longitudinal study of this scope.

News media serve as major sources of health information for consumers, health care providers, and policymakers (Martinson & Hindman, 2005; Pew Project for Excellence in Journalism, 2010; Phillips et al, 1991; Schwartz & Woloshin, 2004; Viswanath et al., 2008). Women have cited news and other mass media as primary sources of health and medical information, with some women reporting relying more on newspapers and magazines than medical professionals (Buick et al., 2005; MacLennan et al., 2004; National Council on Aging Survey, as cited in Whiteman, Cui, Flaws, Langenberg, & Bush, 2001; Newton et al., 1997). Newspaper readership is high for women age 50 and older, particularly among women with high levels of education and income, who also happen to be more likely to use HT (Keating, Cleary, Rossi, Zaslavsky, & Ayanian, 1999).

Even if consumers and health care providers did not actually read the specific newspapers selected for this content analysis, it is likely that they would have been exposed to similar content in other newspaper, broadcast, cable, and online news outlets. *AP Newswire* and similar, top-circulating newspapers, such as *The New York Times* and the *The Washington Post*, have been selected as measures in previous agenda-setting

studies to assess the quantity and quality of news coverage that occurred nationally for specific topics or issues because of the role they play in setting the news agenda for other media outlets across the U.S. (Corbett & Mori, 1999; Davidson & Wallack, 2004; Dearing & Rogers, 1996; Fan, 2002; Fan & Holway, 1994; Gans, 1979; Rogers et al., 1991; Seale, 2002; Shoemaker & Reese, 1996). Even though more and more Americans are going online to get their news, the information that appears in traditional newspapers still dominates online content (Hesse et al., 2005; Kovic, Lulic., & Brumini, 2008; Pew Project for Excellence in Journalism, 2010; Viswanath, et al., 2006). Eighty percent of online news traffic is concentrated on 7% of websites, which are dominated by traditional media outlets like *The New York Times*, *USA Today*, *The Washington Post*, ABC, NBC, CBS, Fox, CNN, and *Time* magazine, which offer online versions of news distributed through their traditional print, broadcast, and cable outlets. News aggregators, such as *Yahoo News* or *Google News*, also tend to pull content from large, traditional news media outlets (Pew Project for Excellence in Journalism, 2010).

The mix of news sources selected for this study also provided substantial content and geographical diversity based on their foci and range. *AP Newswire* stories are printed as written by newspapers throughout the U.S., particularly by smaller, daily newspapers (Gandy, 1982; Nelkin, 1995; Walters & Walters, 1992; Wilson et al., 2010). *The New York Times* is a leading source of health and medical news, and *The Washington Post* serves as an important source of information about issues with potential public policy implications (Dearing & Rogers, 1996; Rogers et al., 1991; Stryker, 2003; Yanovitzky, 2002; Yanovitzky & Bennett, 1999; Yanovitzky & Blitz, 2000). *The Wall Street Journal* has a wide, national, geographic distribution, and its focus on financial news is well-

suiting to capturing pharmaceutical industry-oriented news about HT. The *Los Angeles Times* enhances the geographical diversity of the study with its West Coast location and has a reputation for high-quality science news (Boyle, 2001; Logan, Zengjun, & Wilson, 2000). All these news sources employ specialist health reporters for a potentially more diverse measure of health and medical news (Gandy, 1982; Nelkin, 1995; Walters & Walters, 1992; Wilson et al., 2010).

Print newspaper stories in electronic format were selected due to the longitudinal scope of the study. Unlike other sources, such as magazines, newspaper stories are electronically searchable and retrievable in full-text format for the entire study period, making data gathering tasks manageable. Although it should be noted that the daily format of newspaper stories is quite different from magazine features, which may have contained different information about HT. The LexisNexis database had full-text coverage back to the start date of this study in 1995 and was used to retrieve news stories from the following three sources: *AP Newswire*, *The New York Times*, and *The Washington Post*. Because LexisNexis only indexes abstracts for *The Wall Street Journal*, and the academic version of LexisNexis did not include full-text access for all study years for the *Los Angeles Times*, the ProQuest database was used to retrieve full-text stories from the *The Wall Street Journal* and the *Los Angeles Times* for the entire study period. LexisNexis and ProQuest have similar capabilities in terms of the types of database searches that can be performed.

Creation of search string. Online electronic databases like LexisNexis are commonly used to retrieve data for content analyses (Connelly-Ahern et al., 2009; Stryker, Hornik, & Yanovitzky, 2006). Database search strings, however, can comprise

the external validity of a content analysis study if the search string used does not represent the intended universe of content. Appropriately gathering the intended universe of content can be thought of in terms of a trade-off between recall and precision. A search string with high recall will come close to retrieving the entire universe of content by reducing errors of omission by including the maximum number of possible search terms. A search string with high precision will get close to retrieving the entire universe of content, but will significantly reduce errors of commission by excluding unnecessary search terms. Recall and precision tend to have an inverse relationship; as one improves, the other declines (Stryker et al., 2006).

Stryker et al. (2006) suggested that researchers should consider the trade-offs between recall and precision within the context of their study goals and methods. For example, when human coders are used, recall might be more important than precision, as humans are able to recognize errors of commission and filter out irrelevant material during the coding process. For a computer content analysis, precision might be more important, as a computer can only code based on programmed rules and will code irrelevant content as long as the rules are satisfied, regardless of important contextual factors. Because this study employed human coding, a search string with high recall was favored over precision when trade-offs needed to be made.

The LexisNexis and ProQuest databases were used to develop the search string for this study due to its flexibility. LexisNexis accommodates the use of Boolean operators, wildcard, and truncation terms and segment-specific keyword searching on defined areas of text. *EurekAlert!* was not used for the search string development process due its limited functionality. The database interface only supports basic keyword searches

without Boolean operators, wildcard, or truncation terms, and does not offer options to search only specific segments of documents for keywords. For these reasons the more flexible databases were used to develop the search string. Once the search string was finalized manual searches for each term were conducted to retrieve the actual study sample from *EurekAlert!*

Initial search strings were developed to retrieve relevant press releases and news stories. Initial strings combined search terms that reflected all phrases that have been used to refer to HT historically, along with associated acronyms (e.g., hormone replacement therapy “HRT,” hormone therapy “HT,” estrogen replacement therapy “ERT,” estrogen therapy, “ET”) and all brand-name HT products (e.g., *Premarin, Prempro, Premphase, Menest, Cenestin, Enjuvia*). A list of all brand-name HT products was derived from searching the following two FDA databases that contain information on FDA-approved drugs: *Drugs@FDA* and the *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* (See Appendix B).

All acronyms were excluded after multiple trial searches and reviews of corresponding results indicated that acronyms like “HRT,” “HT,” and “ET” are rarely used in press releases or news stories without the terms being spelled out first at least once. The use of these acronyms also brought in hundreds of irrelevant texts because the acronyms often were used as other abbreviations. For example, HT resulted in a large number of sports stories that listed athletes’ heights (HT) and numerous stories about broadcast and other programs that used ET to refer to Eastern Standard Time. I also discovered that the truncation term, “!”, was needed in some cases. For example, “hormone therapy” is frequently referred to in these texts in its plural form, “hormone

therapies.” For this reason, I added truncation symbols to all terms when appropriate to make certain to retrieve their singular and plural forms. Due to my inclusion of estrogen as a truncated term, “estrogen!,” terms like “estrogen replacement therap!” and “estrogen therap!” could be eliminated, as all these instances were retrieved with more general truncated term, “estrogen!”.

The following search string was finally arrived at for entry into LexisNexis and ProQuest to retrieve press releases and news stories after many trial searches and subsequent adjustments as described above. The search string below reflects what was entered into Lexis Nexis; minor, non-substantive alterations were made to the syntax to accommodate the ProQuest database. For example, the “!” was replaced with the ProQuest truncation term, “*”, for the ProQuest searches.

“hormone therap! OR hormone replacement OR estrogen! OR Activell! OR Alora OR Angeliq OR Cenestin OR Climara OR CombiPatch OR Delestrogen OR Depo-Estradiol OR Divigel OR Elestrin OR Enjuvia OR Estrace OR Estraderm OR Estrasorb OR Estratab OR Estratest OR Estring OR Evamist OR Femhrt OR Femring OR Femtrace OR Menest OR Menostar OR Ogen OR Ortho-Est OR Prefest OR Premarin OR Premphase OR Prempro OR Prometrium OR Provera OR Vagifem OR Vivelle!”

The numerical results of this search string are reported below:

Table 1

Results of First Search String

Database	Sources	Results
LexisNexis	<i>PR Newswire</i>	5,801 documents
LexisNexis	<i>AP Newswire, New York Times, Washington Post</i>	4,760 documents
ProQuest	<i>Wall Street Journal, Los Angeles Times</i>	1,581 documents

As can be seen in the table above, the search string yielded a large number of press releases and news stories. Visual inspection of the retrieved texts indicated that the vast majority were irrelevant to the study, as they did not exemplify press releases or stories that were primarily about HT. For example, the strings retrieved press releases primarily about corporate earnings, corporate personnel changes, and sales forecasts and trends in which HT was just briefly mentioned far into the body text. Many press releases and news stories were also retrieved that were about estrogen or hormones, but completely unrelated to postmenopausal HT. For example, “estrogen!” returned stories on the use of estrogen to treat cancerous breast cancer tumors and stories on birth control pills, and “hormone therap!” retrieved stories on the use of hormones to treat prostate cancer in men. At the same time, however, visual inspection made it clear that eliminating these terms would significantly reduce recall, as these terms were also used in documents that were primarily about HT.

Selecting press releases/stories primarily about HT. Due to the unmanageable and unsatisfactory results reported above, I repeated the search using the LexisNexis and ProQuest headline/title functions. These functions retrieve documents that contain search

string elements in the headline only. The search string below reflects what was entered into Lexis Nexis; minor, non-substantive alterations were made to the syntax to accommodate the ProQuest database. For example, the “!” was replaced with the ProQuest truncation term, “*”, and “HEADLINE” was replaced with the ProQuest function “ti” (for title).

“HEADLINE(hormone therap!) OR HEADLINE(hormone replacement) OR HEADLINE(estrogen!) OR HEADLINE(Activell!) OR HEADLINE(Alora) OR HEADLINE(Angeliq) OR HEADLINE(Cenestin) OR HEADLINE(Climara) OR HEADLINE(CombiPatch) OR HEADLINE(Delestrogen) OR HEADLINE(Depo-Estradiol) OR HEADLINE(Divigel) OR HEADLINE(Elestrin) OR HEADLINE(Enjuvia) OR HEADLINE(Estrace) OR HEADLINE(Estraderm) OR HEADLINE(Estrasorb) OR HEADLINE(Estratab) OR HEADLINE(Estratest) OR HEADLINE(Estring) OR HEADLINE(Evamist) OR HEADLINE(Femhrt) OR HEADLINE(Femring) OR HEADLINE(Femtrace) OR HEADLINE(Menest) OR HEADLINE(Menostar) OR HEADLINE(Ogen) OR HEADLINE(Ortho-Est) OR HEADLINE(Prefest) OR HEADLINE(Premarin) OR HEADLINE(Premphase) OR HEADLINE(Prempro) OR HEADLINE(Prometrium) OR HEADLINE(Provera) OR HEADLINE(Vagifem) OR HEADLINE(Vivelle!)”

The numerical results of this search string are reported below:

Table 2

Results of Second Search String

Database	Sources	Results
Lexis Nexis	<i>PR Newswire</i>	728 documents
Lexis Nexis	<i>AP Newswire, New York Times, Washington Post</i>	446 documents
ProQuest	<i>Wall Street Journal, Los Angeles Times</i>	208 documents

Visual inspection of the results indicated that the headline/title functions did a better job of eliminating irrelevant documents as compared to the full text search results reported above. Using the headline/title functions was also a better theoretical match to agenda building theory because it ensured that the main focus of the article was about HT. Still, even when using the headline/title function, many irrelevant articles were retrieved that included the search terms in the headline, but were not referring to postmenopausal HT, but other therapeutic uses of hormones and estrogen. It was unclear that removing terms was a viable option because removal would result in loss of too many relevant texts. Because human rather than computer coding for this study was used, I decided it would be best to further refine the universe of content through manual coding procedures instead of trying to add proximity terms related to menopause. This decision was made to avoid unnecessary reductions in recall because the total number of documents retrieved with the use of the headline/title functions remained manageable for manual coding.

Once search strategy and terms were finalized, the relevant press releases were retrieved from *EurekAlert!* Because the *EurekAlert!* online archive cannot accommodate

Boolean operators or proximity terms, searches needed to be conducted separately for each individual term in the search string above. All releases retrieved then needed to be manually reviewed to eliminate duplicates. This process resulted in a total of 334 additional, unique press releases from *EurekAlert!* for the study.

After all database searches were complete, a total of 1,062 press releases and 674 news stories met the headline criteria for the study. It was also necessary to further code all press releases and news stories that had any of the search terms in the headline to make sure the terms indeed referred to postmenopausal hormone therapy. The coding instrument was used to accomplish this as described below. Press releases and news stories that did not meet this criterion as outlined in the coding protocol were filtered out of the study, and no more coding was performed on these documents.

In addition, coding categories were created in the press release and news story codebooks to filter out documents retrieved that were not primarily about HT. The coding category in the press release instrument filtered out press releases about organizational news (e.g., corporate mergers, patent disputes, personnel changes, etc.), market predictions (e.g., reports prepared by industry forecasting/market research firms) entertainment products (e.g., books, films, television, theater, etc.), or studies conducted with animals only. The coding category in the news story instrument also filtered out stories with similar content, along with editorials, letters to the editor, and Q&A-style health advice columns.

Quantitative content analysis procedures. The following procedures were followed to extract and analyze quantitative data to answer research questions RQ1 through RQ5. All quantitative data analyses described in this section with the exception

of the intercoder reliability analyses were conducted with the Statistical Package for the Social Sciences (SPSS) version 20, a statistical software and data analytics package.

Intercoder reliability analyses were calculated with the Program for Reliability Assessment with Multiple Coders, often known as PRAM, by Skymeg Software.

Codebook construction. The purpose of a codebook is to operationalize the theoretical context of a study into “analytical constructs” (Krippendorff, 2004, p. 3). Each abstract construct is translated to a concrete measure (Riffe et al., 2005). Each measure must be derived from a single classification principle and be constructed as mutually exclusive and exhaustive (Neuendorf, 2002; Riffe et al., 2005). Mutually exclusive means that only one code is appropriate for the measured construct. If multiple codes are possible, they should all be constructed as separate measures. Exhaustive means that there must be a viable code for every measured construct. This is often accomplished by including “other” or “unable to determine” categories (Neuendorf, 2002, p. 118).

The codebooks for press releases and news stories consisted of a coding protocol with explicit decision rules for identifying the proper coding categories for all measures and a coding sheet that coders used to record data (Riffe et al., 2005) (see Appendices C & D). A separate codebook, each with its own coding protocol and codesheet, was created for press releases and news stories. Major constructs coded for included: press release or publication date and source; variables to ascertain that the press release or news story was primarily about postmenopausal HT; type of organization that produced release; HT brand name mentions; HT benefits and risks mentioned; whether HT risks or benefits were quantified or not and in relative or absolute terms; types of organizations mentioned in press release or news story; types of individuals quoted in press release or

news story; and whether any individual-level or organizational-level conflicts of interest were disclosed.

The press release and news story were the units of analysis for all coding. Although this was necessary due to the volume of texts analyzed in this study, it did not allow for content variables to be associated with specific sources cited within the body of the texts. For example, if a press release or news story contained a claim that HT prevented heart disease, the press release or news story was coded as mentioning this benefit. The coding scheme used was not sensitive enough to detect whether a claim was attributed to a specific organization or individual cited within the text of the press release or news story.

To develop the codebook, I drew on the theoretical and empirical literature to construct coding categories to answer the research questions. Detailed information, such as the list of brand-name HT products and some of the potential risks and benefits of HT were derived from searching *Drugs@FDA* and the *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations*, two FDA databases which contained listings of FDA-approved drugs along with their product labels (USDHHS, FDA, 2011b; USDHHS FDA, 2011c). In addition, I carefully reviewed press releases and news stories about HT and other prescription drugs outside the sources that I used for my study census to refine the draft codebooks and coding sheets. Using material outside of my study boundaries retained the integrity of the data for analysis.

Coding procedures and training. I recruited two undergraduate students in addition to myself, resulting in three total coders, to assess the reliability of the coding instruments. The two undergraduate students were from Norwich University in Vermont;

one studied Communications and the other studied Computer Security & Information Assurance. Both coders conducted the work during their summer breaks and were compensated for their time. I used relevant content outside the study census parameters for coder training and practice (Riffe et al., 2005), referred to as pilot coding (Neuendorf, 2002). The student coders were thoroughly instructed in use of the codebook and categories, but remained blind to the specific study research questions to reduce the potential for coder bias (Neuendorf, 2002). During pilot coding sessions, coders were provided with the same sample of press releases and articles to code individually without discussion. After the coding was complete, disagreements were discussed and the codebook's protocol of instructions and decision rules and the coding sheets were updated as necessary. Several iterations of this process were required to arrive at final codebooks for intercoder reliability testing.

Establishing intercoder reliability. Theoretically, establishing reliability between coders' use of coding categories makes quantitative content analysis procedures reproducible (Krippendorff, 2004; Neuendorf, 2002; Riffe et al., 2005). Neuendorf more realistically described obtaining reliability as a way of ensuring "intersubjective agreement" between coders (p. 141), rather than objectivity as past scholars have claimed (Berelson, 1952; Cartwright, 1953). Reliability is a consistency measure that measures the extent to which different coders apply the same classification rules and arrive at the same category decisions for the same content. Reliability is a necessary, but insufficient, condition for validity. If reliability is achieved it does not mean the categories accurately operationalize the abstract construct intended; only that coders assigned categories consistently (Riffe et al., 2005).

After pilot coding tests indicated high levels of agreement, I drew a random sample of 10% of the total 1,062 press releases and 674 news stories that comprised the actual, final study data for reliability testing. This resulted in 106 press releases and 65 news stories for the intercoder reliability test. Sub-samples of 10% to 20% of the data to be coded for reliability analyses are typical for content analysis studies (Riffe et al., 1995). Reliability analyses were conducted on all measured variables in the codebook, including the criteria used to determine the relevance of each press release or news story for full coding and analysis.

A variety of reliability coefficients exist, ranging from simple percent agreement between coders (Holsti, 1969) to more rigorous formulas that account for chance agreement (see Krippendorff, 2004; Neuendorf, 2002, for reviews). Fleiss' *kappa* coefficient for multiple coders was used to establish reliability because it is a conservative measure that accounts for chance agreement; is appropriate for nominal-level data; and accommodates more than two coders (Fleiss, 1971; Neuendorf, 2002). Fleiss' *kappa* coefficient is an adaption of Cohen's *kappa* for two coders, the most widely used reliability statistic at this time (Neuendorf, 2012). The generalized formula for *Fleiss' kappa* coefficient (Fleiss, 1971) appears below:

$$\kappa = \frac{\bar{P} - \bar{P}_e}{1 - \bar{P}_e}$$

Where $1 - \bar{P}_e$ measures the amount possible, non-chance agreement and $\bar{P} - \bar{P}_e$ measures the amount of non-chance agreement that was actually obtained.

The *kappa* coefficient ranges from .00 when coders agree by chance to 1.00 when coders have perfect agreement. Values less than .00 signify less than chance agreement. While

no exact threshold for what constitutes acceptable reliability exists, many scholars generally agree that *kappa* coefficients of values of .70 or more indicate strong agreement with values of .80 or more indicating excellent agreement (see Neuendorf, 2002). For this reason, a kappa of at least .70 was set as the necessary threshold for a variable to be included in the study.

The free, academic version of PRAM (version 0.4.7), a Program for Reliability Assessment with Multiple Coders, by Skymeg Software, Inc., was used to calculate the Fleiss *kappa* coefficients. PRAM (version 0.4.7) was used because it is one of the few programs that runs the Fleiss adaptation of Cohen's kappa for multiple coders, and the results have been statistically validated by Dr. Kimberly Neuendorf and her research team at Cleveland State University (Neuendorf, 2012).

When conducting the intercoder reliability tests, data for variables that were exactly the same in news stories and press releases were combined. All codebook variables reached the predetermined threshold of .70 or higher with the exception of variables for which the *kappa* coefficient was indeterminate because the variable never took on the value of being present in the sample. When a variable has only one value (in these cases all zeros for "absent"), a reliability coefficient cannot be determined. It can be argued, however, that all coders reliably agreed that the construct was never present. The 40 variables for which the coefficient was indeterminate were kept in the study to see if they emerged in the full study dataset. The most common instances of indeterminate coefficients occurred for less well-known brand name HT products, many of which also never appeared in the full study data. Several variables that measured whether a risk or benefit was quantified in relative or absolute terms were also indeterminate. Appendix E

reports the results of the intercoder reliability tests for all study variables; variables for which a coefficient could not be determined are noted.

Coding and data entry procedures. After the reliability of the coding instruments was established, I coded the full dataset myself. This process took approximately six months. Due to the labor intensive nature of the work, I hired ORI, a market research firm located in Herndon, Virginia, to enter all the data from the coding sheets. I provided ORI with the data file structures, and I periodically mailed them sets of completed codesheets for data entry. When entry was complete, all paper coding sheets were returned to me along with two electronic data files, one for the press releases and one for the news stories. To check on the quality of the data entry, I randomly selected 10% of the cases in the press release data file and compared them with the paper coding sheets; I did the same for the news story data file. No errors were found beyond occasional minor spelling or typographical errors for fields in which verbatim text was entered. Before proceeding to data analysis, I also ran many checks to ensure the internal consistency of the data through cross tabulation procedures. For example, I ran checks to make sure that if an organization was written in a text field, at least one organization type was also marked as present, or if a risk or benefit was marked as quantified, that risk or benefit was also marked as first appearing in the text. No errors were found.

Data analysis. The following data analysis procedures were used to answer research questions addressed through the quantitative content analysis.

Relationships between quantities of press releases and news stories. The first set of research questions (RQ1 series of sub-questions) concerned the relationship between the quantity of press releases and news stories over the study time period. To answer

these questions, the number of press releases and newspaper articles were calculated separately and displayed quarterly from 1995 to 2011, resulting in 68 data points for each of the two sequences (16 years * 4 quarters-per-year). Both sequences were presented visually on a line graph to observe concomitant variation between them. In addition, the Pearson product-moment correlation coefficient was used to test for the magnitude and statistical significance of the correlation over time between the two sequences. Because the relationship between the public relations agenda and news media agenda was conceptualized in this study to be a reciprocal back-and-forth interaction between and among organizations and the news media, and the public relations agenda likely influences the news media agenda fairly immediately at very small time lags, making computation of useful lags unrealistic, no attempt was made to examine cross-lagged correlations between the series to determine the direction of effects or to employ any other time series analysis procedures.

The line graph was then visually inspected for meaningful peaks in public relations activities and news coverage. Previous scholars that have conducted longitudinal studies of news coverage have found that the results are more insightful when data analyses are conducted on the entire time series and on “unique sub-sets of the series” (Trumbo 1995, p. 8; Rogers et al., 1991). For this reason, the dates of key historical events, such as the WHI findings, other important study findings, and FDA approvals and labeling actions were superimposed on the line graph. For example, because quantities of press release and news coverage differed significantly between the pre- and post-WHI time period, and the WHI study findings sparked a major public reevaluation of the benefits and risks of HT, data analyses that examined benefit and risk

presentation were conducted for the overall time period and broken out by the pre- and post-WHI time periods.

In addition to superimposing key dates on the line graph, the line graph was accompanied by a brief, historical narrative of the evolution of HT over the study period to provide important context. Trumbo (1995) argued that, “An empirical analysis of the agenda-setting process should be accompanied by a qualitatively-based historical consideration of the issue under study” to provide an “important contextual framework for the analysis” (p. 8). This historical narrative was written after all quantitative coding for the study was conducted, as the process of engaging with and coding all texts across the study time period lent considerable insight to the narrative. Particular attention was paid to describing any major debates or issues that might have driven organizations’ public relations activities and subsequent news coverage during peak periods of press release and news coverage activity.

Describing patterns within each series. The next sections of the results chapter (RQ2 and RQ3) describe the content of press releases and news stories, first treated separately as two data series. While some research questions posed of each series were descriptive in nature, others looked to discover patterns between variables. For example, analyses were conducted to determine if the type of organization that produced a press release was associated with the quantity and quality of benefit and risk information provided in that release.

Two of the most commonly used techniques for content analyses are simple tabulations and cross-tabulations (Krippendorff, 2004). Tabulated data can be used to report absolute frequencies or counts within a simple coding category, and can also be

represented as relative frequencies in relation to some whole, as in reporting the percentage of a category that occurred within some meaningful total. Cross-tabulations can be used to examine co-occurrences between coding categories within a body of text or across multiple bodies of texts. In addition to reporting frequencies and percentages of co-occurrences, these co-occurrences can be statistically tested to see if the observed patterns of co-occurrences in the columns and rows of a cross-tabulation table differ from the co-occurrences expected by chance based on the table's marginal frequencies.

A tabulation and cross-tabulation strategy was used for most analyses. Because codebook variables were all measured at the nominal level, the chi-square statistic was used to test for statistical significance for the majority of statistical analyses. Tabulation-only analyses that reported data for a single variable employed the chi-square goodness-of-fit test to test whether the distributions across categories of a variable were significantly different from distributions expected under the null hypothesis, otherwise known as chance differences. In all cases, the chi-square goodness-of-fit test was conducted using an alpha of .05. Before conducting each analysis, I examined the data to make sure the assumption that each cell had an expected value of five or more cases was met (Agresti, 2007; Lomax & Hahs-Vaughn, 2012). In just a few cases this assumption was not met. In these cases, I omitted categories too small for testing, collapsed the data when possible to create larger categories, or flagged relevant results as possibly unstable and to be interpreted with caution in the results section.

While a significant chi-square goodness-of-fit test indicates a statistically significant pattern of results, it does not indicate exactly which categories were significantly different from one another for variables with more than two categories. In

these cases, follow-up tests were conducted by examining the standardized residuals as recommended by Agresti (2007) and Lomax and Hahs-Vaughn (2012) to see which categories contributed significantly to the chi-square statistic as evidenced by standardized residuals greater than an absolute value of two.

The chi-square test of independence was used to test for associations between two variables (e.g., type of organization that produced a press release and whether or not heart disease was identified as a potential risk of HT). While the chi-square test of independence can be usefully interpreted with two variables or factors, interpretation becomes more difficult for larger tables (Krippendorff, 2004). When larger tables were tested, post-hoc z -tests for column percentages using the Bonferroni adjustment method were used to examine each pair of percentages to see exactly which percentages were statistically different from one another. The Bonferroni adjustment method holds alpha at .05 for the entire group of comparisons by splitting alpha up equally among each pairwise comparison to avoid inappropriate inflation of Type I error (Lomax & Hahs-Vaughn, 2012).

In a few cases, it was possible to transform the original nominal-level data to continuous measures to facilitate analyses of group means. For example, the data on whether each coded benefit or risk was absent or not in a press release or news story was summed to arrive at a total number of benefits and risks identified in each document. This facilitated analyses such as comparisons for the average number of benefits and risks prior to and after the first WHI announcement. In cases such as this, when only two group means were compared, t -tests were used. Prior to conducting the t -tests, Levene's test for

homogeneity of variance was examined to determine if the t-test for equal or unequal variances should be used (Lomax & Hahs-Vaughn, 2012).

Sometimes more than two-group analyses were called for. For example, some analyses examined the average number of benefits and risks contained in press releases by the type of organization that produced the release. When more than two group means were compared, one-way analysis of variance techniques (ANOVA) were employed. When the omnibus ANOVA test was significant, follow-up post-hoc, t-tests were used to determine which specific group means differed from one another while holding Type I error at .05 (Lomax, 2001). Prior to conducting post-hoc tests, Levene's test for homogeneity of variance was examined. Based on those results, appropriate formulas were run that assumed equal or unequal variances. When variances were equal, the Tukey-Kramer multiple comparison procedure was selected, which adjusts for unequal *ns* per group and assumes equal variances. When variances were unequal, the Games-Howell post-hoc multiple comparison test was used, which also adjusts for unequal *ns* but assumes unequal variances (Lomax, 2001).

Content comparisons between PR and news media agendas. Remaining sub-questions for RQ4 asked about how press releases and news stories differed from one another in terms of content. For these questions, chi-square tests of independence were used to test for statistically significant differences between nominal-level variables. T-tests were used for comparisons of group means between the two series. The same procedures identified earlier to meet the statistical assumptions of both tests (minimum expected cell count and homogeneity of variance) were employed.

Identifying successful agenda-building organizations. RQ5 asked what organizations emerged as successful agenda builders, as evidenced by frequent mentions in press releases and news stories. Coding instructions required that all specific organization names that appeared in press releases and news stories be keyed to a database. Frequencies were run on these database fields to identify organizations that were most frequently mentioned in both data series.

Qualitative content analysis procedures. The following procedures were followed to collect and analyze qualitative data from the relevant texts to answer research questions RQ6 and its associated sub-questions. The supplemental qualitative content analysis procedures in this section were applied only to press releases and news articles that were produced by or that mentioned specific organizations that emerged as key agenda builders, as determined by the quantitative analysis described in the section immediately above this one on identifying key agenda builders. Therefore, all qualitative content analyses were conducted after the quantitative content analyses were complete.

Qualitative content analysis was chosen for these research questions because the types of frames of interest were more likely to involve latent content and less likely to be amenable to strict coding decision rules that might lead to invalid interpretations. Focusing on a key set of organizations for these analyses provided me with a manageable amount of data to thoroughly analyze in an in-depth, qualitative manner. Qualitative data analyses also provided a more detailed and nuanced account of collaborations between organizations as situated within the historical context of the study at different points in time.

While many qualitative approaches to data extraction and analysis exist, I used the approach outlined by Miles and Huberman (1994), which involves working iteratively and systematically between three processes: “data reduction,” “data display,” and “conclusion drawing and verification” (pp. 10-11). Data reduction was achieved by isolating the press releases and news coverage pertinent to the specific organizations of interest by examining the database fields that organization names were entered to. I then made a list of all the unique press release and news story identification numbers. The identification number were then used to extract the documents of interest into two sets of texts, one for press releases and one for news stories, that contained only the relevant documents. The files were then examined and coded as necessary for recurring themes related to the research questions and to make contrasts and comparisons between organizations and between press releases and news stories.

Thematic analyses of frames and collaborations. Relevant press releases and news stories were coded for themes relevant to the research questions. Themes of interest related to three major conceptual areas: 1) overall story frames or angles; 2) constructions and definitions of menopause and HT, and how those definitions related to proposed treatment recommendations; and 3) potential collaborations between organizations. Coded themes were displayed in data display matrices using Excel. Data displays enhance the validity of qualitative research by facilitating processing and interpretation of large amounts of text in an attempt to guard against researcher biases and false assumptions (Miles & Huberman, 1994). During this process I also remained open to discovering important themes, not specifically related to the predetermined, specific research questions.

During the conclusion drawing and verification process, themes were collapsed, expanded, and reorganized as necessary to best describe meaningful patterns found in the data. Actively searching for variant cases was employed to reduce the temptation to over-categorize results. These safeguards are important because the reliability and validity of qualitative research rests primarily on the skills of the researcher (Miles & Huberman, 1994). Major themes were reported through narrative text, supported by example quotations or passages of text for evidence of those themes.

Background profiles of successful agenda-building organizations. This study also employed some supplemental archival research as necessary to shed further light on the organizations that emerged as successful agenda builders over the time period studied (as indicated in RQ6a). Specifically, I explored organizations' websites and annual reports to describe organizations' mission and goals, memberships, and sources of financial support. Original scientific studies that were the subject of substantial publicity by these organizations were also reviewed for any financial conflict of interest disclosure statements. This allowed me to compare how frequently news releases and news articles provided conflict of interest information that was readily available.

Although this procedure was able to provide some preliminary insights about the extent of conflicts of interest between study investigators and research sponsors, it likely yielded conservative estimates in light of the literature on ghostwriting and lack of disclosure in scientific journal articles. Fugh-Berman's (2010) article published in *PLOS Medicine*, included a table of 28 scientific articles for which substantial evidence of Wyeth publication planning and ghostwriting occurred in collaboration with the company's MECC vendor, *DesignWrite*. This table was also consulted as needed. This

supplemental information allowed me to combine contextual background profiles of the organizations with the results of the qualitative analyses on how they attempted to build and frame the news media agenda for HT.

Chapter IV: Results

This chapter presents the data that answer the research questions. The first section of the chapter presents the results to research question one (RQ1) and its associated sub-questions, which examined the over-time relationship between press releases and news stories. The second section presents the results of research questions that were posed about the content of press releases and news stories and answered with quantitative procedures (RQ2 – RQ5). The third section presents the results of research questions that were posed about the content of a sub-set of press releases and news stories that were answered with qualitative procedures (RQ6). The six major organizing research questions for the study, along with their respective sub-questions, are used as headings to organize the results in each section. This results chapter is based on a total of 675 press releases and 429 news stories.

Over Time Relationship Between Press Releases and News Stories

This section presents the results to research question one: What was the relationship between the quantity of press releases about hormone therapy (HT) distributed by organizations via *PR Newswire* and *EurekAlert!* and the quantity of news stories about HT in *AP Newswire* and four, top-circulating U.S. newspapers from 1995 – 2011?

RQ1a: How many press releases about HT appeared between 1995-2011?

A total of 1,062 press releases were originally retrieved from *PR Newswire* and *EurekAlert!* via the search terms for the entire study period. All the releases were coded using the coding instrument for press releases (see Appendix C). A total of 387 press releases were removed from the study early via variable PV4 or PV5 on the coding

instrument because they did not meet the study criteria. More specifically, 172 releases were removed via variable PV4 because the search terms in the headline referred to something other than menopausal hormone therapy (for e.g., hormone therapy for prostate cancer or breast cancer treatment), and 215 releases were removed via variable PV5 because they were primarily about an organization rather than HT, such as announcements about personnel changes or new licensing or marketing agreements between firms ($n=107$); market forecasts by market research firms; publicity for a book, film, movie, theater or other entertainment product ($n=57$), or reports of research studies conducted with animals only ($n=28$).

This left a total number of 675 press releases that were fully analyzed for the study; 392 of these press releases were retrieved from *PR Newswire*, and 283 were retrieved from *EurekAlert!*. All analyses to follow in this results section are based on these 675 releases.

RQ1b: How many news stories about HT appeared between 1995-2011?

A total of 654 news stories were originally retrieved from *AP Newswire*, *The New York Times*, *The Washington Post*, *The Wall Street Journal*, and the *Los Angeles Times* via the search terms for the entire study period. All the news stories were coded using the coding instrument for news stories (see Appendix D). A total of 225 news stories were removed from the study early via variables NV4 or NV5 on the coding instrument because they did not meet the study criteria. More specifically, 171 news stories coded out of the study on variable NV4 because the search terms in the headline were referring to something other than menopausal hormone therapy, and 54 coded out on the next variable NV5 because they were stories primarily about an organization rather than HT

($n=9$), letters to the editor/editorials ($n=35$), entertainment product reviews ($n=3$), Q&A style health advice columns ($n=4$), or stories about research studies conducted with animals only ($n=3$).

This left a total number of 429 news stories that were fully analyzed for the study. In terms of sources, 176 of the news stories were from *AP Newswire*; 85 were from *The New York Times*, 78 were from the *Los Angeles Times*, 46 were from *The Washington Post*, and 44 were from *The Wall Street Journal*. All analyses to follow in this results section are based on these 429 news stories.

RQ1c: Was the amount of press releases positively correlated with the amount of newspaper stories over time?

Before the numbers of press releases and news stories were correlated with one another, a correlation matrix was produced to see how the quantity of press releases correlated with the quantity of news stories in each individual news source and to examine the intercorrelations between each news source. As can be seen in Table 3, the number of press releases was positively correlated with all news sources except, *The Washington Post*. Although the correlation between the number of press releases and news stories in *The Washington Post* was in the right direction in terms of being positive, the coefficient was not statistically significant. *The Washington Post* was positively and significantly correlated with all other news sources with the exception of *The Wall Street Journal*. The lack of positive correlation may have been due to the different foci of these newspapers. *The Washington Post* tends to report more on stories with significant public policy-oriented implications, and the *Wall Street Journal* focuses more on financial news. These newspapers also had the smallest sample sizes compared to the other five sources.

Table 3

Intercorrelations between Press Releases & Individual News Sources (1995-2011)

	Press Releases	AP Newswire	Los Angeles Times	New York Times	Wall Street Journal	Washington Post
Press Releases	–	.324**	.551**	.552**	.325**	.232
AP Newswire	.324**	–	.578**	.334**	.271*	.257*
Los Angeles Times	.551**	.578**	–	.659**	.361**	.467**
New York Times	.552**	.334**	.659**	–	.274*	.425**
Wall Street Journal	.325**	.271*	.361**	.274*	–	.070
Washington Post	.232	.257*	.467**	.425**	.070	–

*p<.05, two-tailed; **p<.01 two-tailed.

To determine if the total number of press releases was positively correlated with the total number of newspaper stories over time, the number of press releases and news stories were totaled separately on a quarterly basis in three-month increments from 1995 to 2011, resulting in 68 data points for each of the two sequences (17 years * 4 quarters per year). A Pearson correlation coefficient indicated a moderately strong, positive, and statistically significant relationship between the press releases and news stories over time, $r = .55, p < .001$.

RQ1d. What overall story frames or themes were associated with peaks in press release and news story activity?

After a statistically significant correlation was obtained between press releases and news stories, the two sequences were plotted together on an area graph to observe patterns of concomitant variation between them (see Figure 4). Individual press releases and news stories were then reviewed within peak periods of press release and/or news activity to arrive at a descriptive set of themes about major issues and events that drove communication about HT during different time periods. Selected key dates were also

superimposed on the graph. Together the descriptive themes and key dates provide historical context to better understand the study's more detailed findings.

Figure 4 is intended to help readers visualize some of the major turning points in the history of HT. The sheer volume of research studies published over the study time period, the shifting and conflicting nature of the findings, and the responses of organizations to those findings, makes anywhere near a full accounting of all major events impossible. Although far from exhaustive, this visual aid provides examples of the types of activities that occurred within different time periods.

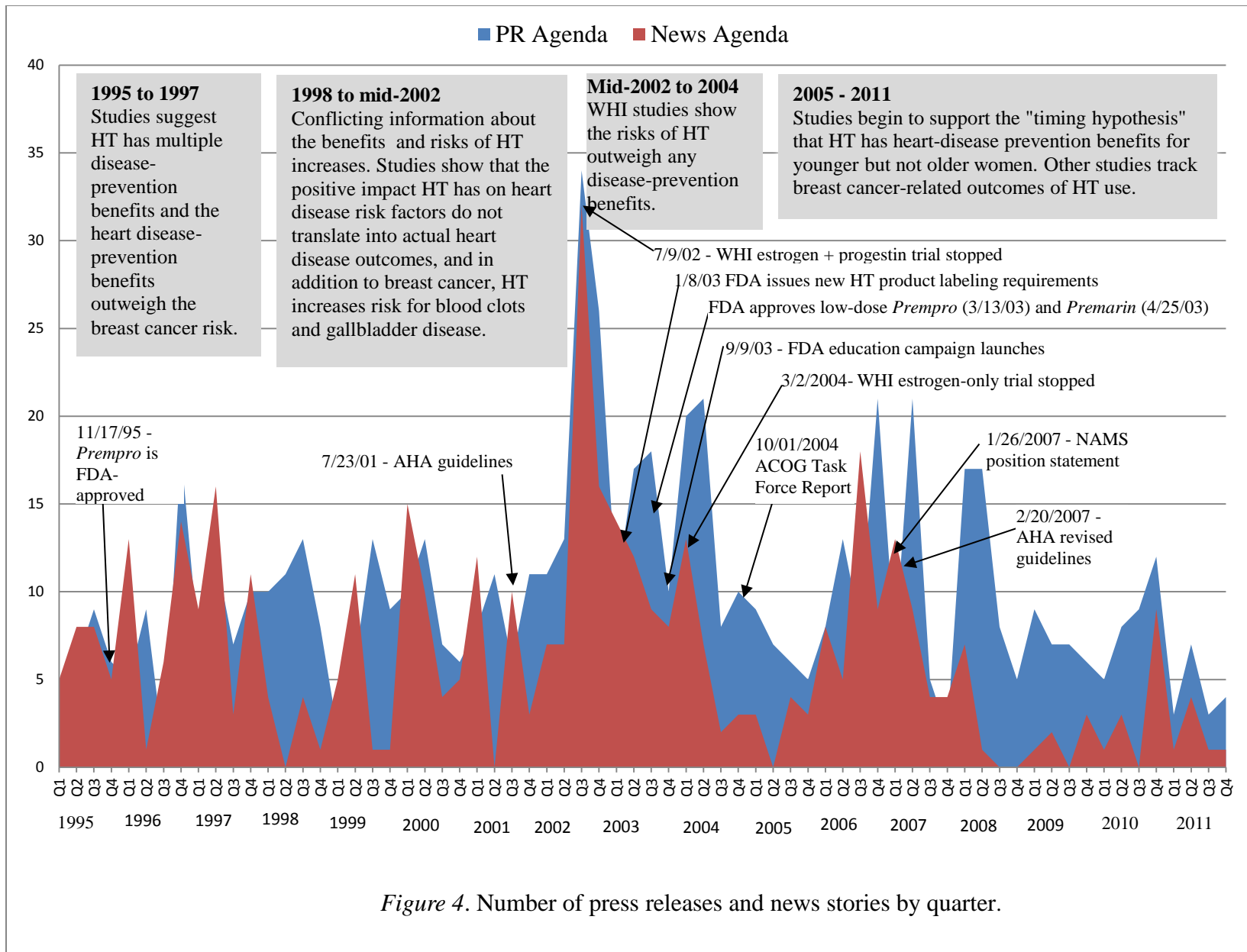
Data showed consistently more press releases than news stories over the entire time period (see Figure 4). The average number of press releases per quarter was 9.9. The average number of news stories per quarter was 6.3. A visual inspection of the over-time graph of the quantities of press releases and news stories over the study time period supported a highly interactive agenda-building process. The graph demonstrated a continual, up-and-down pattern of spikes and valleys for press releases and news stories; sometimes the two sequences appeared to rise together and other times one sequence peaked before the other and vice versa.

Examination of press releases and news stories in terms of their major foci, particularly in terms of peak periods, revealed more similarities than differences in terms of the type of content that drove activity on the part of health and medical organizations and news media. The next section describes the following major content themes seen across the press releases and/or news stories: research findings, regulatory actions and disputes, clinical practice guidelines, product promotion, and legal actions.

Research findings. New research findings about HT were the primary driver of peaks in activity for both press releases and news stories. The vast majority of research studies related to the potential benefits and risks of HT in the areas of heart disease, breast cancer, and osteoporosis, and to a lesser extent, Alzheimer's disease, dementia, and stroke. The press releases and news stories that focused on research findings and some of the corresponding studies published in medical and scientific journals are best characterized within four time periods. These time periods are noted in gray boxes in Figure 4 and described below.

1995 to 1997: Disease-prevention benefits outweigh risks. From early 1995 through late 1997, studies were published suggesting that HT had multiple disease-prevention benefits, including prevention of heart disease, osteoporosis, Alzheimer's disease, and dementia. Studies focused on HT risks centered around the potential breast cancer risk associated with HT use, a topic which continued to generate substantial controversy due to conflicting patterns of findings that began well before 1995 (Brown, 1995). Other studies attempted to place the potential breast cancer risk of HT in the context of its supposed disease-prevention benefits, and concluded that the heart disease-prevention benefits of HT generally outweighed any increased risk of breast cancer.

A few large, highly publicized studies serve as examples of the disease prevention-related evidence that began to emerge during this time period. Results of the Postmenopausal Estrogen/Progestins Interventions (PEPI), a large, randomized clinical trial were reported in the *Journal of the American Medical Association (JAMA)* on January 18, 1995, and November 6, 1996, indicating that estrogen-only and estrogen-plus-progestin HT regimens had favorable effects on cholesterol levels, a



well-established risk factor for heart disease, and increased bone mineral density of the spine and hip (Writing Group for the PEPI Trial, 1995, 1996). On August 15, 1996, *The New England Journal of Medicine (NEJM)* reported data from the Nurse's Health Study, a longitudinal, observational study of female nurses, which concluded that estrogen-only and estrogen-plus-progestin were equally effective at reducing heart disease (Grodstein et al., 1996). Another longitudinal, observational study, the Baltimore Longitudinal Study of Aging (BLSA), published in the June 1997 issue of *Neurology*, found that HT use was associated with reduced risk of Alzheimer's disease (Kawas et al., 1997).

Breast cancer risk-related studies also continued to attract attention during this period of time. On June 15, 1995, the *NEJM* published a study based on data from the Nurse's Health Study, indicating that use of estrogen-only and estrogen-plus-progestin for more than five years was associated with an increased risk of breast cancer (Colditz et al., 1995). A decision analysis model based on previous literature published in *JAMA*, however, on April, 4, 1997, concluded that HT's ability to increase life expectancy due to decreases in cardiovascular disease outweighed the risk of breast cancer for "nearly all women" and recommended "broader use of hormone replacement therapy" (Col et al., 1997, p. 1140). Similarly, more data from The Nurses' Health study published in *NEJM* on June 19, 1997, concluded that HT users had lower mortality rates than non-users due to lower rates of cardiovascular disease, and that these mortality reduction benefits did not disappear due to increased breast cancer deaths until ten or more continuous years of HT use (Grodstein, 1997).

1998 to mid-2002: Conflicting information about benefits and risks increases.

From early 1998 to mid-2002, conflicting information about the benefits and risks of HT continued to increase. Studies began to unexpectedly show that the positive impact HT had on heart disease risk factors and biomarkers, like cholesterol and lipoprotein(a), did not translate into actual heart disease outcomes, and in addition to breast cancer, HT increased risks for blood clots and gallbladder disease. Another study also showed no positive effect of HT on stroke risk.

Although the early months of 1998 continued to demonstrate potential benefits of HT, the tide began to turn by the middle of the year. On April 17, 1998, additional results from the (PEPI) trial were reported in *Circulation*, demonstrating that estrogen-only and estrogen-plus-progestin reduced plasma Lp(a) concentrations, an important biomarker for increased coronary heart disease risk. The results of the Heart Estrogen Replacement Study (HERS I), a randomized, clinical trial to assess the relationship between estrogen-plus-progestin use and actual heart disease outcomes, however, brought disappointing results. Published in *JAMA* on August 19, 1998, HERS I reported that after 4.1 years of follow-up, despite improvements in lipid (cholesterol) profiles, estrogen-plus-progestin did not decrease heart attacks for women with existing heart disease and increased the risk of blood clots and gallbladder disease (Hulley et al., 1998).

More negative findings emerged in the following years. For example, the Estrogen Replacement and Atherosclerosis (ERA) trial published in *NEJM* on August, 24, 2000, found that despite improvements in lipid profiles, women with coronary disease given estrogen-only or estrogen-plus-progestin showed no reduction in the progression of coronary atherosclerosis (Herrington et al., 2000 p. 522). Additional findings from HERS

I, published in *Circulation* on February 6, 2001, reported that estrogen plus progestin had no significant effect on stroke risk as hoped for postmenopausal women with heart disease (Simon et al., 2001). Finally, the results from the HERS II study, which followed HERS I participants for an additional 2.7 years, were published in *JAMA* on July 3, 2002, concluding that study participants still experienced no reduction in heart disease events and continued to experience increased risks for blood clots and gallbladder disease (Grady, 2002, p. 49).

Meanwhile, in addition to the blood clot and gallbladder disease risks being associated with HT, studies continued to demonstrate breast cancer risk. For example, on January 26, 2000, data from the national, longitudinal Breast Cancer Detection Demonstration Project were reported in *JAMA*, indicating that estrogen-plus-progestin increased breast cancer risk more than estrogen alone, and breast cancer risk increased with duration of use for both types of therapy (Schairer, 2000).

July 2002 – 2004: The WHI Studies: HT risks outweigh benefits. The results of the National Institute of Health's (NIH) Women's Health Initiative (WHI) trial marked a major turning point in the history of HT by changing the perception that the benefits of HT outweighed its risks to the perception that the risks of HT outweighed its benefits. The WHI, was a large, randomized clinical trial, which involved 161,808 healthy, menopausal women between the ages of 50 to 79 across the nation to test the effects of estrogen-only and estrogen-plus-progestin hormone therapy, low-fat diet, calcium, and vitamin D supplements on the prevention of heart disease, bone fractures, breast and colorectal cancer. The trial began enrolling participants in 1993 and was not expected to end until sometime in 2005 (Katz, 2003; USDHHS NHLBI, 2005; Writing Group for the

Women's Health Initiative Investigators, 2002). Much to the surprise of scientists, health care professionals, and the public, the estrogen-plus-progestin and the estrogen-only arms of the trial were stopped prematurely when it became clear that the risks to participants taking HT outweighed any potential benefits.

The NIH held a press conference on July 9, 2002, to announce that the WHI estrogen-plus-progestin trial arm was being stopped. Figure 4 shows that press release and news story activity reached its highest point during the time immediately surrounding this announcement. In addition to the announcement, study investigators published their findings in the July 17, 2002, issue of *JAMA*. Results demonstrated that after 5.2 years of follow-up, estrogen-plus-progestin users had increased risks for invasive breast cancer, coronary heart disease, stroke, and pulmonary embolism, and decreased risks for hip and other bone fractures and colorectal cancer. The trial was stopped because the WHI data and safety monitoring board determined that the overall health risks for participants exceeded any benefits. Investigators concluded in the *JAMA* article that estrogen-plus-progestin therapy “should not be initiated or continued for primary prevention of CHD [coronary heart disease]” (Writing Group for the Women's Health Initiative, 2002, p. 321).

On March 2, 2004, the NIH held another press conference to announce that the estrogen-only arm of the WHI trial was also being stopped. This date is also indicated in Figure 4. Again, in addition to the announcement, study results were published in *JAMA* on April 14, 2004. Results demonstrated that after 6.8 years of follow-up, estrogen-only use increased the risk of stroke and deep vein thrombosis (blood clots), had no effect on heart disease, breast cancer, or colorectal cancer, and reduced the risk of hip fracture.

Because no overall benefit was found for participants and data indicated no heart disease benefit, which was a key question of the trial and unlikely to change with additional follow-up, the trial was halted. Investigators concluded in *JAMA* that estrogen-only therapy “should not be recommended for chronic disease prevention in postmenopausal women” (Women’s Health Initiative Steering Committee, 2004, p. 1701).

During this time period, WHI investigators also released disappointing findings from the Women’s Health Initiative Memory Study (WHIMS), a sub-study of the WHI to assess the ability of HT to prevent mild cognitive impairment and dementia. On May 28, 2003, WHIMS investigators reported in *JAMA* that estrogen plus progestin afforded women 65 years of age and older no protection against mild cognitive impairment and increased rates of probable dementia (Shumaker et al., 2003). On June 23, 2004, a *JAMA* article by WHIMS investigators also reported that women 65 years of age and older who took estrogen-only had increased rates of mild cognitive impairment and probable dementia (Shumaker et al., 2004).

2005 – 2011: WHI re-analyses, the “timing hypothesis,” and breast cancer-related outcomes. By late 2004, many organized interests were beginning to claim that the WHI results had been blown out of proportion, that HT still played a valuable role in women’s health, and that the women in the WHI trials were not representative of the typical HT user due their advanced age (for e.g., see Berger, 2004; Boodman, 2005; Neergaard, 2004). It was in this context that re-analyses of the WHI data and additional studies began to appear in the 2005 to 2011 period that were designed to test what became known as the “timing hypothesis,” which proposed that HT could have heart disease benefits for younger, but not older women (for e.g., see Slomski, 2009; Stobbe,

2007). Other studies in this time period continued to track the breast cancer-related outcomes of HT.

Studies that supported the timing hypothesis during this period came primarily from the Nurses' Health Study and re-analyses of the WHI data. For example, on January 24, 2006, the *Journal of Women's Health* published an analysis from the Nurses' Health Study, which found lower rates of coronary heart disease (CHD) for women who began taking estrogen-only or estrogen-plus-progestin close to menopause and no relationship between HT and CHD for older women or women who started HT ten years or more after menopause" (Grodstein, Manson, & Stampfer, 2006, p. 35). The following year, a secondary analysis of the WHI data, published in *JAMA* on April 4, 2007, found that women who started hormone therapy within 10 years of menopause showed a non-statistically significant trend toward less CHD risk and total mortality than women who started later, although the risk of stroke was increased regardless of time since menopause (Rossouw, 2007, p. 1465). The *New England Journal of Medicine* published an ancillary substudy of the estrogen-only arm of the WHI on June 21, 2007, finding that women who were age 50 to 59 at trial enrollment had less calcified coronary artery plaque after trial completion, leading the authors to conclude that their data lent "support for the hypothesis that estrogen therapy may have cardioprotective effects in younger women" (Manson et al., 2007, p. 2599).

Breast cancer also received continued focus during this time period. For example, *JAMA* published a study on April 12, 2006, based on WHI participants, which found that women, ages 50-79 with a prior hysterectomy who were given estrogen-only for 7.1 years had an increased incidence of abnormal mammograms requiring follow-up, but no

increased risk of breast cancer (Stefanick et al., 2006). On April 19, 2007, a secondary data analysis of the National Cancer Institute's (NCI) Surveillance, Epidemiology, and End Results Registries (SEER) was published in *NEJM*, showing that substantial declines seen in estrogen-receptive-positive breast cancer rates among women 50 years of age and older appeared related to national declines in HT prescription use that occurred after the WHI report in 2003 (Ravdin et al., 2007).

Regulatory actions and disputes. A few actions and disputes related to regulation of prescription HT products also stimulated press release and/or news reporting activity over the study time period. The action that attracted attention by both press releases and news stories and had the most repercussions in terms of stimulating additional actions by other organizations was the U.S. Food and Drug Administration's (FDA) change to the product labeling for HT products in response to the WHI findings.

During the entire time period for this study, HT was only FDA-approved for the treatment of vasomotor symptoms (hot flashes and/or night sweats), symptoms of vaginal atrophy, such as vaginal dryness or painful intercourse, and osteoporosis prevention (USDHHS FDA, 2011b). On January 8, 2003, the FDA issued new labeling requirements for all HT products based on the risks that emerged from the WHI estrogen-plus-progestin trial. Although up until that point the WHI study had only tested one dosage and formulation of estrogen-plus-progestin in the form of *Prempro*, the FDA ruled that until proven otherwise, the same risks needed to be assumed for all HT dosages and formulations, including estrogen-only products and HT products with different delivery routes, such as topical creams, gels, and transdermal patches (Superville, 2003).

The new FDA-approved label included black-box warnings about the potential risks for heart disease, heart attack, stroke, and breast cancer, along with a warning statement that HT products are *not* approved for the prevention of heart disease (Superville, 2003). The postmenopausal osteoporosis indication was also changed to encourage consideration of alternative treatments if used “solely for the prevention of postmenopausal osteoporosis.” An additional statement warned that “estrogens with or without progestins should be prescribed at the lowest effective doses and for the shortest duration consistent with treatment goals and risks for the individual woman” (USDHHS FDA, 2011b). The risk of developing “probable dementia in postmenopausal women 65 years of age or older” was also added to the label later on in 2003 after the WHIMS results were reported (USDHHS FDA, 2011b). In addition to the labeling changes, the FDA launched a Congressionally-mandated, nationwide menopausal hormone therapy information campaign about the benefits and risks of HT on September 9, 2003 (Kaufman, 2003; Wyeth Pharmaceuticals, 2003c).

Other regulatory disputes appearing in press releases and news stories related not to labeling, but to issues of access. The first revolved around a new drug application for a generic formulation of *Premarin* submitted to the FDA for approval by Duramed Pharmaceuticals in the mid-1990s. Wyeth had submitted a Citizen petition in 1994, along with several medical and consumer-oriented organizations active in women’s health, to block the FDA approval, alleging that the generic formulation did not meet the requirement of having active ingredients identical to *Premarin*, and therefore, posed unknown risks to women (Wyeth-Ayerst Laboratories, 1996). Despite substantial counter-advocacy by Duramed Pharmaceuticals and other groups, the FDA ruled in favor

of Wyeth on May 5, 1997 (Wyeth-Ayerst Laboratories, 1997). Another issue, which was the focus of more press releases than news stories began to emerge in 2006 and continued sporadically throughout the remainder of the study period about the legality of custom, HT prescriptions written for women by their physicians and compounded from approved ingredients by pharmacists into new formulations, a practice deemed by some pharmaceutical companies as unlawful manufacturing and selling of unapproved drugs (Wyeth Pharmaceuticals, 2006).

Clinical practice recommendations and guidelines. Disappointing results from cardiovascular-oriented trials in the 1998 to 2002 period and the release of the WHI findings also prompted action on the part of medical professional societies and nonprofit health-advocacy organizations that issue clinical practice guidelines for women's health care. For example, primarily in response to the HERS I results, the American Heart Association (AHA) published revised guidelines in its journal, *Circulation*, on July 23, 2001, advising physicians not to prescribe HT for the "sole purpose of preventing heart attacks and strokes in woman who already have cardiovascular disease" (American Heart Association, 2001). After the WHI findings were released, the American College of Obstetricians (ACOG) convened a Hormone Therapy Task Force to review the body of research on HT, which resulted in a report published in its October 1, 2004, issue of the *Journal of Obstetrics & Gynecology*. The report concluded that while "the risks of HT exceed the benefits for the prevention of chronic diseases" HT is the "most effective" treatment for vasomotor symptoms and vaginal atrophy and "healthy symptomatic women" should not be "denied this option based on available data regarding health risks" (ACOG Task Force on Hormone Therapy, 2004, p. 4S, p. 129S).

Another example of shifting guidelines and associated controversies occurred in 2007. In a position statement released on January 1, 2007, and later published in its March 2007 issue of *Menopause*, the North American Menopause Society (NAMS) asserted that the evidence base supported the use of estrogen-only and estrogen-plus-progestin therapy for “menopause-related symptoms and disease prevention in appropriate populations of peri- and postmenopausal women,” citing FDA approval of HT for the prevention of postmenopausal osteoporosis, “strong evidence” of HT’s efficacy in reducing fractures, and research studies indicating that younger women who start therapy early and close to menopause may realize coronary heart disease reduction benefits (NAMS, 2007, p. 168, p. 171; Parker-Pope, 2007). Conversely, in its updated cardiovascular disease prevention guidelines for women published in its journal, *Circulation*, on February 20, 2007, AHA stated that menopausal hormone therapies should not be used to prevent heart disease “because they have been shown to be ineffective in protecting the heart and may increase the risk of stroke” (American Heart Association, 2007).

Product promotion. There was a steady drumbeat of press releases throughout the entire study time period that were strictly marketing-oriented in nature. Common topics of these press releases included the granting of FDA-approval for new products, announcements for new product launches, and competitive-oriented releases that presented the advantages of one product over another. Most releases were produced by pharmaceutical companies that manufactured prescription HT products. Over the entire study time period, the FDA approved a total of 23 new, brand-name HT products, which included a variety of oral tablets, capsules, vaginal inserts, topical lotions, and

transdermal patches, gels, and sprays (see Appendix B). Most brand-name products were also available in different dosages, with each dosage requiring a separate FDA approval.

Pharmaceutical companies often attempted to publicize not just the launch of entirely new products, but the availability of new dosages of existing products as they became available, particularly in the post-WHI period when a trend toward lower-dose HT therapies developed. For example, Wyeth Pharmaceuticals announced FDA-approval for its first low-dose versions of *Prempro* on March 13, 2003, and *Premarin* on April 25, 2003 (Wyeth Pharmaceuticals 2003a, 2003b). After the WHI findings, manufacturers and/or distributors of alternative, non-prescription products also ramped up their efforts to position a variety of products to treat menopausal symptoms, such as herbal formulations to fight hot flashes and lubricants to ease vaginal dryness, as safer alternatives to HT.

Primarily product-oriented news stories, however, were rare. Most news stories tended to refer to HT in general terms, such as hormone therapy, estrogen therapy, estrogen-plus-progestin therapy, or combination therapy rather than by brand name. Market leaders, *Premarin*, introduced to the market in 1942, and *Prempro* introduced to the market in 1995, were exceptions. These drugs were mentioned frequently across the entire study time period because of the large number of news stories about major clinical trials that happened to use them as study drugs, such as HERS and WHI, or for other non-promotional reasons, such as being the subject of lawsuits waged by women against Wyeth in the post-WHI period. In the immediate period of time surrounding the two major WHI announcements (the halting of the estrogen-plus-progestin study arm on July 9, 2002, and the estrogen-only study arm on March 3, 2004), some news stories that

focused more on the decision-making processes of women as a result of WHI addressed the range of prescription and/or non-prescription options for menopausal women.

Legal actions. The last major theme that generated substantial press release and news story activity after the WHI findings was related to lawsuits waged against Wyeth by women who claimed they got breast cancer as a result of taking *Prempro*. In total, more than 4,500 lawsuits were filed against Wyeth after the WHI findings were released, and a few of these suits came to trial and attracted substantial publicity beginning in mid-2006 and continuing throughout 2011 (Agovino, 2006).

The first trial took place in Federal Court in Little Rock, Arkansas, on August 21, 2006. The plaintiff and her defense team argued that the plaintiff's breast cancer was caused by her eight years of *Prempro* use, and that Wyeth engaged in inappropriate practices by failing to conduct long-term studies on breast cancer risk and marketing *Prempro* in a way that downplayed its risks and promoted unproven benefits (Agovino, 2006). Wyeth's defense focused on the inability to make a causal link between the plaintiff's *Prempro* use and her subsequent breast cancer, the plaintiff's failure to read the patient information included with her prescription that warned of a potential breast cancer risk, and the fact that Wyeth's HT drugs are FDA-approved, and therefore, are considered safe (DeMillo, 2006). This first trial resolved in favor of Wyeth, but others focused on similar claims occurred throughout the remainder of the study period, some resolving in favor of the plaintiffs and others in Wyeth's favor (for e.g., see Dale, 2006, 2007, 2009; Chereb, 2007; Demillo, 2007; Zeman, 2008).

Content of Press Releases and News Stories

This quantitative results section addresses research questions two (R2) through five (RQ5). The first section (RQ2) describes the content of press releases; the second section (RQ3) describes the content of news releases; and the third section (RQ4) compares the body of press releases to news stories in terms of their content. The fourth section (RQ5) identifies key organizations that emerged as successful agenda builders as evidenced by frequent mentions of these organizations in both press releases and news stories.

Content of press releases. This section presents the results from the series of questions related to research question two: What was the content of press releases about hormone therapy (HT) distributed by organizations via *PR Newswire* and *EurekAlert!* from 1995-2011? The analyses reported in this section are based on these 675 press releases.

RQ2a: What types of organizations distributed press releases most often? What types of organizations were mentioned in press releases most often? What types of individuals were quoted most often? How did these factors vary by the types of organizations that produced press releases?

Distributing organizations. Six different types of health and medical organizations produced information subsidies in the form of press releases about HT. These organization types are rank-ordered in terms of their prominence from highest to lowest in Table 4.

Table 4

Types of Organizations that Distributed Press Releases (1995-2011)

Type of Organization	Press releases (N=675)	
	<i>n</i> (st. resid.)	%
Pharmaceutical Companies	239 (14.52)	35.4
Academic & Medical Institutions	166 (7.09)	24.6
NonProfit Organizations	96 (-0.04)	14.2
Health Advocacy Organizations (501c3) ^a	76	11.3
Professional/Trade Associations (501c6) ^a	16	2.4
Coalitions ^a	4	0.6
Medical/Scientific Journal Publishers	78 (-1.87)	11.6
Miscellaneous For-Profit Organizations	51 (-4.62)	7.6
U.S. Government	28 (-6.97)	4.1
Other	17 (-8.09)	2.5

^a These 3 categories are sub-categories of the larger nonprofit organization category above. Only the total nonprofit category was used for the chi-square goodness-of-fit test.

Pharmaceutical companies and academic/medical institutions, such as universities, hospitals, and clinical centers were responsible for almost two-thirds (60%) of all press release activity. Nonprofit organizations (14.2%) and medical journal publishers (11.6%) distributed substantially less, but not insignificantly. Notably, the majority of press releases in the nonprofit category were distributed by 501c3 health-advocacy organizations. Only a few press releases in the nonprofit category were distributed by 501c6 medical professional societies/trade associations or coalitions.

The most inactive organization types were those classified as miscellaneous for-profit organizations, which included a range of non-pharmaceutical companies, including firms that marketed supplements and alternative health products, law firms, and public

relations agencies. Surprisingly, given their central role in matters of public health, less than five percent of press releases were distributed by U.S. government agencies.

Organizations that could not be classified into any coherent category were placed in a seventh category, labeled other.

To determine if the observed pattern of results in Table 4 differed from the pattern expected under the null hypothesis, a chi-square goodness-of-fit test was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated that the overall pattern of differences across the seven types of organizations was statistically significant, $\chi^2=399.90$, $df=6$, $p<.001$. Follow-up tests were conducted by examining the standardized residuals to see which categories contributed significantly to the chi-square statistic, as evidenced by standardized residuals greater than an absolute value of two (Agresti, 2007; Lomax & Hahs-Vaughn, 2012). The pharmaceutical and academic/medical institution categories had large, positive residuals, indicating that these organizations distributed proportionally more releases than would be expected by chance. Miscellaneous for-profit organizations, U.S. government agencies, and the other category all had large, negative residuals, indicating that these organizations distributed proportionally less releases than expected by chance (residuals reported in Table 4).

Organizations mentioned in text. Multiple organizations were mentioned in the body text of each press release. The average number of organizations mentioned per release was approximately three ($M=3.19$, $SD =1.86$). Press releases also included multiple types of organizations. The average number of organization types mentioned was approximately two ($M=2.13$, $SD=.91$).

As can be seen in Table 5, more than half of all press releases mentioned an academic/medical institution (59.3%) or a U.S. government agency (53.6%). Pharmaceutical companies (47.1%) and nonprofit organizations (31.7%) were mentioned by less than half of all releases. Miscellaneous for-profit organizations (11.3%) and those classified as other (9.9%) were rarely mentioned.

Table 5

Types of Organizations Mentioned in Body Text of Press Releases (1995-2011)

Type of Organization	Press releases (N=675)	
	<i>n</i> (st. resid.)	%
Academic & Medical Institutions	400 (10.37)	59.3
U.S. Government	362 (7.92)	53.6
Pharmaceutical Companies	318 (5.07)	47.1
Nonprofit Organizations	214 (-1.65)	31.7
Health Advocacy Organizations (501c3) ^a	194	28.7
Professional/Trade Associations (501c6) ^a	31	4.6
Coalitions ^a	5	0.7
Miscellaneous For-Profit Organizations	76 (-10.56)	11.3
Other	67 (-11.15)	9.9

Note . Percentages do not total 100% because the body text of each press release could contain multiple organization types.

^a These 3 categories are sub-categories of the larger nonprofit organization category above. Only the total nonprofit category was used for the chi-square goodness-of-fit test.

To determine if the observed pattern of results in Table 5 differed from the pattern expected under the null hypothesis, a chi-square goodness-of-fit test was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. The results indicated that the overall pattern of differences observed across the six organization types was statistically significant $\chi^2=434.52$, $df=5$,

$p < .001$. Examination of the residuals indicated that academic/medical institutions, U.S. government agencies, and pharmaceutical companies (all with large, positive residuals greater than two) were more likely to be mentioned in press releases than other types of organizations (see Table 5.)

Although medical/scientific journal publishers were included in the coding for organizations distributing press releases, they were not included in the coding for what organizations were mentioned in the body text. This decision was made because preliminary coding had clearly demonstrated that publishers rarely appeared in the body text; instead the name of the actual journal appeared in the text. More than 50.4% ($n=340$) of all press releases mentioned a medical or scientific journal.

Differences by type of organization. To determine whether the types of organizations mentioned in a press release varied by what type of organization produced the release, five chi-square tests of independence were conducted at an alpha level of .05. These analyses tested whether the probability of an organization type being mentioned in the body text of a press release was significantly associated with the type of organization that distributed the release. As can be seen in Table 6, all five tests were statistically significant. Only one analysis contained a cell with an expected frequency of less than five, the test to determine if mentions of miscellaneous for-profit organizations varied by the type of organization distributing the release. Although the chi-square value was highly significant, this test should be interpreted with some caution for this reason.

Table 6

Types of Organizations in Body Text by Type of Organization that Distributed Release (1995-2011)

Org. Type Distributed Release	Pharma (n=239)	Acad/Med Instit. (n=166)	NonProfit (n=96)	Journal Publishers (n=78)	Misc. For- Profit (n=51)	U.S. Gov (n=28)		
Org. Type in Body Text	% (f)	% (f)	% (f)	% (f)	% (f)	% (f)	χ^2 (df=5)	p
Acad/Med Institutions	32.2 _a (77)	98.8 _b (164)	61.5 _c (59)	76.9 _c (60)	33.3 _a (17)	57.1 _{a,c} (16)	205.08	<.001
U.S. Gov	74.1 _a (177)	51.2 _b (85)	36.5 _{b,c} (35)	23.1 _c (18)	35.3 _{b,c} (18)	100.0 _d (28)	122.34	<.001
Pharma	97.9 _a (234)	23.5 _b (39)	21.9 _{b,c} (21)	7.7 _c (6)	19.6 _{b,c} (10)	32.1 _b (9)	374.44	<.001
Nonprofit	25.9 _a (62)	27.1 _a (45)	89.6 _b (86)	7.7 _c (6)	25.5 _{a,c} (13)	3.6 _{a,c} (1)	183.56	<.001
Misc. For- Profit	11.7 _a (28)	2.4 _b (4)	5.2 _{a,b} (5)	1.3 _{a,b} (1)	74.5 _c (38)	0.0 _{a,b} (0)*	226.95	<.001

Note. Cells sharing the same subscript are not significantly different from one another using a z-test for column proportions with the Bonferroni adjustment method.

*This cell had an expected frequency of less than 5.

Post hoc z-tests for column proportions using the Bonferroni adjustment method were then used to follow-up all significant chi-square results to determine which specific column proportions differed from one another. The Bonferroni adjustment method holds alpha at .05 for the entire group of comparisons by splitting alpha up equally among each pair-wise comparison to avoid inappropriate inflation of Type I error (Lomax & Hahs-Vaughn, 2012). The results of these post hoc tests are also presented in Table 6 with the use of lettered subscripts. Only patterns that met this stringent threshold are commented on below.

Unsurprisingly, organizations that distributed a press release were more likely to mention their own organization type in the release than any other organization type; likely because they included their own name in the body text of the release. Almost all of the press releases distributed by a pharmaceutical company mentioned a pharmaceutical

company (97.9%); 98.8% of academic/medical institutions mentioned an academic/medical institution; 89.6% of nonprofits mentioned a nonprofit; 74.5% of miscellaneous for-profit organizations mentioned a for-profit organization, and 100% of government agency releases mentioned a government agency. More than three quarters (76.9%) of releases distributed by medical/scientific journal publishers mentioned academic/medical institutions, likely due to their dissemination of studies conducted by these institutions.

Some organization types also tended to appear frequently in releases distributed by other types of organizations, particularly academic/medical institutions and government agencies. More than half of the releases distributed by nonprofit organizations (61.5%), medical/scientific journal publishers (76.9%), and U.S. government agencies (57.1%) mentioned an academic/medical institution in the body text. Almost three quarters (74.1%) of pharmaceutical company releases mentioned a U.S. government agency.

The chi-square test of independence procedure was used to see if the proportion of medical/scientific journal articles mentioned in press releases varied by the type of organization that distributed the release at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. A significant chi-square value resulted, $\chi^2=232.62$, $df=5$, $p<.001$, indicating an association between organization type and mentions of medical/scientific journals. This procedure was followed-up with post hoc z -tests for column proportions using the Bonferroni adjustment method. Results indicated that medical journal publishers (97.4%, $n=76$), U.S. government agencies (85.7%, $n=24$), and academic/medical institutions (74.7%, $n=124$)

were more likely than all other organization types to mention a medical/scientific journal. Half of nonprofit organizations (51.0%, $n=49$) and almost one-third of miscellaneous for-profit organizations (31.4%, $n=16$) mentioned a medical/scientific journal.

Pharmaceutical companies were less likely than all other organization types to mention a medical/scientific journal, with only 17.6% ($n=42$) citing a journal article in the body text of a release.

Types of individuals quoted. Table 7 shows that physicians and/or scientists were by far the most frequently quoted individuals. Almost two-thirds (62.4%) of all press releases over the study time period included a direct quote from a physician and/or scientist. A substantial number of press releases (39.7%) quoted official spokespersons for an organization, such as chief executive officers (CEOs), directors of research, or marketing and public affairs personnel. All other types of individuals were rarely quoted.

Type of Individual	Press Releases ($N=675$)	
	n (st. resid.)	%
Physician/Scientist	421 (34.89)	62.4
CEO/Spokesperson	268 (18.76)	39.7
Nurses/Other Clinicians	10 (-8.43)	1.5
Attorney	8 (-8.64)	1.2
Everyday Woman	4 (-9.07)	0.6
Everyday Family Member	1 (-9.38)	0.1
Celebrity	1 (-9.38)	0.1
Other	7 (-8.75)	1

Note . Percentages do not total 100% because the body text of each press release could contain quotes from multiple types of individuals.

To determine if the observed pattern of results in Table 7 differed from the pattern expected under the null hypothesis, a chi-square goodness-of-fit test was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated that the observed pattern of differences across the eight categories was statistically significant, $\chi^2=2049.96$, $df=7$, $p<.001$. Follow-up tests were conducted by examining the standardized residuals to see which categories contributed significantly to the chi-square statistic as evidenced by standardized residuals greater than an absolute value of two. The large, positive standardized residuals for the physician and/or scientist and official spokesperson categories indicated that press releases quoted these types of individuals more than any other types of individuals, which all had large, negative standardized residuals (see Table 7).

Differences by type of organization. To determine whether the top two categories of quoted individuals varied by the type of organization that produced the release, two chi-square tests of independence were conducted at an alpha level of .05. These analyses tested whether the probability of a physician and/or scientist or official spokesperson being quoted in the body text of a press release was significantly associated with the type of organization that distributed the release. The assumptions of independence and expected frequencies of at least five cases per cell were met. As can be seen in Table 8, both chi-square tests of independence were statistically significant. Post hoc z -tests for column proportions using the Bonferroni adjustment method were used to follow-up the significant chi-square results to determine which specific column percentages differed

from one another. The results of these tests are reported in the table with subscripts. Only differences that met these stringent tests are described below.

Table 8

Types of Individuals Quoted by Type of Organization that Distributed Release(1995-2011)

Org. Type Distributed Release	Pharma (n=239)	Acad/Med Instit. (n=166)	NonProfit (n=96)	Journal Publishers (n=78)	Misc. For-Profit (n=51)	U.S. Gov (n=28)		
Type Quoted	% (f)	% (f)	% (f)	% (f)	% (f)	% (f)	χ^2 (df=5)	p
Physician/Scientist	53.6 _{a,b} (128)	91.0 _c (151)	77.1 _d (74)	12.8 _e (10)	45.1 _b (23)	82.1 _{a,c,d} (23)	166.95	<.001
CEO/Spokesperson	75.7 _a (181)	3.6 _b (6)	41.7 _c (40)	1.3 _b (1)	35.3 _c (18)	60.7 _{a,c} (17)	273.09	<.001

Note . Cells sharing the same subscript are not significantly different from one another using a z -test for column proportions with the Bonferroni adjustment method.

Academic/medical institutions (91%) were more likely than all other groups, besides U.S. government agencies (82.1%), to quote physicians and/or scientists. Medical/scientific journal publishers (12.8%) were the least likely to feature quotes from physicians and/or scientists. Pharmaceutical companies were more likely (75.7%) than all other groups, besides U.S. government agencies (60.7%), to quote official spokespersons. Medical/scientific journal publishers (1.3%) and academic/medical institutions (3.6%) were least likely to feature quotes from CEOs or official spokespersons.

RQ2b: What benefits and risks were associated with HT? How were benefits and risks presented (qualitative vs. quantitative; relative vs. absolute terms). How did these factors vary by the types of organizations that produced press releases?

Whenever possible, results related to benefits and risks of HT are provided for the entire study period and broken out by the “pre-WHI period,” from January 1, 1995, to July 8, 2002, and “post-WHI period,” from July 9, 2002 to December 31, 2011. The date of July 9, 2002, was used as the starting point for the post-WHI period because it marked

the day that NIH announced that it was stopping the estrogen-plus-progestin trial. It was deemed necessary to break the data related to benefits and risks into two time periods because the WHI study findings provided new evidence and sparked a major public reevaluation of the benefits and risks of HT.

Amount of information about benefits and risks. Across the entire time period studied, two-thirds of press releases (66.4%, $n=448$) mentioned at least one potential benefit of HT, and a little less than two-thirds of press releases mentioned at least one potential risk (60.7%, $n=410$). Although these numbers seem fairly high, only 38.2% ($n=258$) of press releases contained a benefit and a risk together in the same release. More than one-quarter (28.1%, $n=190$) of releases mentioned a benefit with no risk, 22.5% ($n=152$) mentioned a risk with no benefit, and 11.1% ($n=75$) of releases mentioned no information about benefits or risks.

The mean number of benefits per press release was 1.27 ($SD=1.37$). To determine if the mean number of benefits differed prior to and after the initial WHI announcement, a two-tailed, t -test for independent samples assuming equal variances was conducted at an alpha level of .05. The equal variances formula was used because Levine's test for equality of variances returned an insignificant result ($F=1.79$, $p=.18$). Results indicated that press releases were significantly more likely to contain more benefits per press release in the pre-WHI period ($M=1.45$, $SD=1.31$) than the post-WHI period ($M=1.16$, $SD=1.40$), $t(673)=2.73$, $p=.01$.

The mean number of risks per press release was 1.52 ($SD=1.89$). When compared by time period, the reverse pattern occurred. Press releases contained significantly less risks per press release in the pre-WHI period ($M=.53$, $SD=.80$) than in the post-WHI

period ($M=2.17$, $SD=2.10$), according to a two-tailed, t -test for independent samples assuming unequal variances conducted at an alpha level of .05, $t(570)=14.24$, $p<.001$. The unequal variance formula was used after Levine's test for equality of variances returned a statistically significant result ($F=272.06$, $p<.001$). Figure 6 visualizes the trends for mean number of benefits and risks per press release across the two time periods.

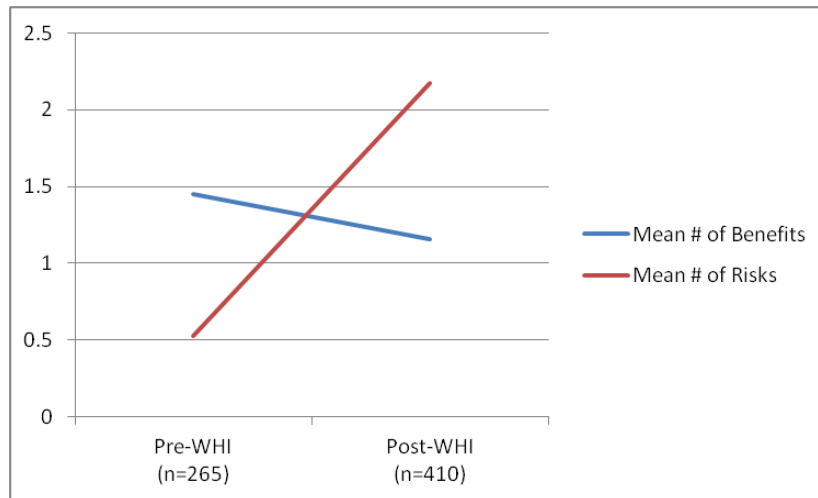


Figure 6: Mean benefits and risks by pre- vs. post-WHI period.

Differences by type of organization. To test whether the mean number of benefits and risks per press release differed by the type of organization that distributed the release, two, one-way ANOVAs were conducted. For benefits, a one-way ANOVA indicated that the mean number of benefits differed significantly by organization type, $F(5, 652) = 5.80$, $p<.001$. Post hoc Tukey-Kramer tests were then used to determine which group means differed significantly from one another. The Tukey-Kramer multiple comparison procedure was selected because it adjusts for unequal n s and assumes equal variances, which was appropriate given that Levene's test for homogeneity of variance was not rejected ($F=.97$, $p=.44$). The results of three post hoc tests are presented in Table 9 with

the use of lettered subscripts. As can be seen in Table 9, pharmaceutical companies, academic/medical institutions, and U.S. government agencies included significantly more benefits per release than medical/scientific journal publishers and miscellaneous for-profit organizations.

Table 9

Mean Benefits and Risks by Type of Organization that Distributed Release (1995-2011)

	Pharm (<i>n</i> =239)	Acad/Med Instit. (<i>n</i> =166)	Non Profit (<i>n</i> =96)	Journal Publishers (<i>n</i> =78)	Misc. For-Profit (<i>n</i> =51)	U.S. Gov (<i>n</i> =28)
	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)
Benefits	1.40 _a (1.18)	1.40 _{a,b} (1.43)	1.18 _{a,b,c} (1.31)	.74 _{c,d} (1.10)	.80 _{c,e} (1.43)	1.82 _{a,b} (1.57)
Risks	1.80 _a (2.36)	1.27 _{a,b} (1.45)	.90 _b (1.19)	1.37 _{a,b} (1.34)	1.18 _{a,b} (1.40)	3.46 _c (2.24)

Note. For benefits, means sharing a common subscript are not statistically different via the Tukey-Kramer posthoc test, which adjusts for unequal *n* s.

Note: For risks, means sharing a common subscript are not statistically different via the Games-Howell post hoc test, which adjusts for unequal *n* s and unequal variances.

For risks, a one-way ANOVA indicated that the mean number of risks differed significantly by organization type, $F(5, 652)=10.78, p<.001$. Games-Howell post hoc multiple comparison tests were then used to determine which group means differed significantly from one another. The Games-Howell procedure was used because it adjusts for unequal *n*s and unequal variances, which was appropriate given that Levene’s test for homogeneity of variance was rejected ($F=30.47, p<.001$). As can be seen in Table 9, U.S. government agencies reported significantly more risks per release than any other organization type. Pharmaceutical companies reported significantly more risks than nonprofit organizations.

Specific benefits. Table 10 reports the most frequently identified potential benefits of HT in press releases by total time period and by the pre- and post-WHI time periods. The total column shows that two of the three FDA-approved indications ranked in the first and second spots: reduction of hot flashes and osteoporosis prevention. Ranking in the third spot was heart disease prevention, an unapproved indication, which was identified more often as a potential benefit of HT than the FDA-approved indication for treatment of vaginal problems, such as vaginal atrophy and dryness, which ranked fourth. Prevention of colon cancer and cognitive decline ranked in the fifth and sixth spots.

Table 10

Benefits for Total Time Period and by Pre- vs. Post-WHI Period

Benefit	Total N=675	Pre-WHI n=265	Post-WHI n=410	Pre- vs. Post-Period Comparisons	
	% (n)	% (f)	% (f)	χ^2 (df=1)	p
Hot Flashes Reduced	34.8 (235)	34.3 (91)	35.1 (144)	0.04	.84
Osteoporosis Prevention	28.0 (189)	35.5 (94)	23.2 (95)	12.08	<.01
Heart Disease Prevention	18.8 (127)	31.3 (83)	10.7 (44)	44.67	<.001
Treatment of Vaginal Atrophy	14.4 (97)	10.9 (29)	16.6 (68)	4.16	.04
Colon Cancer Prevention	5.9 (40)	2.6 (7)	8.0 (33)	8.44	<.01
Cognitive Decline Prevention	5.2 (35)	8.7 (23)	2.9 (12)	10.83	<.01
Other Disease/ Illness-Reduction Benefits	8.7 (59)	8.7 (23)	8.8 (36)	<0.01	.96
Other Overall Health/ Well-Being Benefits	6.4 (43)	6.4 (17)	6.3 (26)	<0.01	.97

The remaining two categories, “other disease/illness-reduction benefits” and “other overall health/well-being benefits” contained infrequent mentions of a variety of purported benefits that were sometimes the subject of miscellaneous research studies, but never developed into any focused research agenda. For example, the other disease/illness-reduction benefits category included mentions of potential benefits like reductions in all cause-mortality, breast cancer, and periodontal disease, and improvements in blood sugar for diabetes patients. The other overall health/well-being category contained references to potential benefits such as improved mood, energy, and sleep, and less skin aging and weight gain.

To determine whether mentioned benefits varied by the pre- and post-WHI period eight chi-square tests of independence were conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. These analyses tested whether each potential benefit was more or less likely to appear in press releases before or after the WHI announcement. As can be seen in Table 10, five of these tests returned statistically significant results: osteoporosis prevention, heart disease prevention, treatment of vaginal atrophy, colon cancer prevention, and prevention of cognitive decline.

A closer look at the directionality of these changes, suggests that patterns may have shifted in response to new evidence generated by the WHI, ongoing research to better understand the WHI findings, and FDA product-labeling actions. Mentions of the unapproved indication of heart disease prevention went down dramatically between the two time periods (from 31.3% to 10.7%) and mentions of the approved indication for treatment of vaginal atrophy-related symptoms increased slightly (from 10.9% to 16.6%).

Other shifts in the texts of press releases can also be seen from the pre- to post-WHI period. Mentions of osteoporosis prevention (35.5% to 23.2%) and prevention of cognitive decline (8.7% to 2.9%) went down significantly, and mentions of colon cancer prevention (2.6% to 8.0%) increased significantly.

Differences by type of organization. To determine whether the identification of specific, potential benefits varied by the type of organization distributing the press release, chi-square tests of independence were conducted at an alpha level of .05. The assumption of independence was met, and analyses were only conducted for the top four benefits for the entire time period rather than within the pre- and post-WHI period to avoid expected cell counts less than five. As can be seen in Table 11 all chi-square tests indicated highly significant associations between the type of organization distributing the release and the identification of each of the four benefits. Follow-up *z*-tests for column proportions using the Bonferroni adjustment method were used to examine differences between specific column percentages. Only those differences that met this stringent test are described below. It should be noted that for the vaginal atrophy row, one cell in the U.S. government column had an expected value of less than five. While the chi-square value was highly significant for this test, interpretation of differences in this row should be approached with some caution.

Table 11

Benefits by Organization Type that Distributed Release (1995-2011)

	Pharma <i>n</i> =239	Acad/Med Instit. <i>n</i> =166	Non Profit <i>n</i> =96	Journal Publishers <i>n</i> =78	Misc. For- Profit <i>n</i> =51	U.S. Gov <i>n</i> =28		
Benefits	% (<i>f</i>)	% (<i>f</i>)	% (<i>f</i>)	% (<i>f</i>)	% (<i>f</i>)	% (<i>f</i>)	χ^2 (<i>df</i> =5)	<i>p</i>
Hot Flashes Reduced	64.4 _a (154)	21.7 _b (36)	15.6 _b (15)	7.7 _b (6)	25.5 _b (13)	28.6 _b (8)	147.38	<.001
Osteoporosis Prevention	33.5 _{a,b} (80)	27.7 _b (46)	22.9 _b (22)	17.9 _b (14)	13.7 _b (7)	57.1 _a (16)	25.58	<.001
Heart Disease Prevention	7.5 _a (18)	31.9 _b (53)	31.2 _{b,c} (30)	12.8 _{a,c} (10)	11.8 _{a,b,c} (6)	10.7 _{a,b,c} (3)	54.17	<.001
Vaginal Atrophy Treatment	26.4 _a (63)	6.0 _b (10)	8.3 _b (8)	6.4 _b (5)	9.8 _{a,b} (5)	14.3 _{a,b} (4)*	44.86	<.001

Note . Cells sharing the same subscript are not significantly different from one another using a *z*-test for column proportions with the Bonferroni adjustment method.

*This cell had an expected frequency of less than 5.

Pharmaceutical companies (64.4%) were far more likely than any other organization type to identify the FDA-approved indication of hot flash reduction as a potential benefit of HT. U.S. government agencies (57.1%) were more likely than all other organization types, besides pharmaceutical companies (33.5%), to mention the FDA-approved indication of osteoporosis prevention. Academic/medical institutions (31.9%) and nonprofit organizations (31.2%) were more likely than pharmaceutical companies (7.5%) to mention a potential heart disease benefit, a controversial, non-FDA approved indication. Conversely, pharmaceutical companies (26.4%) were more likely than academic/medical institutions (6.0%), nonprofit organizations (8.3%), and medical/scientific journal publishers (6.4%) to mention the FDA-approved treatment of vaginal atrophy-related problems as a benefit.

Specific risks. Table 12 reports the most frequently identified potential risks of HT in press releases by total time period and by the pre- and post-WHI periods. For risks

for total time period, breast cancer was the clear leader being mentioned in 40.9% of all press releases; heart disease (27.1%) and stroke (23.4%) took the second and third slots, with each being mentioned in about a quarter of all releases. The uterine cancer category, which primarily contained mentions of endometrial cancer, a cancer of the lining of the uterus, a long-known, well-documented risk of HT ranked fourth (21.3%) and was neck-and-neck with blood clots (21.2%), which ranked in the fifth spot overall. Cognitive decline, gallbladder disease, and the other category, which included more sporadically mentioned potential risks, such as increased lung cancer risk, hearing loss, and asthma were all mentioned in substantially less than 10% of press releases.

Table 12

Risks for Total Time Period and by Pre- vs. Post-WHI Period

	Total N=675	Pre-WHI n=265	Post-WHI n=410	Pre- vs. Post-Period Comparisons	
Risk	% (n)	% (f)	% (f)	χ^2 (df=1)	p
Breast Cancer	40.9 (276)	15.5 (41)	57.3 (235)	116.61	<.001
Heart Disease	27.1 (183)	4.5 (12)	41.7 (171)	112.59	<.001
Stroke	23.4 (158)	1.5 (4)	37.6 (154)	116.69	<.001
Uterine Cancer	21.3 (144)	23.4 (62)	20.0 (82)	1.11	.29
Blood Clots	21.2 (143)	5.7 (15)	31.2 (128)	62.98	<.001
Cognitive Decline	8.6 (58)	0.0 (0)	14.1 (58)	41.01	<.001
Gallbladder Disease	3.6 (24)	1.9 (5)	4.6 (19)	3.54	.06
Other	6.4 (43)	0.8 (2)	10 (41)	35.37	<.001

To determine whether mentioned risks varied by the pre- and post-WHI period eight chi-square tests of independence were conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. These analyses tested whether each potential risk was more or less likely to appear in press releases before or after the WHI announcement. As can be seen in Table 12, six of the tests returned significant results: breast cancer, heart disease, stroke, blood clots, cognitive decline, and other.

When analyzed by time period, it is clear that during the pre-WHI period mentions of the potential risks of HT were quite low. Only the uterine cancer category rose above the 20% threshold, being mentioned in 23.4% of press releases in the pre-WHI period. While this category remained stable from the pre- to post-WHI period, mentions of other potential risks increased significantly and dramatically in response to the WHI findings. Breast cancer risk increased from 15.5% to 57.3%; heart disease increased from 4.5% to 41.7%; stroke increased from 1.5% to 37.6%; blood clots increased from 5.7% to 31.2%; cognitive decline increased from 0% to 14.1%, and the other category increased from less than 1% (0.8%) to 10%.

Differences by type of organization. To determine whether the identification of specific risks varied by the type of organization distributing the press release, chi-square tests of independence were conducted at an alpha level of .05. The assumption of independence was met, and analyses were only conducted for the top five risks for the entire time period rather than within the pre- and post-WHI period to avoid expected cell counts less than five. As can be seen in Table 13 all chi-square tests indicated highly significant associations between the organization type distributing the release and the

identification of each of the five risks. Follow-up z -tests for column proportions using the Bonferroni adjustment method were used to look at differences between specific column percentages. Only those differences that met this stringent test are described below.

Table 13

Risks by Type of Organization that Distributed Release (1995-2011)

	Pharma <i>n</i> =239	Acad/Med Instit. <i>n</i> =166	Non Profit <i>n</i> =96	Journal Publishers <i>n</i> =78	Misc. For- Profit <i>n</i> =51	U.S. Gov <i>n</i> =28		
Risk	% (<i>f</i>)	% (<i>f</i>)	% (<i>f</i>)	% (<i>f</i>)	% (<i>f</i>)	% (<i>f</i>)	χ^2 (df=5)	<i>p</i>
Breast Cancer	33.5 _a (80)	43.4 _a (72)	29.2 _a (28)	47.4 _{a,b} (37)	47.1 _{a,b} (24)	75.0 _b (21)	26.90	<.001
Heart Disease	29.3 _a (70)	25.3 _a (42)	15.6 _a (15)	16.7 _a (13)	27.5 _a (14)	71.4 _b (20)	39.87	<.001
Stroke	26.8 _a (64)	16.9 _a (28)	14.6 _a (14)	21.8 _a (17)	21.6 _a (11)	67.9 _b (19)	40.89	<.001
Uterine Cancer	41.0 _a (98)	12.0 _{b,c} (20)	9.4 _{b,c} (9)	6.4 _c (5)	3.9 _c (2)	28.6 _{a,b} (8)	91.46	<.001
Blood Clots	29.7 _a (71)	13.3 _b (22)	9.4 _b (9)	17.9 _{a,b} (14)	5.9 _b (3)	64.3 _c (18)	64.23	<.001

Note. Cells sharing the same subscript are not significantly different from one another using a z -test for column proportions with the Bonferroni adjustment method.

U.S. government agencies (75.0%) were more likely than pharmaceutical companies (33.5%), academic/medical institutions (43.4%), and nonprofit organizations (29.2%) to identify breast cancer as a potential risk. U.S. government agencies were more likely than any other organization type to mention heart disease (71.4%), stroke (67.9%) and blood clots (64.3%). Pharmaceutical companies (41.0%) were more likely than all other organization types, with the exception of U.S. government agencies (28.6%), to mention uterine cancer.

Benefit and risk presentation. In terms of presentation, quantification of benefits and risks was fairly infrequent. Of the 448 press releases that included information about at least one benefit, only 26.6% ($f=119$) quantified a benefit in any way. Most of the releases that quantified a benefit did so in relative terms only (19.4%, $f=87$); 0.9% ($f=4$) contained absolute and relative information; 0.7% ($f=3$) provided absolute information only; and 5.6% ($f=25$) provided some other type of quantitative information. Of the 410 press releases that included information about at least one risk, only 31.5% ($f=129$) quantified a risk in any way. Most of the releases that quantified a risk did so in relative terms only (19.5%, $f=80$); 5.6% ($f=23$) contained absolute and relative information; 2.7% ($f=11$) provided absolute information only; and 3.7% ($f=15$) provided some other type of quantitative information.

Differences by type of organization. To determine whether the appearance of quantitative information about a benefit in a press release varied by the type of organization that produced the release, a chi-square test of independence was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated a statistically significant association between organization type and whether releases that contained at least one benefit presented any quantitative information about a benefit, $\chi^2=22.25$, $df=5$, $p<.001$. As can be seen in Table 14, follow-up z -tests for column percentages using the Bonferroni adjustment method indicated that academic and/or medical institutions (36.4%) and nonprofit organizations (39.7%) were more likely to produce press releases that quantified a benefit than pharmaceutical companies (16.7%).

<i>Table 14</i>		
<i>Benefits Quantified by Type of Organization that Distributed Release (1995-2011)</i>		
	Contained Quantitative Info.	
# of Press Releases that Included at Least One Benefit	<i>n</i>	%
Pharmaceutical Companies (<i>n</i> =186)	31	16.7 _a
Academic & Medical Institutions (<i>n</i> =121)	44	36.4 _b
Nonprofit Organizations (<i>n</i> =58)	23	39.7 _b
Medical/Scientific Journal Publishers (<i>n</i> =32)	10	31.2 _{a,b}
Miscellaneous For-Profit Organizations (<i>n</i> =20)	3	15.0 _{a,b}
U.S. Government (<i>n</i> =21)	5	23.8 _{a,b}
<i>Note.</i> Cells sharing the same subscript are not significantly different from one another using a z-test for column proportions with the Bonferroni adjustment method.		

To determine whether the appearance of quantitative information about a risk in a press release varied by the type of organization that produced the release, a chi-square test of independence was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated that there was a statistically significant association between organization type and whether releases that contained at least one risk presented any quantitative information about a risk, $\chi^2=81.04$, $df=5$, $p<.001$. As can be seen in Table 15, follow-up z-tests for column percentages using the Bonferroni adjustment method indicated that pharmaceutical companies (3.1%) were less likely than any other type of organization to contain a risk that was quantified in any way.

<i>Table 15</i>		
<i>Risks Quantified by Type of Organization that Distributed Release (1995-2011)</i>		
	Contained Quantitative Info.	
# of Press Releases that Included at Least One Risk	<i>f</i>	%
Pharmaceutical Companies (<i>n</i> =128)	4	3.1 _a
Academic & Medical Institutions (<i>n</i> =106)	45	42.5 _b
Nonprofit Organizations (<i>n</i> =49)	16	32.7 _b
Medical/Scientific Journal Publishers (<i>n</i> =62)	37	59.7 _b
Miscellaneous For-Profit Organizations (<i>n</i> =27)	8	29.6 _b
U.S. Government (<i>n</i> =22)	11	50.0 _b

NOTE: Cells sharing the same subscript are not significantly different from one another using a z-test for column proportions with the Bonferroni adjustment method.

RQ2c: How often were specific brand-name HT products mentioned in press releases? How did brand-name mentions vary by the types of organizations that produced press releases?

Brand name drugs were mentioned in 39.7% (*n*=268) of all press releases. In total, thirty-eight different brand names appeared across the press releases. Most of these brands were sporadically mentioned with concentrations of mentions based on relatively few brands. Table 16 presents a rank-ordered list of the most frequently occurring ten brands. To determine if the observed pattern of results in Table 16 differed from the pattern expected under the null hypothesis, a chi-square goodness-of-fit test was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated that brand name mentions differed significantly from one another, $\chi^2=356.04$, $df=9$, $p<.001$. Analysis of the standardized residuals indicated that *Premarin* and *Prempro* clearly stuck out from the pack, as evidenced by large, positive standardized residuals well in excess of two, compared to other brands with negative residuals. *Prempro* and *Premarin* were both

mentioned in more than 10% of all press releases; all other brands were mentioned in less than 5% of releases.

Table 16

Top-10 Mentioned Brand Names (1995-2011)

	Frequencies (stand. resid.)	% of Total Press Releases (N=675)
Brand	<i>n</i>	%
Premarin	117 (14.98)	17.3
Prempro	75 (7.57)	11.1
Cenestin	29 (-0.55)	4.3
Estrasorb	24 (-1.43)	3.6
Estratest	17 (-2.67)	2.5
Prometrium	15 (-3.02)	2.2
Climara/Pro	12 (-3.55)	1.8
Premphase	12 (-3.55)	1.8
Provera	10 (-3.90)	1.5
Enjuvia	10 (-3.90)	1.5

Differences by type of organization. To determine if whether a brand-name HT product was mentioned varied by the type of organization that produced the release, a chi-square test of independence was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated a significant association between type of organization and brand-name mentions, $\chi^2=356.04$, $df=9$, $p<.001$. As can be seen in Table 17, post hoc *z*-tests for

column proportions using the Bonferroni adjustment method indicated that pharmaceutical companies were more likely to mention a brand name in their press releases than any other organization type. Almost all 84.9% of pharmaceutical company releases mentioned a brand name. All other organizations were about equally likely to mention brand names. Medical journal publishers (2.6%), however, were less likely than miscellaneous for-profit organizations (31.4%) and government agencies (28.6%) to mention brand names in their releases.

Table 17

<i>Brand Name Mentions by Type of Organization that Distributed Release (1995-2011)</i>		
	Brand Name Mentioned	
Type of Organization	<i>n</i>	%
Pharmaceutical Companies (<i>n</i> =239)	203	84.9 _a
Academic & Medical Institutions (<i>n</i> =166)	25	15.1 _{bc}
Nonprofit Organizations (<i>n</i> =96)	13	13.5 _{bc}
Medical/Scientific Journal Publishers (<i>n</i> =78)	2	2.6 _c
Misc. For-Profit Organizations (<i>n</i> =51)	16	31.4 _b
U.S. Government (<i>n</i> =28)	8	28.6 _b

Note . Cells sharing the same subscript are not significantly different from one another using a z-test for column proportions with the Bonferroni adjustment method.

RQ2d: How often were pharmaceutical industry-related financial conflicts of interest mentioned in press releases? How did identification of conflicts of interest vary by the types of organizations that produced press releases?

This study measured three potential types of financial conflicts of interest (COI) between organizations and the pharmaceutical industry: research study-level conflicts, organizational-level conflicts, and individual-level conflicts. Disclosure of financial conflicts in press releases was rare. Only 12.7% (*n*=86) of press releases mentioned any type of COI during the study time period. In terms of type of COI, research funding conflicts were the most often identified. Approximately 10% (11.3%, *n*=76) of press

releases disclosed a financial conflict related to a research study. Only 1.5% ($n=10$) mentioned organizational-level conflicts, and less than 1% (0.7%, $n=5$) mentioned individual-level conflicts.

Differences by organization type. To determine if whether a financial conflict of interested was identified varied by the type of organization that produced the release, a chi-square test of independence was conducted at an alpha level of .05. The assumption of independence was met, and the assumption of expected frequencies of at least five cases per cell was violated for only one category, the U.S. government category. Results indicated a significant association between type of organization and identification of a financial COIs, $\chi^2=38.07$, $df=5$, $p<.001$. As can be seen in Table 18, post hoc z -tests for column proportions using the Bonferroni adjustment method indicated that U.S. government agencies (32.1%) and academic/medical institutions (23.5%) were more likely than other organization types to disclose a COI. This claim should be interpreted with a bit of caution, however, as the expected cell count in the government category was less than five.

<i>COI Disclosures by Type of Organization that Distributed Release (1995-2011)</i>		
	Included Any COI Disclosures	
	<i>n</i>	%
Pharmaceutical Companies ($n=239$)	22	9.2 _a
Academic & Medical Institutions ($n=166$)	39	23.5 _b
Nonprofit Organizations ($n=96$)	11	11.5 _{ab}
Medical/Scientific Journal Publishers ($n=78$)	4	5.1 _a
Misc. For-Profit Organizations ($n=51$)	1	2.0 _a
U.S. Government ($n=28$)	9*	32.1 _b
<i>Note.</i> Cells sharing the same subscript are not significantly different from one another using a z -test for column proportions with the Bonferroni adjustment method.		
*This cell had an expected frequency of less than five.		

Content of news stories. This section presents the results from the series of questions related to research question three: What was the content of news stories about HT in *AP Newswire* and four, top-circulating U.S. newspapers from 1995 – 2011? As reported earlier, there were a total of 429 news stories from January 1, 1995 to December 31, 2011, which include 176 news stories from *AP Newswire*; 85 from *The New York Times*, 78 from the *Los Angeles Times*, 46 from *The Washington Post*, and 44 from *The Wall Street Journal*. All analyses to follow in this results section are based on these 429 news stories.

RQ3a: What types of organizations were mentioned in news stories most often?

What types of individuals were quoted most often?

Organizations mentioned in text. Multiple organizations were mentioned in the text of each news story. The average number of organizations mentioned per news story was between three and four ($M=3.55$, $SD=2.03$). News stories also included multiple types of organizations. The average number of organization types mentioned was approximately two ($M=2.14$, $SD=1.10$).

As can be seen in Table 19, almost two-thirds of all news stories mentioned an academic/medical institution (65.3%) and half mentioned a U.S. government agency (50.8%). Pharmaceutical companies (43.8%) and nonprofit organizations (35.7%) were mentioned by less than half of all releases. Miscellaneous for-profit organizations (7.5%) and organizations classified into the other category (10.7%) were more rarely mentioned.

<i>Table 19</i>		
<i>Types of Organizations Mentioned in News Stories</i>		
	News Stories (N=429)	
Type of Organization	<i>n</i>	%
Academic & Medical Institutions	280 (10.29)	65.3
U.S. Government	218 (5.27)	50.8
Pharmaceutical Companies	188 (2.84)	43.8
Nonprofit Organizations	153 (0.01)	35.7
Health Advocacy Organizations (501c3) ^a	143	33.3
Professional/Trade Associations (501c6) ^a	16	3.7
Coalitions ^a	1	0.2
Miscellaneous For-Profit Organizations	32 (-9.77)	7.5
Other	46 (-8.64)	10.7
<p>Note. Percentages do not total 100% because the body text of each press release could contain multiple organization types.</p> <p>^a These 3 categories are sub-categories of the larger nonprofit organization category above. Only the total nonprofit category was used for the chi-square goodness-of-fit test.</p>		

To determine if the observed pattern of results in Table 19 differed from the pattern expected under the null hypothesis, a chi-square goodness-of-fit test was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated that the observed pattern of results across the six major categories differed significantly from what would be expected by chance, $\chi^2=311.90$, $df=5$, $p<.001$.

Follow-up tests were conducted by examining the standardized residuals to see which categories contributed significantly to the chi-square statistic, as evidenced by standardized residuals with an absolute value greater than two. Academic/medical

institutions, U.S. government agencies, and pharmaceutical companies were mentioned in news stories more than expected by chance based on their large, positive standardized residuals. Miscellaneous for-profit organizations and those classified into the other category were mentioned less than expected by chance based on their large, negative standardized residuals.

Medical/scientific journal publishers were not included in the coding for what types of organizations were mentioned in news stories. This decision was made because preliminary coding had clearly demonstrated that publishers rarely appeared in the body text; instead the name of the actual journal appeared in the text. Slightly more than half (51.7%, $n=222$) of all news stories cited a medical or scientific journal or publication.

Types of individuals quoted. Table 20 shows that physicians and/or scientists and official spokespersons, such as CEOs, research and marketing directors, and public affairs personnel were by far the most frequently quoted individuals in news stories. Almost two thirds (62.9%) of all direct quotes across the news stories for the entire time period came from physicians/scientists, and a third (32.9%) came from official spokespersons of organizations. All other types of individuals were rarely quoted.

<i>Table 20</i>		
<i>Types of Individuals Quoted In News Stories</i>		
News Stories (N=429)		
Type of Individual	<i>n</i> (<i>st. resid.</i>)	%
Physician/Scientist	270 (26.33)	62.9
CEO/Spokesperson	141 (9.98)	32.9
Everyday Woman	32 (-3.83)	7.5
Attorney	30 (-4.09)	7.0
Nurses/Other Clinicians	3 (-7.51)	0.7
Celebrity	2 (-7.64)	0.5
Everyday Family Member	1 (-7.76)	0.2
Other	13 (-6.24)	3.0

Note . Percentages do not total 100% because the body text of each press release could contain quotes from multiple types of individuals.

To determine if the observed pattern of results in Table 20 differed from the pattern expected under the null hypothesis, a chi-square goodness-of-fit test was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated that the pattern of differences across the eight categories was statistically significant, $\chi^2=1050.89$, $df=7$, $p<.001$. Follow-up tests were conducted by examining the standardized residuals to see which categories contributed significantly to the chi-square statistic as evidenced by standardized residuals greater than an absolute value of two. The large, positive standardized residuals for the physician and/or scientist and official spokesperson categories indicated that news stories quoted these types of individuals more than any

other types of individuals, which all had large, negative standardized residuals (see Table 20).

RQ3b: What benefits and risks were associated with HT? How were benefits and risks presented (qualitative vs. quantitative; relative vs. absolute terms).

Amount of information about benefits and risks. News stories frequently reported on both the potential benefits and risks of HT. Across the study time period, 80.7% ($n=346$) of news stories included at least one potential benefit, and 86.5% of news stories ($n=371$) included at least one potential risk. More than two-thirds of news stories (68.5%, $n=294$) contained a benefit and a risk together in the same release; 12.1% ($n=52$) of news stories mentioned a benefit with no risk, 17.9% ($n=77$) reported a risk with no benefit, and only 1.3% ($n=6$) of news stories provided no information about benefits or risks.

The average number of benefits per news story was 2.25 ($SD=1.85$). To determine if the mean number of benefits differed prior to and after the initial WHI announcement, a two-tailed, t -test for independent samples assuming equal variances was conducted at an alpha level of .05. The equal variances formula was used because Levine's test for equality of variances returned an insignificant result ($F=.776, p=.38$). News stories were significantly more likely to contain more benefits per story in the pre-WHI period ($M=2.80; SD=1.65$) than the post-WHI period ($M=1.78; SD=1.88$), $t(427)=5.93, p<.001$.

The average number of risks per news story was 2.25 ($SD=1.68$). When compared by time period, the reverse pattern occurred. News stories contained significantly less risks per story in the pre-WHI period ($M=1.47, SD=1.27$) than in the post-WHI period ($M=2.93, SD=1.69$) according to a two-tailed, t -test for independent samples assuming unequal variances conducted at an alpha level of .05, $t(417)=10.23, p<.001$. The unequal

variance formula was used after Levine's test for equality of variances returned a significant result ($F=28.64, p<.001$). Figure 7 visualizes the trends for mean number of benefits and risks per news story across the two time periods.

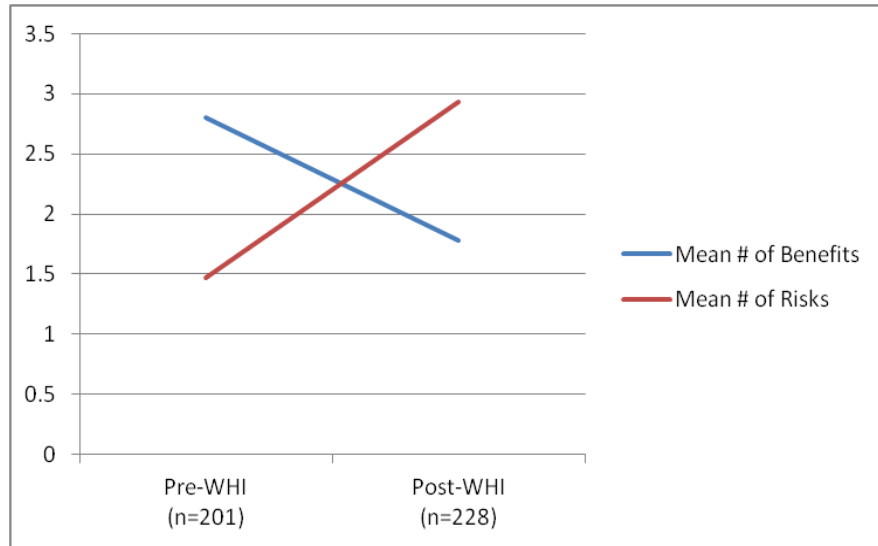


Figure 7: Mean benefits and risks by pre- vs. post-WHI period.

Specific benefits. Table 21 reports the most frequently identified potential benefits of HT in news stories by total time period and by the pre- and post-WHI time periods. The total column shows that two of the three FDA-approved indications ranked in the first and second spots: osteoporosis prevention and reduction of hot flashes. More than half of news stories identified osteoporosis prevention (54.3%) and hot flash reduction (51.3%) as potential benefits of HT. More than two-thirds of news stories identified heart disease prevention (38.9%), a non-FDA approved indication. The FDA-approved indication of treatment for vaginal atrophy-related problems received about the same amount of mentions as less established benefits that attracted substantial attention in the research world, such as prevention of cognitive decline (15.6%) and colon cancer (12.4%), and a variety of miscellaneous potential benefits classified in the other

disease/illness-reduction benefits (13.3%) and other overall health/well-being benefits (12.8%) categories.

Table 21

Benefits for Total Time Period and by Pre- vs. Post-WHI Periods

	Total N=429	Pre-WHI n =201	Post-WHI n =228	Pre- vs. Post-Period Comparisons	
Benefit	% (n)	% (f)	% (f)	χ^2 (df=1)	p
Osteoporosis Prevention	54.3 (233)	77.6 (156)	33.8 (77)	82.74	<.001
Hot Flashes Reduced	51.3 (220)	44.8 (90)	57.0 (130)	6.41	.01
Heart Disease Prevention	38.9 (167)	66.2 (133)	14.9 (34)	118.05	<.001
Vaginal Atrophy Treatment	15.9 (68)	13.4 (27)	18.0 (41)	1.66	.20
Cognitive Decline Prevention	15.6 (67)	25.9 (52)	6.6 (15)	30.17	<.001
Colon Cancer Prevention	12.4 (53)	11.4 (23)	13.2 (30)	0.29	.59
Other Disease/ Illness-Reduction Benefits	13.3 (57)	17.4 (35)	9.6 (22)	5.59	.02
Other Overall Health/ Well-Being Benefits	12.8 (55)	12.4 (25)	13.2 (30)	0.05	.82

To determine whether mentioned benefits varied by the pre- and post-WHI period eight chi-square tests of independence were conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. These analyses tested whether each potential benefit was more or less likely to appear in news stories before or after the WHI announcement. As can be seen in Table 21, five of these tests returned statistically significant results: osteoporosis prevention, hot flashes, heart disease prevention, prevention of cognitive decline, and other disease/illness-reduction benefits.

Four of the five significant tests demonstrated a downward trend from the pre- to post-WHI period. All these benefits were disease-prevention oriented in nature. Heart disease prevention mentions decreased dramatically; 66.2% of news stories identified heart disease prevention as a possible benefit in the pre-WHI period compared to only 14.9% in the post-WHI period. Osteoporosis prevention followed a similar pattern, dropping from being identified in 77.6% of news stories to 33.8%. Cognitive decline and other less, well-supported disease and illness reduction claims also went down. The only category that increased was the FDA-approved indication for hot flashes. Less than half of news stories (44.8%) identified hot flash reduction as a benefit of HT in the pre-WHI period compared to well over half (57.0%) in the post-WHI period.

Specific risks. Table 22 reports the most frequently identified potential risks of HT in news stories by total time period and by the pre- and post-WHI time periods. For risks for total time period, breast cancer was the most frequently identified risk, with almost three-quarters (72.5%) all news stories mentioning a potential breast cancer risk associated with HT. Heart disease (41.5%) followed. Stroke (34.5%), uterine cancer (30.5%), and blood clots (25.4%) were all mentioned by more than a quarter of news stories. Cognitive decline, gallbladder disease, and the other category, which included more sporadically mentioned potential risks, such as increased lung cancer, hearing loss, and asthma, were all substantially below the 10% threshold.

Table 22

Risks for Total Time Period and by Pre- vs. Post-WHI Period

Risk	Total <i>N</i> =429	Pre-WHI <i>n</i> =201	Post-WHI <i>n</i> =228	Pre- vs. Post-Period Comparisons	
	% (<i>n</i>)	% (<i>f</i>)	% (<i>f</i>)	χ^2 (<i>df</i> =1)	<i>p</i>
Breast Cancer	72.5 (311)	58.7 (118)	84.6 (193)	36.06	<.001
Heart Disease	41.5 (178)	13.9 (28)	65.8 (150)	118.34	<.001
Stroke	34.5 (148)	8.0 (16)	57.9 (132)	117.88	<.001
Uterine Cancer	30.5 (131)	37.3 (75)	24.6 (56)	8.19	<.01
Blood Clots	25.4 (109)	17.9 (36)	32.0 (73)	11.22	<.01
Cognitive Decline	8.4 (36)	1.0 (2)	14.9 (34)	26.92	<.001
Gallbladder Disease	3.3 (14)	5.5 (11)	1.3 (3)	5.85	.02
Other	8.7 (37)	4.5 (9)	12.3 (28)	8.25	<.001

To determine whether mentioned risks varied by the pre- and post-WHI period eight chi-square tests of independence were conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. These analyses tested whether each potential risk was more or less likely to appear in news stories before or after the WHI announcement. As can be seen in Table 22, all eight of the tests returned statistically significant results.

News stories identified each risk more in the post-WHI period with the exceptions of uterine cancer risk and gallbladder disease, which both decreased slightly. Perhaps most notable in the pre-WHI period was the high frequency of reporting on the potential for increased breast cancer risk. More than half of news stories (58.7%) identified this

potential risk in the pre-WHI period, a percentage that increased to 84.6% in the post-WHI period. The most dramatic increases in risk were for heart disease and stroke; mentions of a potential heart disease risk increased from 13.9% in the pre-WHI period to 65.8% in the post-WHI period, and mentions of stroke increased from 8.0% to 57.9%.

Benefit and risk presentation. In terms of benefit presentation, less than one-third of news stories (30.3%, $f=105$) that identified at least one benefit of HT ($n=346$) contained any quantitative information about a benefit. When benefits were quantified they were most often presented in relative terms. Almost a quarter of news stories that quantified a benefit contained relative information only (22.0%, $f=76$); 2.6% ($f=9$) contained absolute and relative information; 2.6% ($f=9$) provided absolute information only; and 3.2% ($f=11$) provided some other type of quantitative information. Of the 371 news articles that included information about at least one risk, 37.7% ($f=140$) quantified a risk in some way. About one-fifth (19.7%, $f=73$) contained relative information only; 10.0% ($n=37$) contained absolute and relative information; 5.9% ($f=22$) provided absolute information only, and 2.2% ($f=8$) provided some other type of quantitative information.

RQ3c: How often were specific brand-name HT products mentioned in news stories?

Brand-name drugs were mentioned in almost half 46.6% ($n=200$) of all news stories. In total, thirty-four different brand names appeared across the news stories, however, only a few brands were mentioned with any frequency. Table 23 below presents a rank-ordered list for the ten most frequently mentioned brands. A chi-square goodness-of-fit test was conducted at an alpha level of .05 to determine if the pattern of frequencies for the individual brands that ranked in the top ten spots differed from what would be

expected under the null hypothesis. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated that the pattern of differences was statistically significant, $\chi^2=765.66$, $df=9$, $p<.001$. Analysis of the residuals indicated that *Premarin* and *Prempro* were clearly mentioned more often than any other brands, as evidenced by large, positive standardized residuals greater than an absolute value of two. All other categories had large, negative residuals (See Table 23).

Table 23

Top-10 Mentioned Brand Names (1995-2011)

Brand	Frequencies (st. residuals)	% of Total News Stories ($N=429$)
Premarin	128 (17.65)	29.8
Prempro	126 (17.29)	29.4
Estratab	11 (-3.53)	2.6
Provera	11 (-3.53)	2.6
Vivelle/Vivelle-dot	8 (-4.07)	1.9
Estrace	5 (-4.62)	1.2
Cenestin	4 (-4.80)	0.9
Elestrin	4 (-4.80)	0.9
Estratest	4 (-4.80)	0.9
Prometrium	4 (-4.80)	0.9

RQ3d: How often were pharmaceutical industry-related financial conflicts of interest mentioned in news stories?

Disclosure of potential pharmaceutical industry-related financial conflicts of interest (COI) was fairly uncommon. Only 9.6% ($n=41$) of news stories mentioned any type of COI, which included research study-level financial conflicts, organizational-level conflicts, and individual-level conflicts. In terms of the specific types of COI, research funding conflicts were the most often mentioned. Still, only 5.4% ($n=23$) of news stories disclosed a conflict related to a research study. Only 0.5% ($n=3$) mentioned organizational-level conflicts, and 4.0% ($n=17$) mentioned individual-level conflicts.

Content comparisons between press releases and news stories. This section presents the results from the series of questions related to research question four: How did the press releases and news stories compare in terms of content from 1995-2011?

RQ4a: How did press releases and news stories compare in terms of the types of organizations mentioned and types of individuals quoted?

Organizations mentioned. The organizations found in the body text of press releases mirrored the organizations mentioned in news stories closely. Press releases and news stories mentioned similar types of organizations with the same approximate frequency. As can be seen in Table 24, the organizations mentioned in both sequences ranked in the same exact order from highest to lowest. Five separate chi-square tests of independence were conducted at an alpha level of .05 to determine if each organization type was more or less likely to appear in press releases or news stories. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. As can be seen in Table 24, academic/medical institutions were slightly more likely

to appear in news stories than press releases (65.3% vs. 59.3%). No other differences were statistically significant.

Table 24

Organization Types in Body Text: PR Releases vs. News Stories (1995-2011)

Organization Type	Press Releases	News Stories	Press Releases vs. News Comparisons	
	<i>N</i> =675	<i>N</i> =429	χ^2 (<i>df</i> =1)	<i>p</i>
	% (<i>n</i>)	% (<i>n</i>)		
Academic & Medical Research Institutions	59.3 (400)	65.3 (280)	4.00	.04
U.S. Government	53.6 (362)	50.8 (218)	0.83	.36
Pharmaceutical Companies	47.1 (318)	43.8 (188)	1.14	.29
Nonprofit Organizations	31.7 (214)	35.7 (153)	1.85	.17
Miscellaneous For-profit Organizations	11.3 (76)	7.5 (32)	3.63	.06

Medical and scientific journals were also cited at roughly the same rate. Just about half of all press releases (50.4%, *n*=340) and news stories (51.7%, *n*=222) cited a medical or scientific journal article. A chi-square test of independence conducted at alpha .05 determined that these percentages did not differ beyond what would be expected by chance, $\chi^2=0.20$, *df*=1, *p*=.66.

Individuals quoted in text. To determine if press releases and news stories differed in terms of the types of individuals they quoted, five chi-square tests of independence were conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests (the everyday family members and celebrity categories were eliminated from this analysis because they were rarely mentioned and resulted in cell size instability problems). As can be seen in Table 25, some differences were found between press releases and news stories in terms of the

types of individuals quoted. While medical experts, such as physicians and nurses or other clinicians were quoted with the same frequency, other types of individuals were quoted differentially. Press releases were more likely to contain quotes from CEOs and other official organizational spokespersons than news stories (39.7% vs. 32.9%). Conversely, news stories were more likely to contain quotes from attorneys than press releases (7.0% vs. 1.2%). News stories were also more likely to quote everyday women about their experiences with menopause or HT than press releases (7.5% vs. 0.6%).

Table 25

Types of Individuals Quoted in Press Releases vs. News Stories (1995-2011)

Type of Individual Quoted	Press Releases	News Stories	Press Releases vs. News Comparisons	
	<i>N</i> =675	<i>N</i> =429	χ^2 (<i>df</i> =1)	<i>p</i>
	% (<i>n</i>)	% (<i>n</i>)		
Physician/Scientist	62.4 (421)	62.9 (270)	0.04	.85
CEO/Spokesperson	39.7 (268)	32.9 (141)	5.26	.02
Nurses/Other Clinicians	1.5 (10)	0.7 (3)	1.38	.24
Attorney	1.2 (8)	7.0 (30)	26.62	<.01
Everyday Woman	0.6 (4)	7.5 (32)	39.21	<.01

RQ4b: How did press releases and news stories compare in terms of benefits and risks associated with HT and risk and benefit presentation (qualitative vs. quantitative; relative vs. absolute terms)?

Amount of information about benefits and risks. To test whether the amount of benefits and risks differed for press releases and news stories across the total study time period, *t*-tests for independent samples were conducted at an alpha level of .05 to

compare the mean number of benefits per press release and news story and the mean number of risks per press release and news story. For benefits, a two-tailed, *t*-test for unequal variance was used because Levene’s test for homogeneity of variance was rejected ($F=50.64, p<.001$). For risks, a two-tailed *t*-test for equal variances was used because Levene’s test for homogeneity of variance was not rejected ($F=2.015, p=.16$). As can be seen in Table 26, news stories contained more benefits per story and risks per story than press releases.

Table 26

<i>Benefits & Risks: Press Releases vs. News Stories (1995-2011)</i>							
	Total PR Releases (<i>N</i> =675)		Total News Stories (<i>N</i> =429)		<i>t</i>	<i>df</i>	<i>p</i>
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>			
Benefits	1.27	1.37	2.25	1.85	9.49	723	<.001
Risks	1.52	1.89	2.25	1.68	6.47	1102	<.001

Note. The *df* for benefits is adjusted via the unequal variances formula.

Differences by pre- and post-WHI period. Because significant differences were found for press releases and news stories in terms of the reporting of specific benefits and risks by the pre- and post-WHI time periods in previous analyses, the mean number of benefits and risks was also compared within each time period. Again *t*-tests for independent samples were conducted to test for significant differences at an alpha level of .05. Levene’s test for homogeneity of variance was rejected for benefits in the pre-WHI period ($F=15.52, p<.001$), risks in the pre-WHI period ($F=34.01, p<.001$), benefits in the post-WHI period ($F=16.16, p<.001$), and risks in the post-WHI period ($F=19.46, p<.001$). For this reason a two-tailed, independent *t*-test assuming unequal variances was used for all comparisons. As can be seen in Table 27, when broken out by time period, news

stories still contained more benefits and more risks per story than what was contained in press releases.

Table 27

Benefits & Risks: Press Releases vs. News Stories in Pre- and Post-WHI Periods

	Pre-WHI					Post-WHI				
	Press Releases (n=265)	News (n=201)				Press Releases (n=410)	News (n=228)			
	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>t</i>	<i>df</i>	<i>p</i>	<i>M</i> (<i>SD</i>)	<i>M</i> (<i>SD</i>)	<i>t</i>	<i>df</i>	<i>p</i>
Benefits	1.45 (1.31)	2.80 (1.65)	-9.52	371	<.001	1.16 (1.40)	1.78 (1.88)	-4.35	369	<.001
Risks	0.53 (.80)	1.47 (1.27)	-9.16	318	<.001	2.17 (2.10)	2.93 (1.69)	-5.03	556	<.001

Note . For all t-tests the unequal variance formula was used (adjusted dfs) because Levene's test was rejected.

Specific benefits. To determine whether press releases and news stories were more or less likely to report on specific, potential benefits, six chi-square tests of independence at an alpha level of .05 were conducted to compare the percentages for each benefit across the two datasets. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. Table 28 shows that news stories were significantly more likely than press releases to report on all potential benefits with the exception of vaginal atrophy; news stories and press release were equally likely to identify treatment of vaginal atrophy-related symptoms as a benefit of HT. In the case of heart disease prevention, colon cancer prevention, and prevention of cognitive decline, the percent of news stories that identified each benefit was approximately double the percent of press releases.

Table 28

Benefits: Press Releases vs. News Stories (1995-2011)

	Press Releases <i>N</i> =675	News Stories <i>N</i> =429	Press Releases vs. News Comparisons	
Benefit	% (<i>n</i>)	% (<i>n</i>)	χ^2 (<i>df</i> =1)	<i>p</i>
Hot Flashes Reduced	34.8% (235)	51.3% (220)	29.36	<.001
Osteoporosis Prevention	28% (189)	54.3% (233)	76.91	<.001
Heart Disease Prevention	18.8% (127)	38.9% (167)	54.31	<.001
Vaginal Atrophy Treatment	14.4% (97)	15.9% (68)	0.45	.50
Colon Cancer Prevention	5.9% (40)	12.4% (53)	14.05	<.001
Cognitive Decline Prevention	5.2% (35)	15.6% (67)	34.04	<.001

Differences by pre- and post-WHI period. To further analyze differences between the identification of specific benefits in press releases and news stories, comparisons were made within the pre and post-WHI periods. Again, chi-square tests for independence at an alpha level of .05 were conducted to compare the percentages for each potential benefit across press releases and news stories, but this time separately within each time period. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. Table 29 shows that in the pre-WHI period news stories were more likely to identify all benefits besides vaginal atrophy-related problems, conforming to the same pattern that was revealed for the total time period. A slightly different pattern emerged, however, in the post-WHI period for the case of heart disease prevention. News stories were no more likely than press releases to identify heart disease prevention as a potential benefit. News stories were more likely to identify every

other benefit with the exception of vaginal atrophy, but the differences were much less pronounced than in the pre-WHI period.

Table 29

Benefits: Press Releases vs. News Stories, Pre- vs. Post-WHI Period

Benefit	Pre-WHI				Post-WHI			
	Press releases (n=265)	News Stories (n=201)	Press Releases vs. News Comparisons		Press releases (n=410)	News Stories (n=228)	Press Releases vs. News Comparisons	
	% (f)	% (f)	χ^2 (df=1)	p	% (f)	% (f)	χ^2 (df=1)	p
Hot Flashes Reduced	34.3 (91)	44.8 (90)	5.24	.02	35.1 (144)	57.0 (130)	28.67	<.001
Osteoporosis Prevention	35.5 (94)	77.6 (156)	81.63	<.001	23.2 (95)	33.8 (77)	8.36	<.01
Heart Disease Prevention	31.3 (83)	66.2 (133)	55.82	<.001	10.7 (44)	14.9 (34)	2.39	.12
Vaginal Atrophy Treatment	10.9 (29)	13.4 (27)	0.67	.41	16.6 (68)	18.0 (41)	0.20	.65
Colon Cancer Prevention	2.6 (7)	11.4 (23)	14.70	<.001	8.0 (33)	13.2 (30)	4.30	.04
Cognitive Decline Prevention	8.7 (23)	25.9 (52)	25.02	<.001	2.9 (12)	6.6 (15)	4.82	.03

Specific risks. To determine if press releases and news stories were more or less likely to identify specific risks, six chi-square tests of independence were conducted at an alpha level of .05 between press releases and news stories to see if the percentages across press releases and news stories differed significantly for each risk. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests.

Table 30 shows that news stories were significantly more likely to identify breast cancer, heart disease, stroke, and uterine cancer risks. The difference in identification of breast cancer risk was the most striking; 40.9% of press releases identified breast cancer as a risk compared to 72.5% of news stories. Press releases and news stories were equally likely to identify blood clots, cognitive decline, and gallbladder disease as potential risks.

Table 30

Risks: Press Releases vs. News Stories (1995-2011)

	Press Releases	News Stories	Press Releases vs. News Comparisons	
	<i>N</i> =675	<i>N</i> =429		
Risk	%	%	χ^2 (<i>df</i> =1)	<i>p</i>
Breast Cancer	40.9 (276)	72.5 (311)	105.23	<.001
Heart Disease	27.1 (183)	41.5 (178)	24.65	<.001
Stroke	23.4 (158)	34.5 (148)	16.11	<.001
Uterine Cancer	21.3 (144)	30.5 (131)	11.88	<.01
Blood Clots	21.2 (143)	25.4 (109)	2.66	.10
Cognitive Decline	8.6 (58)	8.4 (36)	0.01	.91
Gallbladder Disease	3.6 (24)	3.3 (14)	0.07	.80

Differences by pre- and post-WHI period. To further analyze differences between the identification of specific risks across press releases and news stories, comparisons were made within the pre and post-WHI periods. Again, chi-square tests for independence at an alpha level of .05 were conducted to compare the percentages for each potential risk across press releases and news stories, but this time separately within each time period. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. The cognitive decline and gallbladder disease categories were eliminated from this analysis due to small cell counts.

As can be seen in Table 31, when broken down by time period, similar patterns emerged. News stories were more likely than press releases in both time periods to identify breast cancer, heart disease, and stroke as risks. The large difference for breast

cancer in the total time period table was also notable within both time periods, but more so in the pre-WHI period. News stories in the pre-WHI period were almost four times more likely than press releases to identify breast cancer as a potential risk (58.7% vs. 15.5%). While news stories were more likely to mention uterine cancer and blood clots in the pre-WHI period, this difference was not sustained in the post-WHI period.

Table 31

Risks: Press Releases vs. News Stories by Pre- vs. Post-WHI Period

	Pre-WHI				Post-WHI			
	Press releases (n=265)	News Stories (n=201)	Press Releases vs. News Comparisons		Press releases (n=410)	News Stories (n=228)	Press Releases vs. News Comparisons	
	% (f)	% (f)	χ^2 (df=1)	p	% (f)	% (f)	χ^2 (df=1)	p
Benefit								
Breast Cancer	15.5 (41)	58.7 (118)	95.05	<.001	57.3 (235)	84.6 (193)	49.57	<.001
Heart Disease	4.5 (12)	13.9 (28)	12.88	<.001	41.7 (171)	65.8 (150)	33.99	<.001
Stroke	1.5 (4)	8.0 (16)	11.58	<.01	37.6 (154)	57.9 (132)	24.49	<.001
Uterine Cancer	23.4 (62)	37.3 (75)	10.67	<.01	20.0 (82)	24.6 (56)	1.80	.18
Blood Clots	5.7 (15)	17.9 (36)	17.60	<.001	31.2 (128)	32.0 (73)	0.04	.84

Benefit and risk presentation. To determine if press releases or news stories were more or less likely to quantify benefits and to present them in relative or absolute terms, three chi-square tests of independence were conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. Press releases and news stories did not differ in their propensity to quantify benefits; 26.6% (f=119) of press releases that included at least one benefit (n=448), quantified a benefit in some way compared to 31.5% (f=105) of news stories that included at least one benefit (n=346), $\chi^2=1.38$, $df=1$, $p=.24$. In terms of type of

quantitative presentation, Table 32 shows that press releases and news stories were equally likely to present information in relative terms. Although the small cell sizes warrant some caution, it appears that news stories were significantly more likely than press releases to quantify a benefit in absolute terms (5.2% compared to 1.6%).

Table 32

<i>Relative & Absolute Benefit Info: Press Releases vs. News Stories (1995-2011)</i>				
Type of Quantitative Information	Press Releases that Identified at Least One Benefit (n=448)	News Stories that Identified at Least One Benefit (n=346)	χ^2 (df=1)	p
Any relative benefit information in press release or news story	20.8 (93)	24.6 (85)	1.63	0.20
Any absolute benefit information in press release or news story	1.6 (7)	5.2 (18)	8.48	<.01
<i>Note.</i> Each document could include both types of information, one type of information only, or neither.				

To determine if press releases or news stories were more or less likely to quantify risks and to present them in relative or absolute terms, three chi-square tests of independence were conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met for all tests. Press releases and news stories did not differ in terms of the frequency of providing quantitative information. About one-third (31.5%, $f=129$) of press releases that identified a risk ($n=410$) quantified it in some way as did 37.7% ($f=140$) of news stories that identified a risk ($n=371$), a difference that was no greater than what would be expected by chance, $\chi^2=3.39$, $df=1$, $p=.07$. Table 33 shows that press releases and news stories also tended to provide quantitative information in relative terms at about the same frequency. News stories, however, were more likely than press releases to provide risk information

in absolute terms; 15.9% of news stories that contained risk information provided an absolute presentation format compared to only 8.3% of press releases.

Table 33

<i>Relative & Absolute Risk Info.: Press Releases vs. News Stories (1995-2011)</i>				
Type of Quantitative Information	Press Releases that Identified at Least One Risk (n=410)	News Stories that Quantified at Least One Risk (n=371)	χ^2 (df=1)	p
Any relative risk information in press release or news story	25.1 (103)	29.6 (110)	2.01	0.16
Any absolute risk information in press release or news story	8.3 (34)	15.9 (59)	10.75	<.01
<i>Note.</i> Each document could include both types of information, one type of information only, or neither.				

RQ4c: How did press releases and news stories compare in terms of mentioning specific brand-name HT products?

To determine if press releases and news stories differed in terms of their likelihood of mentioning brand-name HT products, a chi-square test of independence was conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Results indicated that news stories were more likely than press releases to use brand names. Almost half (46.6%, n=200) of news stories mentioned at least one brand-name HT product compared to 39.7% (n=268) of press releases, $\chi^2=5.14$, $df=1$, $p=.02$. Table 34 lists the top-ten mentioned brands in press releases and news stories side-by-side in rank order from the most to least frequently mentioned. The pattern of brand names across the two datasets was similar. Six of the brands in the top-ten for press releases were also in the top-ten for news stories. *Premarin* and *Prempro* were by far the most mentioned brands in both press releases and news stories.

Table 34

Top-Ten Brand Names: Press Release vs. News Stories (1995-2011)

Press Releases (N=675)		News Stories (N=429)	
Brand	% (n)	Brand	% (n)
Premarin	17.3 (117)	Premarin	29.8 (128)
Prempro	11.1 (75)	Prempro	29.4 (126)
Cenestin	4.3 (29)	Estratab	2.6 (11)
Estrasorb	3.6 (24)	Provera	2.6 (11)
Estratest	2.5 (17)	Vivelle/Vivelle-dot	1.9 (8)
Prometrium	2.2 (15)	Estrace	1.2 (5)
Climara/Pro	1.8 (12)	Cenestin	0.9 (4)
Premphase	1.8 (12)	Elestrin	0.9 (4)
Provera	1.5 (10)	Estratest	0.9 (4)
Enjuvia	1.5 (10)	Prometrium	0.9 (4)

RQ4d: How did press releases and news stories compare in terms of mentioning pharmaceutical industry-related financial conflicts of interest?

To determine if press releases or news stories were more or less likely to include information about financial conflicts of interest a chi-square test of independence conducted at an alpha level of .05. The assumptions of independence and expected frequencies of at least five cases per cell were met. Only 12.7% ($n=86$) of press releases and only 9.6% ($n=41$) of news stories mentioned any type of COI (individual, organizational, or research study) during the whole time period, a difference that was not statistically significant, $\chi^2=2.61$, $df=1$, $p=.11$. As discussed previously, research study-related conflict of interest disclosures accounted for the vast majority of COI information. Press releases 11.3% ($n=76$) were about twice as likely as news stories 5.4% ($n=23$) to mention pharmaceutical industry funding of research studies, $\chi^2=11.18$, $df=1$, $p<.001$.

Other forms of COI (organizational-level and individual-level) were too infrequent to statistically test.

RQ5: What specific organizations emerged as successful agenda builders as evidenced by frequent mentions of these organizations in both press releases and news stories?

To determine the successful agenda builders, I ran frequencies on the database fields that contained the verbatim text for organization names that appeared in press releases and news stories. Next, I rank-ordered the organizations from the most to least mentioned. This ranking was conducted separately for the series of press releases and news stories. To arrive at a cut-off point for each series, I calculated the mean number of times each organization was mentioned across each dataset. For press releases, there were a total of 522 different organizations mentioned; each organization was mentioned in an average of 3.98 press releases ($SD=14.39$). For news stories there were a total of 285 different organizations mentioned; each organization was mentioned in an average of 5.25 news stories ($SD=15.37$). Adding one standard deviation to the mean for press releases resulted in 18.37 ($3.98 + 14.39$); adding one standard deviation to the mean for news stories resulted in 20.62 ($5.25 + 15.37$). This information combined with my examination of the rank-ordered frequency distributions for each series prompted me to eliminate organizations for consideration that were mentioned in 19 or fewer press releases or news stories. By putting the initial threshold for inclusion at 20 or more press releases or news stories, I isolated the top 16% of organizations in the upper tail of the frequency distribution.

Next, I listed the organizations that made the cutoff point in both sequences side by side in Table 35, which lists the organizations for each series in rank order. I then defined the top agenda builders as the organizations that appeared in both the press release and news sequences. These organizations are highlighted in bold type in Table 35.

Table 35
Organizations Mentioned in At Least 20 Press Releases and News Stories: 1995 - 2011

Press Releases (N=675)		News Stories (N=429)	
	<i>n</i>		<i>n</i>
Food & Drug Administration (FDA)	208	Wyeth (or formerly Wyeth-Ayerst)	164
National Institutes of Health (NIH)*	184	National Institutes of Health (NIH)*	135
Wyeth (or formerly Wyeth-Ayerst)	148	Food & Drug Administration (FDA)	99
Duramed Pharmaceuticals	43	Harvard University (includes Brigham & Women's Hospital)	85
North American Menopause Society (NAMS)	41	North American Menopause Society (NAMS)	44
Wake Forest University (includes Wake Forest Baptist Medical Center)	31	Univ. of California, Los Angeles (UCLA) (includes UCLA's Harbor & Olive View Medical Centers)	41
Univ. of California, San Francisco (USCF)	29	American Heart Association (AHA)	33
Solvay Pharmaceuticals	27	University of California, San Francisco (USCF)	32
American College of Obstetricians & Gynecologists (ACOG)	25	Columbia University (also includes Columbia-Presbyterian Medical Center)	26
Univ. of California, Los Angeles (UCLA) (includes UCLA's Harbor & Olive View Medical Centers)	25	American College of Obstetricians & Gynecologists (ACOG)	25
American Heart Association (AHA)	24	Wake Forest University (includes Wake Forest Baptist Medical Center)	21
Novavax, Inc.	24		
Harvard University (includes Brigham & Women's Hospital)	23	*Includes global references to NIH and to specific institutes, NHLBI, NCI, and NIA	
Yale University (includes Yale Medical Center & New Haven Hospital)	22		
Stanford University (includes Stanford Medical Center)	20		
*Includes global references to NIH and to specific institutes, NHLBI, NCI, and NIA			

This left ten organizations that represented the different types of organizations of interest to this study. Wyeth Pharmaceuticals was included for the pharmaceutical industry. Four academic/medical institutions were included: Wake Forest University, University of California-San Francisco (UCSF), University of California-Los Angeles (UCLA) and Harvard University. Three organizations in the nonprofit, health advocacy

category were also represented: the North American Menopause Society (NAMS), the American College of Obstetricians & Gynecologists (ACOG), and the American Heart Association (AHA). Finally, two U.S. government agencies were also included: the Food & Drug Administration (FDA) and the National Institutes of Health (NIH). The qualitative content analyses in the following section focused on press releases and news stories that mentioned these ten organizations.

Qualitative Analyses of Successful Agenda-Building Organizations

This qualitative results section addresses research question six (RQ6). The first section (RQ6a) used supplementary document analysis to describe successful agenda-building organizations in terms of their mission and goals, memberships, financial support, and any potential financial conflicts of interest in relation to the pharmaceutical industry. This information was then used to see if any financial conflicts found were disclosed in press releases and reported in news stories. The second section (RQ6b) explored potential collaborations between successful agenda-building organizations by examining whether any joint efforts were evident in the source or contact fields of press releases, or if common co-occurrences and associations between organizations emerged in the body text of the press releases. News stories that mentioned these organizations were also analyzed for common or divergent themes in these areas. Section RQ6c examined how these organizations constructed and defined menopause, and how those constructions related to proposed treatment recommendations. News stories that mentioned these organizations were also analyzed for common or divergent themes in these areas.

Collaborations between organizations. This section addresses research question six (RQ6) which asked: How, if at all, did organizations that emerged as key agenda builders via the quantitative content analysis procedures (as determined by RQ5 above) collaborate with other organizations to build the news media agenda?

RQ6a: What are the profiles of the most successful agenda-building organizations in terms of organization type, mission and goals, memberships, and financial support? Were any potential pharmaceutical industry-related financial conflicts of interest evident through archival analysis of these organizations' websites or materials, such as annual reports, or financial disclosures available on scientific articles or elsewhere? Were pharmaceutical industry-related financial conflicts of interest disclosed in press releases produced by these organizations or that mentioned these organizations or in news stories that mentioned these organizations?

The previous section identified ten organizations that were the most successful agenda builders as defined by their frequent mentions in press releases and news stories. This section briefly describes the financial interrelationships between these organizations with a focus on pharmaceutical industry support. General patterns of disclosure of pharmaceutical industry support that were found in press releases and news stories are also described.

Wyeth Pharmaceuticals. Wyeth Pharmaceuticals, formerly called Wyeth-Ayerst Research, and now a wholly-owned subsidiary of Pfizer, is the manufacturer of leading HT brands *Premarin* and *Prempro* (Pfizer, 2009). Wyeth funded large, randomized trials to assess the efficacy of HT for chronic disease prevention, including the Heart Estrogen Replacement Study (HERS), designed to test HT's ability to reduce heart attack in

women with heart disease, and the Women's Health Initiative Memory Study (WHIMS) designed to assess HT's ability to prevent Alzheimer's disease (Kolata & Petersen, 2002). Wyeth also donated the study drugs for other NIH-funded clinical trials that assessed the relationship between HT use and prevention of heart disease, colon cancer, and osteoporosis, including the Postmenopausal Estrogen/Progestin Interventions trial (PEPI), the Estrogen Replacement and Atherosclerosis (ERA) trial, and the entire WHI study.

The National Institutes of Health (NIH). The NIH is a federal, publicly-funded, medical research agency. Three institutes funded HT-related research through grants to various academic/medical institutions: the National Heart Lung & Blood Institute (NHLBI), the National Cancer Institute (NCI), and the National Institute on Aging (NIA). For example, NHLBI funded the WHI study, the Estrogen Replacement and Atherosclerosis (ERA) trial, the Postmenopausal Estrogen/Progestins Interventions (PEPI) trial, and the Nurses' Health Study. NCI funded several studies that explored the relationship between HT use and breast cancer risk. The NIA funded studies related to memory, cognitive decline, and Alzheimer's disease, with one of the more notable studies based on its epidemiological study, the Baltimore Longitudinal Study on Aging.

Academic/Medical Institutions. The four academic/medical institutions, Wake Forest University, UCSF, UCLA, and Harvard University were featured prominently in medical journals, press releases, and news stories due to their roles as grantees in executing major clinical trials funded by NIH and Wyeth Pharmaceuticals. Wake Forest University's Bowman Gray School of Medicine was the national clinical coordinating center for the PEPI trial, the ERA trial, and the WHIMS study. Harvard Medical School and its Brigham & Women's Hospital served as a clinical site for the WHI study and the

NHLBI-funded Nurses' Health Study. UCSF was the national coordinating center for the HERS I and HERS II trials. The Harbor-UCLA Medical Center was a clinical site for the WHI study, and its LA Biomedical Research Institute conducted many secondary analyses of the breast cancer-related WHI data.

American Heart Association (AHA). AHA is a 501c3 nonprofit organization with a mission "to build healthier lives, free of cardiovascular diseases and stroke." AHA funds heart- and stroke-related research, publishes two scientific journals, and conducts educational outreach to health care professionals and the public. During the study time period, AHA issued clinical guidelines as the evidence base related to HT and heart and stroke outcomes evolved. AHA is supported by donations from individuals, foundations, and a broad cross-section of health and non-health oriented corporations. Wyeth-Ayerst was listed, along with other pharmaceutical companies, in AHA's 2010-2011 annual report in a section that recognized lifetime giving of \$1,000,000 or more (American Heart Association, 2012b).

North American Menopause Society (NAMS). NAMS is a 501c3 nonprofit organization "dedicated to promoting the health and quality of life of all women during midlife and beyond through an understanding of menopause and healthy aging." NAMS provides continuing education for physicians, publishes a scientific journal, and produces and distributes consumer education materials. During the study time period, NAMS issued clinical practice guidelines and position statements on the relationship between HT and a variety of health and quality of life outcomes. NAMS is funded primarily through dues collected from its membership, which consists primarily of physicians, and charitable contributions from individuals, foundations, and corporations (North American

Menopause Society, 2012a). Annual reports from 2006 to 2008 listed primarily pharmaceutical companies as corporate supporters, including Wyeth Pharmaceuticals each year, but no dollar amounts were available. Beginning in 2009, NAMS' annual reports stopped listing corporate supporters (North American Menopause Society, 2012b).

American College of Obstetricians & Gynecologists (ACOG). ACOG is a 501c(3) nonprofit membership organization “dedicated to the advancement of women’s health care through continuing medical education, practice, and research” (American Congress of Obstetricians & Gynecologists, 2012). ACOG provides continuing education opportunities for its members, who are primarily practicing obstetricians and gynecologists, publishes a scientific journal, and produces a variety of educational materials for consumers. During the study time period, ACOG convened a Task Force to review the state of the evidence on HT and published clinical practice guidelines. Sources of financial support for ACOG include membership fees and donations from individuals and corporations. In its 2010-2011 report to donors, its corporate support section listed primarily pharmaceutical companies active in women’s health, but these companies were not connected to any specific dollar amounts. Wyeth Pharmaceuticals was not listed in this report, and no other previous reports were available.

Food & Drug Administration (FDA). The FDA is federal, publicly-funded, regulatory consumer protection agency with authority over food and drug products. During the study time period, the FDA reviewed new drug applications for a variety of HT products, mandated labeling revisions to HT products based on emerging evidence, and launched a national menopause education campaign to educate women about the

benefits and risks of HT in the aftermath of the WHI findings. Although the FDA is primarily funded by U.S. taxpayers, pharmaceutical companies fund a substantial portion of its activities through fees paid when submitting new drug applications (USDHHS FDA, 2009).

Examination of journal articles published by the four academic/medical institutions for major trials referenced in this results section were reviewed for financial support disclosures. When Wyeth Pharmaceuticals was the sole funder of a trial, as in the case of WHIMS and HERS, this information was routinely disclosed. Disclosure of Wyeth's donation of study medications for trials was more rarely identified. Disclosure of study investigators' individual-level, financial conflicts of interest varied by the medical journal and date of publication. *JAMA* provided the most detailed information, but this type of information only began to emerge in 1998, with earlier *JAMA* publications including much less information. Studies reviewed from *NEJM*, *Circulation*, and *Neurology* supplied no information. When individual-level conflicts were disclosed, sometimes multiple authors reported receiving grants, consulting, or speaking fees from a variety of pharmaceutical companies, including Wyeth. An article in *PLOS Medicine*, which included a list of 28 published journal articles that were later determined through litigation to be ghostwritten by Wyeth's contractor, DesignWrite, was also reviewed (Fugh-Berman, 2010). No publications from faculty members from the four academic/medical institutions that emerged as top agenda builders appeared on this list. Two prominent academics who played key leadership roles at AHA and NAMS during the study time period did appear on the list.

Examination of the press releases produced and distributed by the top-ten agenda-building organizations revealed that some types of financial conflicts were more likely to be disclosed than others. Press releases distributed by the NHLBI routinely disclosed that Wyeth had supplied the study drugs for its PEPI, ERA, and WHI trials, and had funded the WHIMS sub-study of the WHI. Wyeth also distributed press releases announcing its support of these major trials as evidence of its commitment to women's health. For example, in a press release announcing its \$16 million investment in WHIMS, its contribution of more than 100,000,000 *Premarin* and *Prempro* tablets for the larger WHI trials, and its \$40 million Heart and Estrogen/Progestin Replacement Study (HERS), Wyeth Pharmaceuticals, then Wyeth-Ayerst Laboratories, said it was part of their "commitment to and long history in understanding the science of women's specialized health needs" (Wyeth-Ayerst Laboratories, 1996).

The press releases of most academic/medical institutions disclosed the role of Wyeth when it was the primary funder of a trial. Disclosure of Wyeth's support in the form of supplying study drugs occurred as well, but more infrequently, and none of the releases by academic/medical institutions included any information about the potential financial conflicts of its faculty investigators. For example, Wake Forest University disclosed that Wyeth-Ayerst was the funding source for the WHIMS trial and acknowledged Wyeth's and other pharmaceutical companies' contribution of study drugs for the PEPI trial. UCSF releases related to the HERS trials identified Wyeth-Ayerst as the study's sponsor. Harbor-UCLA Medical Center's releases credited NIH support for its analyses of the WHI data, but did not mention Wyeth's contribution of study drugs. AHA also distributed press releases about studies from the HERS trial that were

published in its journal, *Circulation*, but did not supply any information about Wyeth's funding of the trial.

Disclosures by nonprofit organizations about organizational-level financial conflicts, such as charitable contributions made by pharmaceutical companies to support their mission or specific activities were almost non-existent in press releases. Although of the three nonprofit organizations that emerged as successful agenda builders, only AHA issued a substantial number of press releases to examine, which is an issue that will be discussed in the following section. Still, only one release was found that acknowledged pharmaceutical support of an organization. This release, which publicized the results of an AHA-funded study on HT and heart disease prevention in younger women, had an editor's note at the bottom of the release acknowledge that "foundations and corporations – including pharmaceutical, device, manufacturer and other companies – make donations and fund specific American Heart Association/American Stroke Association programs and events" (AHA, 2008).

Information in news stories with respect to financial conflicts of interest were similar to what appeared in press releases and on scientific publications, perhaps an indicator that when conflict of interest information is made available journalists will include it. News reports about WHIMS and HERS often identified Wyeth as the sponsor. During this time period, just about all the news stories identified *Premarin* and *Prempro* as the drugs used in the WHI and Wyeth as their manufacturer, but only a few stated that Wyeth had actually donated the study drugs for the trial. The isolated cases in which individuals' financial conflicts were reported tended to be based on studies published in *JAMA* that included the disclosure. For example, a story released by the *Associated Press*

on June 22, 2004, about a study published in *JAMA* from the WHIMS trial included the following: “The analysis by Shumaker, Rapp and colleagues was funded by Wyeth and Wake Forest. Shumaker has served as a consultant for Wyeth” (Associated Press, 2004).

RQ6b: Did these organizations tend to collaborate with other organizations to produce joint press releases as evidenced by the press release source and contact fields? Did mentions of these organizations tend to frequently be associated with mentions of other organizations in the text of press releases? How did these patterns of organizational associations compare to the patterns of associations found in news stories that mentioned these same organizations?

To answer RQ6b, press releases that mentioned the top-ten agenda builders as defined in this study were sorted into the following two categories: releases that were actually produced by the ten organizations and releases that were produced by other organizations but contained a reference to one or more of the top-ten organizations in the body text. Examination of the release source and contact fields yielded few examples of joint efforts in producing releases; most releases were identified as the product of one organization. What became apparent, however, was that some organizations actively tried to build the news media agenda by distributing releases and others appeared to be more passive, rising to the top of the agenda through the publicity efforts of other organizations that cited them. It should be noted that organizations may have distributed releases through channels other than *PR Newswire* or *EurekAlert!*, or conducted media relations in other ways. Nevertheless, based on the available evidence in this study, some interesting patterns emerged.

Wyeth Pharmaceuticals was the most actively involved organization, distributing more press releases than any of the other nine organizations, followed by academic/medical institutions and the NIH. Wyeth distributed a total of 58 releases across a broad range of topics related to HT, including research findings, regulatory issues, clinical practice guidelines, lower-dose formulations of *Premarin* and *Prempro*, and lawsuits by plaintiffs alleging that *Prempro* caused their breast cancer. Combined, the four academic/medical institutions distributed a total of 35 releases, which focused primarily on research study findings. The NIH, including NHLBI, NCI, and NIA distributed a total of 21 releases, which were focused on findings from Institute-funded studies and announcements about the cessation of the WHI trials. Many of these releases included quotes and contact information for principal investigators at the four academic/medical institutions, who ran clinical sites or served on NIH steering committees or advisory panels. Medical journal publishers also used *Eurekalert!* to distribute press releases announcing articles published by these academic/medical institutions in their journals.

Wyeth played a large role in publicizing not just the findings of studies it directly funded, but other studies with implications for its products, through position statements issued as press releases. A distinct pattern emerged in terms of how Wyeth framed these releases. Studies with findings that were positive for HT were enthusiastically endorsed; studies with negative findings were refuted as inconsistent with other evidence, picked apart on methodological grounds, reinterpreted as not meaning what the authors thought it did, or altogether ignored. For example, studies showing a favorable effect of HT on cholesterol levels presented at the annual meeting of the American College of Cardiology

in 2000 were positioned in a Wyeth release as supporting a “a growing body of epidemiological studies that have shown ERT and HRT to impact on body systems in a way that may help decrease the risk of coronary heart disease” (Wyeth-Ayerst Laboratories, 2000). Commenting on a study published in *JAMA* in 1995, which found no breast cancer risk associated with HT use, Wyeth asserted that the study “supports the majority of studies that have not shown an association between estrogen use and increased breast cancer risk” (Wyeth-Ayerst Laboratories, 1995b). Conversely, in a 2002 release announcing the unexpected, negative results from its HERS II trial to see if HT prevented heart attacks, Wyeth made no mention of its role in designing and funding the trial and argued that the findings applied only to “older women with heart disease, not the typical woman on HRT” (Wyeth Pharmaceuticals, 2002).

Other interesting patterns surfaced in the nonprofit category of organizations. Although these organizations only distributed a total of 15 releases, references to AHA, NAMS, and ACOG were prevalent in the releases of other organizations. A good portion of these references appeared in releases reporting research findings presented at these organizations’ annual scientific meetings. Pharmaceutical companies also often used statistics compiled by these three nonprofit organizations to support a problem or need that could be fulfilled by their products. For example, in a press release for a competitor product to HT in the heart disease area, an Eli Lilly press release stated: “Heart disease is the number-one killer of women in the U.S. and developed countries. According to the American Heart Association, more than one in three women over the age of 65 has some form of cardiovascular disease” (Eli Lilly & Company, 1998). Announcing FDA approval of its generic conjugated estrogens vaginal cream, Barr Pharmaceuticals

distributed a press release which said, “According to the North American Menopause Society (NAMS), an estimated 10 to 40 percent of post-menopausal women suffer from symptoms related to vaginal atrophy” (Barr Pharmaceuticals, 2008).

Clinical practice guidelines written by NAMS and ACOG were also frequently used in pharmaceutical companies’ press releases to justify their products in terms of the scientific evidence base. For example, in a press release distributed in 2004, Wyeth Pharmaceuticals applauded ACOG’s Hormone Therapy Task Force report, describing it as the “evidence-based consensus among leading women’s health experts” and stating that:

The American College of Obstetricians and Gynecologists (ACOG) Hormone Therapy Task Force confirms that estrogens and estrogens plus progestins are ‘highly effective’ in relieving postmenopausal vasomotor symptoms, are the ‘most effective treatment’ for severe symptoms, and may be the appropriate ‘first choice therapy’ for the prevention of osteoporosis in women with menopausal symptoms” (Wyeth Pharmaceuticals, 2004).

The FDA only distributed one press release during the study time period that was retrieved via the databases used in this study. A review of the FDA website, however, indicated that there were perhaps a few, but not many, press releases distributed by the FDA in relation to HT that were not captured by this study’s search strategy. Still, the FDA emerged as the top-mentioned organization in press releases, primarily due to the large number of press releases distributed by pharmaceutical companies that mentioned the FDA’s role in the approval process for new drugs, formulations, and product labeling.

For news stories reviewed that contained mentions of the top-ten agenda-building organizations, some patterns of associations between organizations seemed to hold. Based on the frequency analysis conducted for RQ5 alone, presented previously in Table 35, it is clear that news stories and press releases mentioned similar organizations. News stories in general, however, tended to take the next step to explore the viewpoints of organizations more than press releases. For example, while news stories cited organizations like AHA, ACOG, and NAMS for statistics related to chronic disease prevalence and other problems, they also often included quotes from executives and physicians associated with those organizations on various issues related to HT. News stories also tended to include more opposing viewpoints about topics, whereas, press releases typically presented one viewpoint and mentioned the efforts of other organizations that supported those viewpoints.

RQ6c: How did these organizations construct and define menopause, and how did these definitions relate to proposed treatment recommendations in press releases that were produced by these organizations or that mentioned these organizations? How did these definitions and treatment recommendations compare to those used in news stories that mentioned these same organizations?

Menopause was defined differently in press releases in the pre- and post-WHI periods as were corresponding treatment recommendations. In the early years of the study, menopause was rarely addressed in specific ways. The focus of releases was more on HT and its ability to prevent chronic diseases that begin to occur in postmenopausal women. Rather than being attributed to the process of aging overall or lifestyle choices, such as diet or exercise, chronic diseases were attributed specifically to estrogen

depletion. Many releases framed chronic diseases as “the problem” so to speak rather than the experience of menopause. This was true of almost all of the ten organizations studied.

One major theme was the tradeoff between heart disease risk and breast cancer risk, along with the recurring message that heart disease claims more lives than breast cancer. For example, a 1997 Wyeth press release about findings reported in *NEJM* from the observational Nurses’ Health Study, which indicated that nurses who used HT had 53% less coronary heart disease deaths than nurses who never used HT, included the following quote: “After age 45, the risk of death from cardiovascular disease outweighs the risk of death from breast cancer. In fact, coronary heart disease kills 233,000 women in contrast to 43,000 women who die of breast cancer in the United States each year” (Wyeth-Ayerst Laboratories, 1997). Similarly, a NHLBI press release about another study published in *NEJM* that same year, which found that women with higher bone mass had higher rates of breast cancer, raising speculation about the potential role of estrogen, Dr. Claude Lenfant, Director of the NHLBI, cautioned that “the findings should be kept in perspective since, for most women, estrogen may provide crucial benefits against heart disease and osteoporosis.” This commentary was followed by text stating that, “Heart disease is the leading cause of death among American women. While about 44,000 women died of breast cancer in 1994, approximately 370,000 died of heart disease” (NHLBI, 1996).

During the post-WHI period, press releases, particularly those released by pharmaceutical companies, began to shift toward more focus on the symptoms related to menopause, particularly hot flashes, and the need for women to be proactive and make

the best decision for themselves given the risks and benefits of HT therapy. While hot flash reduction was certainly mentioned in the pre-WHI period, it was typically mentioned almost as a convenient addition to the chronic disease prevention benefits of HT. In the post-WHI period, however, press releases distributed by Wyeth and other pharmaceutical companies emphasized that many postmenopausal women suffered from menopausal symptoms that significantly lowered their quality of life. For example, in a press release by Wyeth on October 24, 2002, urging “practical guidance” for women on initiating hormone therapy, Wyeth argued that the benefits of treating “menopausal symptoms,” along with “concomitant prevention of postmenopausal osteoporosis prevention,” outweigh the risks of HT when used on a short-term basis. The releases went on to state:

While menopausal symptoms represent the primary reason women seek treatment with HT, prevention of postmenopausal osteoporosis is also an important approved use of HT. Menopausal symptoms have a significant impact on many women's lives and can impair their ability to function normally on a daily basis.

News stories were somewhat similar to press releases in terms of their orientation toward the chronic disease prevention benefits of HT in the pre-WHI period. In fact, “Study: Estrogen Use Should Begin at Menopause, Continue Indefinitely,” was the headline for the first news story for this study, which ran in the *Associated Press* on January 3, 1995. Another Associated Press story on June 19, 1997, about the Nurses’ Health Study data published in *NEJM* that found reduced death due to coronary disease included the following comment:

Patients often fear breast cancer more than heart disease or hip fracture, although the last two afflictions kill a lot more women, the researchers noted. Breast cancer claims about 43,000 women a year compared with 233,000 for heart disease – the leading killer of women – and 65,000 for hip fracture, they said”(Coleman, 1997).

A fair number of news stories, however, focused in on the breast cancer risk more than press releases, acknowledging that it was a real concern for women, even very early on in the pre-WHI period. For example, a story in the *Washington Post* in response to the *NEJM* study published on June 15, 1995, which found increased rates of breast cancer in women who took HT and participated in the Nurses’ Health Study said the report had “generated fear and some skepticism among women, many of whom rushed to call their doctors to discuss it, physicians reported.” The article also included quotes from women who were unconcerned, saying they would continue to take their medication, and from women who were scared, confused, and angry (Shen & Smith, 1995).

During the immediate post-WHI period, several news stories focused on the difficult decision women faced about whether to take HT or not, particularly for women who experienced hot flashes. These stories tended to include quotes from physicians and women about their perspectives on the issue. Several investigators at the top-four academic/medical institution were quoted in these stories, likely due to their involvement with the trials and knowledge of the science. For example, Dr. Deborah Grady, Director of the Mount Zion Women's Health Clinical Research Center at UCSF and one of the principal investigators for the HERS studies stated in a July 16, 2002, *New York Times* article that, “If a woman can't sleep and can't work, and estrogen is the only therapy that makes her feel well, it's reasonable to take some risk. It all depends on how much

discomfort she's willing to put up with and how much risk she's willing to take" (Duenwald, 2002, p. F1).

Some of the news stories during this time period mentioned non-prescription alternatives to treat hot flashes, such as black cohosh, soy, reducing caffeine intake, breathing techniques, and dressing in loose and light clothing. These alternatives did not appear in the press releases of the top-ten agenda building organizations, although many alternative health and supplement manufactures did issue press releases about their products during this time period. For the most part, the top-ten agenda-building organizations stayed focused on the argument that HT was still a reasonable option for short-term use by menopausal women without a history of heart disease. Newer, lower-dose HT formulations emerging on the market were also suggested as options, although both press releases and news stories were careful to make clear that there was no evidence that these lower doses were necessarily safer. Commenting on alternative herbal and dietary supplements in an *Associated Press* story on July 19, 2002, Dr. Wulf Utian, executive director of NAMS, who was later identified in 2010 for authoring scientific articles ghostwritten by Wyeth, stated, "All the snake oil salesmen selling cures for menopause will be out there advertising. There is virtually nothing that is much better than a placebo unless it is a prescription drug" (Haney, 2002).

During both the pre-WHI and post-WHI periods a large number of press releases and news stories featured the results of research studies. In many cases these studies were non-controlled, observational studies, suggestive of HT's ability to prevent chronic diseases, or controlled studies that only measured HT's effect on surrogate indicators or risk factors, like cholesterol, but not actual disease outcomes like heart disease. These

types of studies had little immediate clinical value, as they did not meet the rigorous standards required by the FDA to expand HT's indications. The press releases for these types of studies were carefully crafted to be scientifically accurate by using qualifying terms like "may" or "suggest." For example, press releases distributed by the NIH and academic/medical institutions commonly featured headlines like "Effect of Hormone Therapy on Risk of Heart Disease May Vary by Age and Years Since Menopause," (NHLBI, 2007), "Study Suggests ERT Stimulates Blood Flow to the Key Memory Centers in Brain" (NIA, 2000), and "Hormone Replacement Therapy May Help Prevent Heart Vessel Disease, Says Wake Forest Researcher" (Wake Forest University, 2002). A review of news stories based on findings from the NIH and academic/medical institutions confirmed that journalists were careful to carry over these same types of qualifying terms to their news stories. Although these communications were carefully worded, in their totality, they likely served to confuse the public by suggesting unproven benefits of HT.

Chapter V: Discussion

This longitudinal study used a theoretical framework proposed by Zoch and Molleda (2006) that combines agenda building, framing, and information subsidies to explore how a variety of health and medical organizations used public relations efforts to build and shape the news media agenda for postmenopausal hormone therapy (HT) from 1995 to 2011. The theoretical framework was applied to a quantitative content analysis of 675 press releases distributed by *PR Newswire* and *EurekaAlert!*, and 429 news stories that appeared in the *Associated Press Newswire (AP)*, *The New York Times*, *The Washington Post*, *Los Angeles Times*, and *The Wall Street Journal*. Supplemental qualitative content analysis procedures were also used to understand the financial relationships and potential collaborations that existed between ten organizations that emerged from the quantitative content analysis as the most successful agenda builders, and how these organizations framed problems associated with menopause and potential treatments. In addition to press releases and news stories that were relevant to these organizations, the organizations' websites, annual reports, and key scientific publications were reviewed for financial disclosures.

Findings revealed that six different types of health and medical organizations produced information subsidies in the form of press releases about HT: pharmaceutical companies, academic/medical institutions, nonprofit organizations, medical/scientific journal publishers, miscellaneous for-profit organizations, and U.S. government agencies. Substantial evidence supported the premise that the public relations agendas of these organizations played a role in setting and shaping the news media agenda for HT. A moderately strong, positive, and statistically significant relationship between the quantity

of press releases and news stories was found over the study time period ($r = .55, p < .001$). Findings also supported the transference of specific objects and attributes from the public relations agenda to the news agenda. Striking similarities were found between the content of press releases and news stories for overall story themes, types of organizations mentioned, types of individuals quoted, disclosure of pharmaceutical industry conflicts of interest, brand-name HT products mentioned, the benefits and risks associated with HT at different points in time, and how those benefits and risks were framed in terms of their magnitude and potential tradeoffs. Although press releases and news stories mentioned specific benefits and risks with just about the same relative frequency, news stories reported on all benefits and risks more often, particularly the potential for breast cancer risk. Similarly, although press releases and news stories mentioned the same types of organizations, news stories tended to explore the viewpoints of organizations and individuals associated with those organizations in more depth.

Interesting differences by organization type about the benefits and risks of HT were found. Although pharmaceutical companies, academic/medical institutions, U.S. government agencies, and nonprofit organizations did not differ significantly in terms of the quantity of benefits per press release, the specific benefits communicated did vary, particularly when it came to more controversial, non-FDA approved, off-label indications. Academic/medical institutions and nonprofit organizations were more than four times as likely as pharmaceutical companies to mention a potential non-FDA approved heart disease-prevention benefit. U.S. government agencies reported more risks per release than any other organization type, and pharmaceutical companies reported significantly more risks per release than nonprofit organizations, although sticking

closely to the risks mandated at any point in time by FDA labeling requirements. Overall, this study found that pharmaceutical companies were more cautious and careful communicators than expected, often pasting the FDA-approved product labeling at the end of their releases, perhaps in an effort to avoid regulatory consequences.

The most successful agenda builders that emerged from the quantitative content analysis were Wyeth Pharmaceuticals, NIH, FDA, Wake Forest University, UCSF, UCLA, Harvard University, AHA, NAMS, and ACOG. Although some organizations actively tried to build the news media agenda by distributing releases, others appeared to be more passive, rising to the top of the agenda through the publicity efforts of other organizations. Supplemental document analysis found that Wyeth financially subsidized the efforts of at least eight of the other organizations and played a primary role in generating attention not only to its own organization through press releases, but to the efforts of the other nine organizations. Wyeth proactively commented on the findings released by the academic/medical institutions about major HT-related clinical trials, which all received financial support directly or indirectly from Wyeth. Wyeth, along with other pharmaceutical companies, frequently cited the three nonprofit organizations, AHA, NAMS, and ACOG in its press releases for statistics on disease prevalence and clinical practice guidelines to demonstrate a need for and justify their products.

There were also similarities in the way the top-ten agenda-building organizations framed the problems associated with menopause and proposed treatment recommendations, suggesting if not direction collaboration, certainly a high degree of synergy between the organizations. In the pre-WHI period, press releases and news coverage focused on HT and its ability to prevent chronic diseases that occur in

postmenopausal women. Chronic disease was framed as the “problem,” estrogen depletion as the “cause,” and HT as the “solution.” One major theme that emerged was the tradeoff between heart disease risk and breast cancer risk for women considering HT, along with the recurring message that HT was a beneficial choice because heart disease claims more lives than breast cancer. During the post-WHI period, press releases, particularly those released by pharmaceutical companies, and news stories, shifted to a focus on the symptoms related to menopause, particularly hot flashes, and the need for women to be proactive and make the best decision for themselves given the risks and benefits of HT, with short-term and/or low-dose HT still offered as a viable solution for younger postmenopausal women. Alternative, non-prescription remedies received no attention from the ten organizations. News media gave somewhat more attention to alternative approaches, but this attention was short-lived and primarily restricted to the time period immediately following the WHI announcements.

Theoretical Implications

This study provided a systematic look at what types of health and medical organizations produce sources of information about prescription drug news; what their resources and goals are; how they act individually, and perhaps jointly with other organizations, to influence news content; and how these processes might influence the quality of news about prescription drugs. Findings from this study contributed to public relations scholarship by demonstrating the viability of Zoch and Molleda’s (2006) theoretical framework for a health and medical context and by contributing support for each component of the framework: agenda building, information subsidies, and framing. Perhaps more importantly, this study extended Zoch and Molleda’s (2006) framework by

uncovering how organizations may work not just in isolation, but jointly, through behind-the-scenes funding mechanisms and third-party techniques to build and frame the news media agenda.

While organizations often issue information subsidies directly to journalists, they also do so indirectly through a variety of third-party techniques. Third-party techniques refer to getting other experts, organizations, or coalitions that are perceived as more disinterested in an issue and credible to deliver a message (Palenchar & Fitzpatrick, 2009; Rampton & Stauber, 2002). Although more blatantly unethical practices, such as the use of front groups, have been explored in the public relations literature (see Palenchar & Fitzpatrick, 2009), literature is lacking on how more legitimate organizations might use third-party techniques to communicate messages to news media. This study's pattern of findings suggested that pharmaceutical companies may make substantial use of third-party strategies by subsidizing the efforts of academic/medical institutions and nonprofit health advocacy organizations that communicate to news media about the benefits and risks of prescription drugs.

Agenda building. The finding that the amount of press releases and news stories during the study time period were positively and moderately correlated with one another contributes substantially to the agenda building literature. Although scholars have argued for more studies that trace information studies through the process to see how they influence the news media agenda (Cameron et al., 1997; Gandy, 1982; Kioussis et al. 2006; Shoemaker & Reese, 1996; Zoch & Molleda, 2006), only a few studies have examined the relationship between the salience of issues and topics in press releases and news media over time, and these studies have been limited to investigations of political

candidates, political issues, and corporate reputation (Kiouisis et al. 2006; Kiouisis et al., 2007; Kiouisis, 2009). The results of this exploratory study provided empirical support for the agenda-building concept in a health and medical context and lay the foundation for future research studies that employ statistical modeling approaches to examine whether a causal relationship exists.

Thematic analyses of the types of content that were associated with heightened press release and/or news activity also provided deeper insight into the agenda-building process. A continual, up-and-down pattern of spikes and valleys for the quantities of press releases and news stories over time, which appeared to be initiated sometimes by press releases and sometimes by news stories suggested a high degree of interactivity between the public relations and news agendas. Activities performed by organizations, such as releasing research findings, engaging in regulatory-related actions and disputes, issuing clinical practice guidelines, and responding to legal actions stimulated the most news coverage, and press releases that were purely product promotional in nature had much less influence. While past scholarship has conceptualized agenda building as an interactive, reciprocal process driven by the agendas of organizations and publics and the news media and policy agendas all interacting with one another (Cobb & Elder, 1972; Corbett & Mori, 1999; Gozenbach, 1996; Kiouisis et al., 2007; Lang & Lang, 1981; Schneider, 1977; Walters & Gray, 1996), this study was able to highlight the significant role organizations played in this process for a health and medical issue.

Information subsidies. Data obtained in the course of this investigation contributed to the information subsidies literature by detailing how organizations use information subsidies to build the news media agenda in both explicit and implicit

ways. Pharmaceutical companies yielded a higher degree of explicit influence on the news media agenda than expected based on past scholarship suggesting that journalists prefer information subsidies produced by U.S. government agencies, academic/medical institutions, and non-profit organizations (e.g., Berkowitz & Adams, 1990; Cho, 2006; Curtin, 1999; Dunwoody, 1986; Friedman, 1986b; Gandy, 1982; Gans, 1979; Tanner, 2004; Van Trigt et al., 1994; Wallington et al., 2007; Qui, 2006). Although academic/medical institutions and U.S. government agencies appeared in more than 50% of press releases and news stories, pharmaceutical companies were close behind, appearing in 47.1% of press releases and 43.8% of news stories, surpassing nonprofit organizations. This conclusion may be limited, however, by equating mentions of organizations with influence. For example, after the WHI announcements, Wyeth Pharmaceuticals was often mentioned in news stories that associated the company with the drugs that had caused harm in the WHI trials or with lawsuits by women who claimed *Prempro* caused their breast cancer. Clearly, these are the types of mentions that Wyeth would have preferred to avoid.

Perhaps more compelling were the data generated about how pharmaceutical companies may influence the news media agenda in less explicit ways through third-party strategies. Although no empirical studies previously existed in this area, literatures related to information subsidies, third-party techniques, and conflict of interest in medicine (Batt, 2005; Beder et al., 2003; Burton & Rowell, 2003a; Gandy, 1982; IOM, 2009; Palenchar & Fitzpatrick, 2009; Rampton & Stauber, 2002), suggested that pharmaceutical companies would fund the efforts of U.S. government agencies, academic/medical institutions, and nonprofit organizations, and that these organizations

would in turn influence the news media through press releases about these efforts. Wyeth's funding of U.S. government agencies, academic/medical institutions, and nonprofit organizations with the ability to advance its strategic interests for HT was extensive, disclosure of these financial conflicts by Wyeth and the organizations and individuals receiving funding on scientific publications, organizational materials, and press releases were poor and inconsistent, and similar frames about HT were communicated to the news media by these organizations. Additionally, Wyeth played a proactive role in generating attention not only to its own organization through press releases, but to the efforts of the other organizations it subsidized. These exploratory findings offer initial support to justify future research to delve into these strategies more comprehensively.

Framing. Findings from the quantitative and qualitative components of this study provided support for the transference of specific frames from the public relations agenda to the news media agenda. Second-level agenda setting research has indicated that news media attention can influence how people think about an object by selecting and or emphasizing some of its substantive attributes and ignoring or downplaying others (Kiousis et al. 2006, 2007; McCombs, 1992; McCombs & Ghanem, 2001). Patterns of resemblance between press releases and news stories for HT brand names and the benefits and risks associated with HT, not just over the entire study time period, but also within the pre- and post-WHI time periods, indicated that attribute frames were successfully transferred from organizations to the news media agenda. The finding that pharmaceutical companies were more cautious and careful communicators than expected with regard to benefits and risks, combined with the finding that non-profit organizations

and academic medical institutions were more likely to communicate about off-label benefits, suggest that in the prescription drug context there may be some underlying strategy to what attributes of a product different organizations convey to the news media, lending further support to the potential role third-party techniques may play in a regulatory environment.

Past research has also found that the way an issue or problem is framed can lead to different causal attributions and treatment recommendations (Entman, 1993; Iyengar, 1991). This study also found support for the transference of these types of frames to news media. Press releases and news stories framed HT as the solution to what was framed as estrogen-induced chronic disease in the pre-WHI period and shifted gears in the post-WHI period framing HT as a solution to menopausal symptoms, particularly hot flashes. The finding related to the tradeoff between heart disease and breast cancer risk was one of the more intriguing findings in this study. Gandy (1982) suggested that by strategically controlling access to information through the production and distribution of information subsidies, organized interests can succeed in “changing the stock of information” on which decisions are made (Gandy, 1982, p. 13). In the years leading up to the WHI announcement, the efforts of multiple organizations succeeded in shifting the risk-benefit profile of HT by reinforcing the message that the potential for breast cancer was less worrisome than a purported heart-disease prevention benefit, which was never empirically supported with a controlled clinical trial or approved by the FDA, through the sponsorship, publication and promotion of observational studies or trials that only examined surrogate outcomes like risk factors. While many scientists, including those at Wyeth, likely believed that pending evidence from the HERS and WHI trials would

eventually confirm a heart disease prevention benefit, the recommendations were premature and served to expand the market for HT considerably for several years while Wyeth, and the rest of the medical community, waited for what they mistakenly thought would be confirmatory evidence.

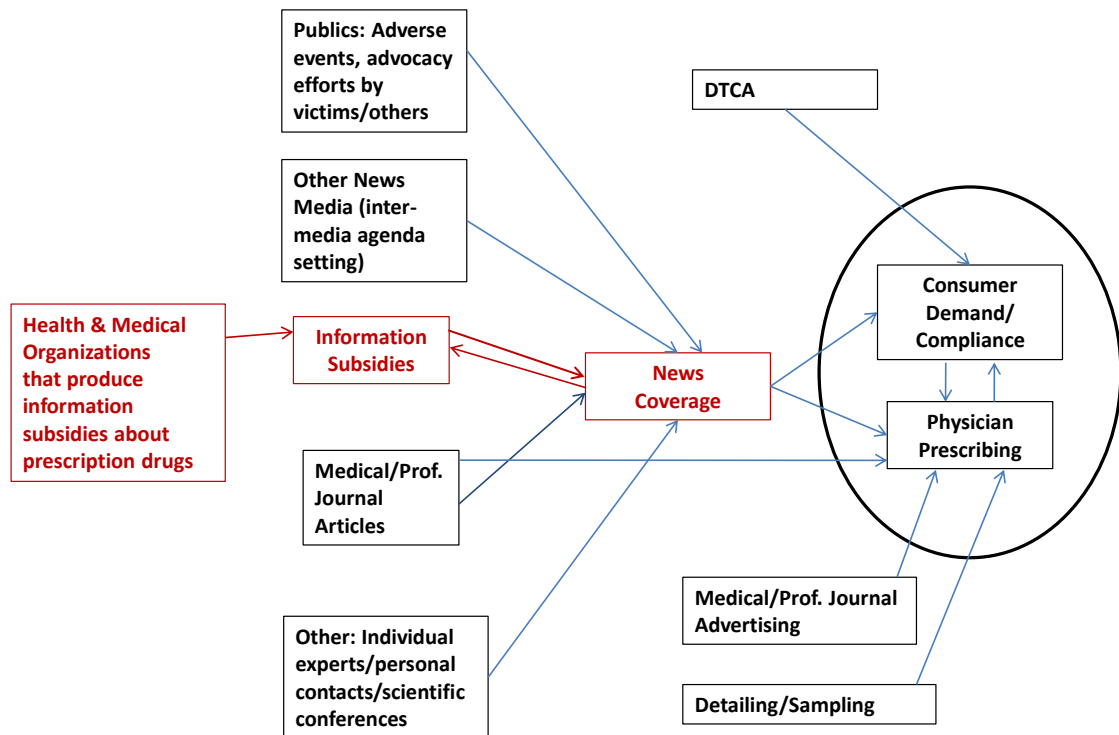
Research on Prescription Drug Promotion

This study adds a new perspective to the growing literature on prescription drug promotion, which thus far has only taken into account overtly promotional sources of information such as direct to consumer advertising, by conceptualizing news as promotional with potentially similar consequences. Figure 1, Chapter II, pictured below outlined the overall focus and scope of the study. This figure proposed that a variety of health and medical organizations would produce carefully-framed information subsidies to build the news media agenda about HT in ways that furthered their strategic interests. These subsidies were conceptualized as having the potential to act like a form of prescription drug promotion, similar to direct to consumer advertising, medical journal advertising, detailing and sampling, and medical/scientific journal articles, which have been shown to influence physician prescribing practices, consumer demand, and prescribing rates (e.g., Donohue & Berndt, 2004; FDA, 2004; Gonul et al., 2001; Iizuka & Jin, 2006; Mizik & Jacobson, 2004; Rizzo, 1999; Rosenthal, Berndt, Donohue, Epstein, & Frank, 2003; Wang, Ausiello, & Stafford, 1999; Zachry et al., 2002).

The process of effects for press releases was envisioned as an indirect one, in which the content of press releases is diffused to physicians and consumers through news media. This study only explored the red boxes and arrows in Figure 1. The purpose was to explore how information subsidy production and distribution by a variety of health and

medical organizations shaped the quantity and quality of news coverage. The link from news coverage to potential outcomes, such as prescription drug use, was not explored in this study.

Figure 1: Focus and Scope of Study



The overall pattern of findings summarized in this chapter supported the viability of the portion of the model tested in this study. A variety of health and medical organizations did in fact attempt to build the news media agenda by producing subsidies in the form of press releases about HT. The positive correlation found between the amount of press releases and the amount of news stories about HT over the study time period offered some initial, preliminary support for the claim that press releases influenced the news media agenda. Correlation alone, however, is a rather weak indicator. The more compelling evidence in this study was the convergence of findings

related to the actual content of press releases and news stories, which lent further support to the positive correlation found.

While not tested in this particular study, the proposition that news media may play a key role in influencing prescription drug use by diffusing information about the uses, benefits, and risks of prescription drugs seems promising. News media may also disseminate information about prescription drugs that is quite different from FDA-regulated sources of information because pharmaceutical companies are prohibited by law from promoting off-label benefits. Prescription drug information transmitted through news media and medical journals, however, is not subject to these FDA regulations, which cover paid-promotional efforts only like detailing, medical journal advertising, and DTCA (see Leffler, 1981; Morris & Griffin, 1992; Sheehan, 2003). A substantial proportion of press releases, particularly those distributed by academic/medical institutions and nonprofit organizations, served to promote off-label indications for HT, such as prevention of heart disease and Alzheimer's disease. In the pre-WHI period, almost one-third (31.3%) of press releases and two-thirds (66.2%) of news stories suggested a heart-disease prevention benefit of HT, and 8.7% of press releases and 25.9% of news stories suggested HT could prevent Alzheimer's disease and other forms of cognitive decline.

Findings from this study suggest that in addition to the specific activities that academic/medical institutions and nonprofit organizations perform with pharmaceutical industry funding, they may also serve as valuable, unregulated conduits for the industry to reach physicians and consumers. Information subsidies, particularly ones delivered through the type of complex third-party strategies that were found in this study, make it

difficult for consumers of news to fully understand the interests and motivations of the organizations or actors behind the information they receive. In the case of HT, this situation may have resulted in sub-optimal message processing and decision-making outcomes because understanding where information comes from is one way that individuals assess its credibility and potential for bias (Bodensteiner, 1997; Fitzpatrick & Palenchar, 2006; Lofgran, 2004; Steinman et al., 2006).

Practical Implications

The findings from this study have several practical implications for improving the quality of prescription drug news in ways that may help avoid misperceptions about their FDA-approved indications and facilitate better decision making. Although some have blamed news media for presenting a distorted picture of HT by emphasizing its benefits and excluding or downplaying its potential risks (for e.g., Fugh-Berman & Pearson, 2002; Katz, 2003; Moynihan et al., 2002), this study found that many of the problems related to the quality of HT news originated from the health and medical organizations that journalists relied on as sources. Therefore, the following recommendations focus on public relations practitioners that work for health and medical organizations that disseminate information about prescription drugs and journalists.

When communicating with news media, health and medical organizations have a responsibility to communicate evidence-based information about prescription drugs in ways that can be clearly understood by consumers. Throughout the study time period, efforts by the NIH and academic/medical institutions to publicize their scholarly work, along with Wyeth Pharmaceutical's tactics to draw attention to studies that were favorable to HT, likely played a large role in promoting unproven, off-label benefits of

HT. Although these press releases were carefully worded with qualifying terms like “may” or “suggest,” it is unlikely that the public at large understands the implications of such nuances. When considered within the context of studies that reported on risks associated with HT, often for the same disease areas, it is not surprising that women report confusion and frustration about HT recommendations (Buick et al., 2005; Wathen, 2006). The efforts of scientists and the organizations they work for to publicize discoveries one study at a time, which are typically devoid of meaning when separated from the context of previous literature, creates a pattern of continual, conflicting findings and confusion. A review of the NHLBI website of scientific publications from the WHI trials, which had not been updated since May 12, 2011, listed 409 scientific publications from the WHI trials alone, with 88 of those publications examining the effects of hormone therapy and all reaching a variety of different conclusions (NHLBI, 2011).

The NIH is in the best position to facilitate change in this area by working with its own public information officers and its university grantees to facilitate better communication. One recommendation would be to consider the target audience for its press releases. If a scientific publication related to the effects of a prescription drug on the market has no immediate implications for changes to clinical practice and may suggest unapproved indications, they may be better left for scientific circles to debate their merits through professional journal publications and scientific conferences until clear implications emerge. If organizations do promote these types of scientific articles to news media, press releases should include a clear statement that the findings have no implications for how the drug should be currently prescribed and consider including information about the drug’s approved indications to avoid misperceptions.

Based on past scholarship about communicating the risks and benefits of medical interventions, the FDA published an evidence-based user's guide with recommendations for communicators. The guide recommends providing quantitative, not just qualitative, information about benefits and risks, and conveying quantitative information in absolute terms whenever possible, rather than in just relative terms, which tends to inaccurately inflate perceptions of the magnitude of benefits and risks (Fischhoff, Brewer, & Downs, 2011). This study found substantial room for improvement in this area. Roughly one-third of press releases and news stories provided quantitative information when identifying potential benefits and risks, and relative presentations were by far the most frequently used format. Again, the NIH could foster positive change in this area by working with its Institute communicators and grantees to make sure these evidence-based guidelines are used in all publicity efforts.

Health and medical organizations can also contribute to more ethical communication by transparently disclosing all financial conflicts of interest in press releases and other information subsidies. The extent of financial conflicts of interest between government agencies, academic/medical institutions, nonprofit organizations, and Wyeth Pharmaceuticals found in this study and the low rate of disclosure of those conflicts is troubling. Some organizations like the Institute of Medicine (IOM) have called for public policies that encourage more disclosure and transparency about financial conflicts of interest in medicine (see IOM, 2009). The results of this study support recommendations made by the Institute of Medicine (IOM) for Congress "to create a national program that requires pharmaceutical, medical device, and biotechnology companies and their foundations to publicly report payments to physicians, researchers,

health care institutions, professional societies, patient advocacy and disease-specific groups, providers of continuing medical education, and foundations created by any of these entities” in the interest of greater disclosure and transparency (IOM, 2009, p. 9).

Health and medical journalists also need to be more diligent about investigating the funding sources behind the information subsidies they receive. Examination of scientific publications, annual reports, and other organizational materials, along with questioning of individual sources about any financial conflicts is necessary to accurately report on collaborations that may exist between seemingly separate organizations. In the absence of such efforts, journalists may fail to detect the role pharmaceutical companies may have played in the production of information released about prescription drugs by other types of organizations, such as academic/medical institutions and nonprofit health advocacy groups. Finally, journalists need to be more discriminating about the use of press releases that promote a single study. Single studies are rarely meaningful when they are not contextualized within the past medical literature. Journalists should rigorously question the sources of such releases so they can better contextualize the findings and clearly communicate to readers whether the findings have any immediate implications for how a drug should be prescribed or used.

Study Limitations

This study had limitations primarily related to its sampling strategy. Retrieval of press releases was limited to those distributed by *PR Newswire* and *EurekAlert!*, and it is possible that organizations may have distributed press releases via other means. Retrieval of news stories was limited to *AP Newswire*, *The New York Times*, *Washington Post*, *Los Angeles Times*, and *Wall Street Journal*. Although *AP Newswire* was included to reflect

stories likely published in regional and more local papers, it is possible that regional and local papers contained content that was quite different. This study also included only print news, and the inclusion of broadcast and cable news may have yielded different results.

Longitudinal studies can pose a challenge due to the difficulty of finding reliable indicators that reach far back in time. In the case of *EurekAlert!*, press releases were only available for 1996 and later. For this reason, the total amount of press releases might be underestimated for 1995. There are also limitations associated with the creation of any search string to retrieve documents electronically. Although the search terms were rigorously examined for recall and precision through repeated trials, no search term is perfect. It is likely that some combination of terms was omitted, resulting in the omission of press releases and news stories that were relevant to the study.

Another limitation of the study was the use of the press release and news story as the unit of analysis for all coding. Although this was necessary due to the volume of texts analyzed in this study, it did not allow for content variables to be associated with specific sources cited within the body of the texts. For example, if a press release or news story contained a claim that HT prevented heart disease, the press release or news story was coded as mentioning this benefit. The coding scheme used was not sensitive enough to detect whether a claim was attributed to a specific organization or individual cited within the text of the press release or news story. In the case of news stories, this also meant that the coding did not capture whether specific claims were made by journalists themselves or just reported on by journalists and attributed to other sources.

Future Research

Several directions for future research are suggested based on the results obtained in this investigation. The first would be employ additional data analysis procedures to better compare press releases and news stories on specific content elements. This study primarily used chi-square analyses to compare the frequency with which specific content elements appeared in press releases and news stories. Although risks and benefits were compared for the entire time period and within the pre- and post-WHI period, even these period-based analyses spanned a fairly large period of time. For this reason, it is not possible to determine whether press releases and news stories were talking about the same thing at the same points in time. Another, more time-sensitive approach would be to see if specific elements of content in press releases and news stories positively correlate with one another over time.

Another direction would be to complete the picture this longitudinal study has created by adding prescribing data for HT products, which is available for the study time period via the National Ambulatory and Medical Care Survey. Data to assess pharmaceutical spending on direct to consumer advertising, medical journal advertising, detailing, and sampling can also be obtained from market research firms. The addition of these data sequences would help determine how pharmaceutical companies use advertising and public relations tactics synergistically to stimulate demand for their products.

Replicating this study for other prescription drugs would also be important to see if the pattern of findings found in this study is relevant for other products. A more detailed study focused exclusively on nonprofit health and medical organizations with a

more extensive effort to investigate their funding sources might also be productive. For the case of HT specifically, analysis of women's magazines to see if the content was similar to what was found in this study or different would be useful. Magazines may have played a role in transmitting some of the more popular myths about HT's ability to improve well-being and appearance, such as mood and skin, which appeared infrequently in this study.

Conclusion

This study confirmed the utility of the theoretical framework proposed by Zoch and Molleda (2006) for understanding how organizations conduct media relations strategically to build and frame the news media agenda. Theoretically, this study enhanced understanding of agenda building, information subsidies, and framing by exploring the interconnections between them to see how organizations produced and framed information subsidies, alone and in collaboration with others, to build the news media agenda. Hormone therapy (HT) for postmenopausal women provided a productive context to test this theoretical framework and provided further contributions to the literatures on prescription drug promotion and conflict of interest in medicine, along with practical suggestions to improve communication about the benefits and risks of prescription drugs.

A key strength of this study was its longitudinal design, which allowed me to observe how organizations used information subsidies to respond to changing circumstances that unfolded over time. Another strength was its use of multiple methodologies. Quantitative content analysis established a reproducible, stable fact pattern over time, which was supplemented with qualitative content analysis to add depth

and nuance and archival document analysis to provide historical context. Future scholars can build upon this study and its methodology to further advance public relations theory in the area of media relations and to better understand the strategies and tactics of the pharmaceutical industry and other health and medical organizations that communicate about prescription drugs and other medical interventions.

Appendix A: Newspaper Circulation Figures

Table A1: Circulation Figures for Selected Newspapers

Newspaper	Daily Circulation	Sunday Circulation	National Rank based on Circulation	Owner
<i>The Wall Street Journal</i>	2,117,796	1,994,121	1	News Corporation
<i>The New York Times</i>	916,911	1,339,462	3	The New York Times Company
<i>Los Angeles Times</i>	605,243	948,889	4	Tribune Company
<i>The Washington Post</i>	550,821	852,861	6	The Washington Post Company

Audit Bureau of Circulation, 2011

Appendix B: Brand Name HT Drugs

Table B1: Brand Name Prescription HT Drugs/Dates of Entry to Market (1995 to Present)

This table was used to generate keywords for database search strings. It was also used for contextual background when interpreting the data historically over time to understand when different brand-name HT drugs and formulations entered the U.S. market.

Estrogen-Only Products				
Brand Name	Active Ingredient	Manufacturer	Dosage/Route/ Strength	FDA Approval Date
Alora	Estradiol	Watson Labs	Transdermal; .1MG	12/20/1996
Alora	Estradiol	Watson Labs	Transdermal; .05MG	12/20/1996
Alora	Estradiol	Watson Labs	Transdermal; .075MG	12/20/1996
Alora	Estradiol	Watson Labs	Transdermal; .025MG	4/5/2002
Cenestin	Estrogens, Conjugated Synthetic A	Teva Womens	Tablet; Oral; 0.625 MG	3/24/1999
Cenestin	Estrogens, Conjugated Synthetic A	Teva Womens	Tablet; Oral; 0.9 MG	3/24/1999
Cenestin	Estrogens, Conjugated Synthetic A	Teva Womens	Tablet; Oral; 1.25MG	3/13/2000
Cenestin	Estrogens, Conjugated Synthetic A	Teva Womens	Tablet; Oral; 0.3MG	6/21/2002
Cenestin	Estrogens, Conjugated Synthetic A	Teva Womens	Tablet; Oral; 0.45 MG	2/5/2004
Climara	Estradiol	Bayer Healthcare	Transdermal .1MG	12/22/1994
Climara	Estradiol	Bayer Healthcare	Transdermal .075 MG	3/23/1998
Climara	Estradiol	Bayer Healthcare	Transdermal .05 MG	12/22/1994
Climara	Estradiol	Bayer Healthcare	Transdermal .06 MG	5/27/2003
Climara	Estradiol	Bayer Healthcare	Transdermal .0375	5/27/2003
Climara	Estradiol	Bayer Healthcare	Transdermal .025	3/5/1999
Delestrogen	Estradiol Valerate	JHP Pharms	Injectable 40 MG/ML	Prior to 1/1/1982
Delestrogen	Estradiol Valerate	JHP Pharms	Injectable 20 MG/ML	Prior to 1/1/1982
Delestrogen	Estradiol Valerate	JHP Pharms	Injectable 10 MG/ML	Prior to 1/1/1982

Estrogen-Only Products (Continued)				
Brand Name	Active Ingredient	Manufacturer	Dosage/Route/ Strength	FDA Approval Date
Depo-Estradiol	Estradiol Cypionate	Pharmacia and Upjohn	Injectable 5MG/ML	Prior to 1/1/1982
Divigel	Estradiol	Upsher Smith	Transdermal Gel 0.1%	6/4/2007
Elestrin	Estradiol	Azur Pharma II	Transdermal Gel 0.06%	12/15/2006
Enjuvia	Estrogens, Conjugated Synthetic B	Teva Womens	Tablet; Oral; 1.25MG	5/10/2004
Enjuvia	Estrogens, Conjugated Synthetic B	Teva Womens	Tablet; Oral; 0.3MG	12/20/2004
Enjuvia	Estrogens, Conjugated Synthetic B	Teva Womens	Tablet; Oral; 0.45 MG	12/20/2004
Enjuvia	Estrogens, Conjugated Synthetic B	Teva Womens	Tablet; Oral; 0.9 MG	4/27/2007
Enjuvia	Estrogens, Conjugated Synthetic B	Teva Womens	Tablet; Oral; 0.625 MG	5/10/2004
Estrace	Estradiol	Warner Chilcott	Vaginal Cream 0.01%	1/31/1984
Estrace	Estradiol	Bristol Myers Squibb	Tablets; Oral 2MG	Prior to 1/1/1982
Estrace	Estradiol	Bristol Myers Squibb	Tablets; Oral 1MG	Prior to 1/1/1982
Estraderm	Estradiol	Novartis	Transdermal 0.05 MG	9/10/1986
Estraderm	Estradiol	Novartis	Transdermal 0.1 MG	9/10/1986
Estrasorb	Estradiol Hemihydrate	Medicis	Emulsion Topical 0.25%	10/9/2003
Estratab	Estrogens, Esterified	Solvay	Tablet; Oral 2.5 MG; 1.25 MG; 0.625 MG; 0.3MG	Discont.
Estring	Estradiol	Pharmacia and Upjohn	Vaginal Insert .0075 MG	4/26/1996
Evamist	Estradiol	KV Pharm	Transdermal Spray 1.53 MG	7/27/2007
Femring	Estradiol Acetate	Galen Ltd.	Vaginal Insert 0.1MG	3/20/2003
Femring	Estradiol Acetate	Galen Ltd.	Vaginal Insert 0.05 MG	3/20/2003
Femtrace	Estradiol Acetate	Warner Chilcott	Tablet; Oral 1.8 MG	8/20/2004
Femtrace	Estradiol Acetate	Warner Chilcott	Tablet; Oral 0.9 MG	8/20/2004

Estrogen-Only Products (Continued)				
Brand Name	Active Ingredient	Manufacturer	Dosage/Route/ Strength	FDA Approval Date
Femtrace	Estradiol Acetate	Warner Chilcott	Tablet; Oral 0.45 MG	8/20/2004
Menest	Estrogens; Esterified	Monarch Pharms	Tablet; Oral; 0.3MG	Prior 1/1/1982
Menest	Estrogens; Esterified	Monarch Pharms	Tablet; Oral; 0.625 MG	Prior 1/1/1982
Menest	Estrogens; Esterified	Monarch Pharms	Tablet; Oral; 1.25MG	Prior 1/1/1982
Menest	Estrogens; Esterified	Monarch Pharms	Tablet; Oral; 2.5MG	Prior 1/1/1982
Menostar	Estradiol	Bayer Healthcare	Trandermal 0.014 MG	6/8/2004
Ogen	Estropipate	Pharmacia and Upjohn	Tablet; Oral 6MG	Prior to 1/1/1982
Ogen	Estropipate	Pharmacia and Upjohn	Tablet; Oral 3MG	Prior to 1/1/1982
Ogen	Estropipate	Pharmacia and Upjohn	Tablet; Oral 1.5MG	Prior to 1/1/1982
Ogen	Estropipate	Pharmacia and Upjohn	Tablet; Oral .75MG	Prior to 1/1/1982
Ortho-Est	Estropipate	Sun Pharm INDS	Tablet; Oral 1.5 MG	7/17/1991
Ortho-Est	Estropipate	Sun Pharm INDS	Tablet; Oral 0.75 MG	2/27/1991
Premarin	Estrogens; Conjugated	Wyeth	Tablet; Oral; 1.25 MG	Prior to 1/1/1982
Premarin	Estrogens; Conjugated	Wyeth	Tablet; Oral; 0.3MG	Prior to 1/1/1982
Premarin	Estrogens; Conjugated	Wyeth	Tablet; Oral; 0.625 MG	Prior to 1/1/1982
Premarin	Estrogens; Conjugated	Wyeth	Tablet; Oral; 0.9 MG	1/26/1984
Premarin	Estrogens; Conjugated	Wyeth	Tablet; Oral; 0.45 MG	7/16/2003
Premarin	Estrogens; Conjugated	Wyeth	Cream; Topical, Vaginal; 625MG	Prior 1/1/1982
Premarin	Estrogens; Conjugated	Wyeth	Injectable; 25MG/VIAL	Prior 1/1/1982
Vagifem	Estradiol	Novo Nordisk Inc.	Tablet; Vaginal 10 MCG	11/25/2009
Vivelle	Estradiol	Novartis	Transdermal Film 0.1 MG	10/28/1994

Estrogen-Only Products (Continued)				
Brand Name	Active Ingredient	Manufacturer	Dosage/Route/ Strength	FDA Approval Date
Vivelle	Estradiol	Novartis	Transdermal Film 0.05 MG	10/28/1994
Vivelle-dot	Estradiol	Novartis	Transdermal Film 0.1MG	1/8/1999
Vivelle-dot	Estradiol	Novartis	Transdermal Film 0.075 MG	1/8/1999
Vivelle-dot	Estradiol	Novartis	Transdermal Film 0.05 MG	1/8/1999
Vivelle-dot	Estradiol	Novartis	Transdermal Film 0.0375 MG	1/8/1999
Vivelle-dot	Estradiol	Novartis	Transdermal Film 0.025 MG	5/3/2002
Estrogen + Progestin Products				
Brand Name	Active Ingredient	Manufacturer	Dosage/Route/ Strength	FDA Approval
Activella	Estradiol; Norethindrone Acetate	Novo Nordisk Inc	Tablet; Oral 1MG; 0.5MG	11/18/1998
Activella	Estradiol; Norethindrone Acetate	Novo Nordisk Inc	Tablet; Oral 0.5MG;0.1MG	12/28/2006
Angeliq	Estradiol; Drospirenone;	Bayer Healthcare	Tablet; Oral; 1MG/.5MG	9/28/2005
Angeliq	Ethinyl Estradiol; Drospirenone	Bayer Healthcare	Tablet; Oral; 0.25MG;0.5MG	2/29/2012
Climara Pro	Estradiol; Levonorgestrel	Bayer Healthcare	Transdermal 0.045 MG/0.015 MG	11/21/2003
CombiPatch	Estradiol; Norethindrone Acetate	Novartis	Transdermal 0.05 MG; 0.25 MG	8/7/1998
CombiPatch	Estradiol; Norethindrone Acetate	Novartis	Transdermal 0.05MG;0.14MG	8/7/1998
Femhrt	Ethinyl Estradiol; Norethindrone Acetate	Warner Chilcott	Tablet; Oral 0.005; 1MG	10/15/1999
Femhrt	Ethinyl Estradiol; Norethindrone Acetate	Warner Chilcott	Tablet; Oral 0.0025; 0.5MG	1/14/2005
Prefest	Estradiol; Norgestimate	Teva Women's	Tablet; Oral 1MG, 1MG, N/A 0.09 MG	10/22/1999

Estrogen + Progestin Products (Continued)				
Brand Name	Active Ingredient	Manufacturer	Dosage/Route/ Strength	FDA Approval
Premphase 14/14	Estrogens, Conjugated; Medroxyprogesterone Acetate	Wyeth	Tablet, Oral-28; 0.625 MG/.625 MG; N/A 5 MG	11/17/1995
Prempro	Estrogens, Conjugated; Medroxyprogesterone Acetate	Wyeth	Tablet, Oral-28; 0.625 MG/2.5 MG	11/17/1995
Prempro	Estrogens, Conjugated; Medroxyprogesterone Acetate	Wyeth	Tablet, Oral-28; 0.625 MG/5 MG	01/09/1998
Prempro	Estrogens, Conjugated; Medroxyprogesterone Acetate	Wyeth	Tablet, Oral-28; 0.45 MG/1.5 MG	03/12/2003
Prempro	Estrogens, Conjugated; Medroxyprogesterone Acetate	Wyeth	Tablet, Oral-28; 0.3 MG/1.5 MG	06/04/2003
Progesterone/Progestin Products (used in conjunction with estrogen)				
Brand Name	Active Ingredient	Manufacturer	Dosage/Route/Stren gth	FDA Approval
Prometrium	Progesterone	Abbott Labs	Capsule; Oral 200 MG	10/15/1999
Prometrium	Progesterone	Abbott Labs	Capsule; Oral 100 MG	5/14/1998
Provera	Medroxyprogesterone Acetate	Pharmacia and Upjohn	Tablet; Oral 10MG	Prior to 1/1/1982
Provera	Medroxyprogesterone Acetate	Pharmacia and Upjohn	Tablet; Oral 5MG	Prior to 1/1/1982
Provera	Medroxyprogesterone Acetate	Pharmacia and Upjohn	Tablet; Oral 2.5MG	Prior to 1/1/1982

Data Sources:

Drugs@FDA (USDHHS, FDA, 2011b)

Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (USDHHS, FDA, 2011c)

Appendix C: Protocol and Codebook for Press Releases

Coding Protocol/Instructions for Press Releases

The protocol below describes each variable and demonstrates how the variable looks on the code sheet. The code sheet for press releases follows this protocol of instructions.

Each press release should be coded on a separate coding sheet.

PV1: Coder #

Please enter the coder # assigned to you in the blank.

PV1: Coder #: _____

PV2: Press Release ID#

Please enter the ID number that is written on the press release that you will code. You can find the number in the upper right hand corner of the first page of the release.

PV2: Press Release ID#: _____

PV3: Release Date

Write-in the two digit month, two-digit day, and four-digit year that appears on the press release. You will find the date at the top of the first page listed under the source.

PV3: Release Date: _____(Month) _____(Day) _____(Year)

PV4. Primarily about HT

This study is focused on press releases primarily about menopausal hormone therapy (HT). Some releases may have qualified for inclusion based on the search terms appearing in the headline, but the search terms were really being used in the context of something different than menopausal HT. These releases should be eliminated. For example, some releases that use the term “hormone therapy” or “hormone therapies” refer to therapies given after a sex change or treatments for prostate cancer in men or breast cancer in women, not menopause. As another example, the term estrogen may come up in a range of releases (e.g., stories about puberty, birth control pills) that have nothing to do with HT. Releases may also appear that discuss the role of declining estrogen in menopause, but never mention HT treatment in any way. These releases should all be eliminated based on the question below:

PV4: Do any of the study search terms that were identified in the headline refer to hormone therapy (HT) for menopause or symptoms or conditions associated with menopause?

_____(1) Yes _____(0) No – IF NO, ELIMINATE

If you indicated “no” above, you can stop coding the document. Place the document in the elimination file. Place this code sheet in the completed code sheet file. Code the next document. Make sure to use a new code sheet for each document, regardless of whether or not the document is eliminated.

PV5: Type of Release Description

This study is focused on press releases that are primarily about menopausal hormone therapy (HT). Sometimes the study search terms may appear in the headline, but the release is not focused on HT in a way that provides any substantive information about its use in the treatment of menopausal women. For example, releases that focus on news about the organizations involved in the production or distribution of HT (and only mention HT briefly, in passing) should be eliminated. This may include releases that report on mergers, acquisitions, patent disputes, licensing and marketing agreements between firms, personnel news, or quarterly financial earnings. Press releases that publicize services by market research/forecasting firms or entertainment products, such as film, television, books, or theater productions should also be eliminated. A press release that reports on a study about HT that was solely conducted in animals without discussion of any findings or implications for humans should also be eliminated.

PV5: Which of the following BEST describes this press release?

	Circle Code
Publicity <u>primarily</u> about the organization as opposed to HT (e.g. mergers/acquisitions/patent disputes/licensing and marketing agreements between firms/personnel news/quarterly financial earnings reports in which HT is <u>just briefly mentioned in passing</u>)	1
Publicity by industry/market forecasting firms (e.g., Report Linker market trend reports, etc.)	2
Publicity for film/television/book/theater/other entertainment products	3
Story about study conducted in animals only	4
None of the Above	0

If you circled 1, 2, 3, or 4 above, ELIMINATE and stop coding the document. Place the document in the elimination file. Place this code sheet in the completed code sheet file. Code the next document. Make sure to use a new code sheet for each document, regardless of whether or not the document is eliminated.

PV6: Organization Names/Produced Release

Look at the SOURCE field at the bottom of the press release. Write the full names of any organizations listed in the SOURCE field of the release.

PV7: Types of Organizations/Distributed Release

Look at the SOURCE field at the bottom of the press release. For each organization listed, classify it into the category below that best describes the type of organization it is. Each category has a brief description next to it. Below each category are a few examples of organizations that would be coded into each category. To determine nonprofit status (501c3 or 501c6) use the *GuideStar* database. If the organization cannot be found in the *GuideStar* database, review the organization's website if available.

If an organization type appears more than once in the same release, you only need to mark its category in the grid below once.

PV7. Are any of the following types of organizations listed in the SOURCE field of the release?

Organization Types	Yes (1)	No (0)
a) Pharmaceutical Company A company that manufacturers/sells prescription drugs (e.g., Wyeth, Duramed, Eli Lilly, Solvay Pharmaceuticals)		
b) Other For-Profit Company Any other for-profit company that is not a pharmaceutical company (e.g., Natural Products, Ltd., CVS, Walmart)		
c) U.S. Government Any federal government agency or entity (e.g., National Institutes of Health, Office of Women's Health, National Heart, Lung, & Blood Institute, Food & Drug Administration, Centers for Disease Control & Prevention)		
d) Academic/Medical Institutions Universities, hospitals, medical centers, or other clinical centers involved in medical research and treatment (e.g., Harvard University, Emory University, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, University of Massachusetts Medical Center, Hospital of the University of Pennsylvania, Ralph Lauren Cancer Center, Memorial-Sloan Kettering Cancer Center)		

e) Medical Professional Societies /Trade Associations (501c6) Nonprofit 501c6 professional membership organizations (e.g., American Medical Association, AMA; American College of Obstetricians & Gynecologists (ACOG); the Endocrine Society; and Pharmaceutical Research Manufacturers of America (PhRMA)		
f) Health Advocacy Organizations (501c3) Nonprofit 501c3 patient or disease-specific health-advocacy organizations or foundations (e.g., National Women’s Health Network, American Heart Association, National Osteoporosis Foundation, Alzheimer’s Foundation)		
g) Coalition An organized group of multiple organizations or constituents (e.g., National Breast Cancer Coalition)		
h) Medical/Scientific Journal Publishers Publishers of medical/scientific journals (e.g., Blackwell Publishing, JAMA and Archives Journals)		
i) Other (OTH) Any organization type not mentioned above, including non-U.S.-based international organizations that cannot be classified above.		

PV8: Organization Names/Release Contact

Look at the CONTACT fields of the release. Write the full names of any organizations listed in the CONTACT field of the release.

PV9: Types of Organizations/Release Contact

For each organization listed in the CONTACT field classify it into the category below that best describes the type of organization it is. Each category has a brief description next to it. Below each category are a few examples of organizations that would be coded into each category. To determine nonprofit status (501c3 or 501c6) use the *GuideStar* database. If the organization cannot be found in the *GuideStar* database, review the organization’s website if available.

If an organization type appears more than once in the same release, you only need to mark its category in the grid below once.

Organization Types	Yes (1)	No (0)
a) Pharmaceutical Company A company that manufactures/sells prescription drugs (e.g., Wyeth, Duramed, Eli Lilly, Solvay Pharmaceuticals)		
b) Other For-Profit Company Any other for-profit company that is not a pharmaceutical company (e.g., Natural Products, Ltd., CVS, Walmart)		
c) U.S. Government Any federal government agency or entity (e.g., National Institutes of Health, Office of Women's Health, National Heart, Lung, & Blood Institute, Food & Drug Administration, Centers for Disease Control & Prevention)		
d) Academic/Medical Institutions Universities, hospitals, medical centers, or other clinical centers involved in medical research and treatment (e.g., Harvard University, Emory University, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, University of Massachusetts Medical Center, Hospital of the University of Pennsylvania, Ralph Lauren Cancer Center, Memorial-Sloan Kettering Cancer Center)		
e) Medical Professional Societies /Trade Associations (501c6) Nonprofit 501c6 professional membership organizations (e.g., American Medical Association, AMA; American College of Obstetricians & Gynecologists (ACOG); the Endocrine Society; and Pharmaceutical Research Manufacturers of America (PhRMA)		
f) Health Advocacy Organizations (501c3) Nonprofit 501c3 patient or disease-specific health-advocacy organizations or foundations (e.g., National Women's Health Network, American Heart Association, National Osteoporosis Foundation, Alzheimer's Foundation)		
g) Coalition An organized group of multiple organizations or constituents (e.g., National Breast Cancer Coalition)		
h) Medical/Scientific Journal Publishers Publishers of medical/scientific journals. (e.g., Blackwell Publishing, JAMA and Archives Journals)		
i) Other (OTH) Any organization type not mentioned above, including non-U.S.-based international organizations that cannot be classified above.		

PV10: Risks

This coding activity on HT risks has 4 parts for each potential risk mentioned in the release text.

Part 1

First, if the risk is identified as possible anywhere in the release text, put an X in the “yes” category in the “Identified?” column. If it is not identified in the text, put an X in the “no” category in the “Identified?” column.

You should code “Identified?” as “yes,” if the possibility of the risk of HT is mentioned in the text, even if the text says there is some uncertainty about the risk/science is not conclusive, etc. You should code based on what is being identified in the releases as a possible risk at the present time. You should not code “yes” if the release says that something is not a risk, or was thought be a risk in the past, but no longer is. A mark of “yes” indicates that the release is making at least some suggestion that the risk is currently possible for some women who take HT.

For example, if a release said:

“Hormone therapy has been linked to a greater risk of dementia and heart attacks when given to women after 65.”

Dementia and heart disease would both be coded as “yes” in the “Identified?” column.

For example, if a release said:

“In the past, it was thought that hearing loss was a possible risk of HT, but current evidence indicates that this is not the case.”

Hearing loss would be coded as “no” in the “Identified?” category. The words hearing loss are present in the text, but the text is clearly suggesting this is not believed to be a risk of HT at the current time.

Part 2

For each risk that was checked as “yes” in the “Identified?” category, check whether the probability of the risk occurring was quantified in any way in the “Quantified?” column. Check “yes” if any numbers at all were used. Check no if no numbers were used at all.

Part 3

For each risk that was checked “yes” in the “Identified?” column, check whether the risk was presented in relative terms or not. Relative risk presentations present numbers that compare the chance of a risk occurring in individuals exposed to a risk factor vs. those not exposed. These numbers are often percents, but could also be in the form of rates or ratios.

For example, you would check “yes” in the “Relative?” column if the following text appeared in a release.

“Among smokers, 3.4 percent of hormone users died of lung cancer, compared with 2.3 percent in the placebo group.”

You would also check “yes” in the “Relative?” column if the following text appeared in a release.

“This part of the study was halted when researchers saw a 26 percent higher risk of breast cancer in women taking Prempro.”

Part 4

For each risk that was checked “yes” in the “Quantified?” column, check whether the risk was presented in absolute terms or not. Absolute risk presentations quantify a risk in terms of how many individuals in the population will actually experience the risk in terms of a given number of individuals or over a given period of time.

For example, the following passage would be coded as “yes” for the “Relative?” category above and “yes” for the “Absolute” category.

“Several experts stressed, however, that the absolute risk of dying from breast cancer was very low - in the new study 25 women died from breast cancer among those taking the hormones compared with 12 among those who took a placebo. The risk translates into about 1.3 additional deaths from breast cancer each year for every 10,000 women taking hormones, the study found.”

In the above text, the comparison of 25 women (taking hormones) vs. 12 women (placebo) is a relative risk comparison. The last sentence that translates how often the event will actually occur per 10,000 women per year is an absolute risk presentation.

Below is how the grid will look on the code sheet:

PV10. For each potential risk of HT below, check whether it was identified as possible or not in any part of the release. If identified, check whether the probability of the risk was quantified in any way. If quantified, check if it was quantified in relative and/or absolute terms.

Risk	Identified?		Quantified?		Relative?		Absolute?	
	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)
a) Breast cancer								
b) Cognitive (e.g., dementia/Alzheimer's)								
c) Gallbladder disease								
d) Heart attack/Heart Disease/Cardiovascular disease								
e) Stroke								
f) Thrombosis/blood clots								
g) Uterine/endometrial cancer (also includes ovarian cancer)								
h) Other 1 (Specify)								
i) Other 2 (Specify)								

PV11: Benefits

Follow the same rules as above (as outlined for PV10: Risks) for any of the following potential benefits identified in the release.

PV11. For each potential benefit of HT below, check whether it was identified as possible or not in any part of the release. If identified, check whether the probability of the benefit was quantified in any way. If quantified, check if it was quantified in relative and/or absolute terms.

Benefit	Identified?		Quantified?		Relative?		Absolute?	
	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)
a) Cognitive Decline Reduced (e.g., dementia, Alzheimer's, etc.)								
b) Colon/Colorectal Cancer Reduced								
c) Heart Attack/Heart Disease/Cardiovascular Disease								
d) Hot Flashes/Night Sweats (vasomotor symptoms) Reduced								
e) Mood Problems Reduced (e.g., depression, irritability)								
f) Osteoporosis/Fractures Reduced								

g) Sex Life Improved (more libido/sexual activity, etc.)								
h) Skin Improved (less wrinkling/aging, etc.)								
i) Sleep Problems/Insomnia Reduced								
j) Vaginal Problems Reduced (atrophy, dryness, etc.)								
k) Other1 (Specify)								
l) Other2 (Specify)								

PV12. Brand Name Mentions

PV12. For each brand name below, check whether it appeared or not in any part of the release.

	Yes (1)	No (0)		Yes (1)	No (0)
Activella/Activelle			Evamist		
Alora			FemHRT		
Angeliq			Femring		
Cenestin			Femtrace		
Climara/Pro			Menest		
CombiPatch			Menostar		
Delestrogen			Ogen		
Depo-Estradiol			Ortho-Est		
Divigel			Prefest		
Elestrin			Premarin		
Enjuvia			Premphase		
Estrace			Prempro		
Estraderm			Prometrium		
Estrasorb			Provera		
Estratab			Vagifem		
Estratest			Vivelle/Vivelle-dot		
Estring			Other1/(Specify):		
			Other2/(Specify):		

PV13: Medical/Scientific Journal Referenced

If the release refers to or mentions a medical professional or scientific journal anywhere in the text, check “yes.” If not, check “no.” Examples of medical professional and scientific journals are: the *Journal of the American Medical Association* (JAMA), the *New England Journal of Medicine*, *Journal of Women’s Health*, and *Science*, etc.

PV13. Does the release refer to a medical professional or scientific journal anywhere in the text?

_____ Yes (1)

_____ No (0)

PV14: Journal Name

V14: If any medical professional or scientific journals were mentioned in the text of the release, write the full names of all of them below.

PV15: Organization Names/Mentioned in Body Text

V15: Write the full names of any organizations mention in the body text of the release.

PV16: Types of Organizations/Mentioned in Body Text

For each organization mentioned in the body text of the release, classify it into the category below that best describes the type of organization it is. Each category has a brief description next to it. To determine nonprofit status (501c3 or 501c6) use the *GuideStar* database. If the organization cannot be found in the *GuideStar* database, review the organization’s website if available.

If an organization type appears more than once in the same release, you only need to mark its category in the grid below once.

Organization Types	Yes (1)	No (0)
a) Pharmaceutical Company A company that manufactures/sells prescription drugs (e.g., Wyeth, Duramed, Eli Lilly, Solvay Pharmaceuticals)		
b) Other For-Profit Company Any other for-profit company that is not a pharmaceutical company (e.g., Natural Products, Ltd., CVS, Walmart)		
c) U.S. Government Any federal government agency or entity (e.g., National Institutes of Health, Office of Women's Health, National Heart, Lung, & Blood Institute, Food & Drug Administration, Centers for Disease Control & Prevention)		
d) Academic/Medical Institutions Universities, hospitals, medical centers, or other clinical centers involved in medical research and treatment (e.g., Harvard University, Emory University, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, University of Massachusetts Medical Center, Hospital of the University of Pennsylvania, Ralph Lauren Cancer Center, Memorial-Sloan Kettering Cancer Center)		
e) Medical Professional Societies /Trade Associations (501c6) Nonprofit 501c6 professional membership organizations (e.g., American Medical Association, AMA; American College of Obstetricians & Gynecologists (ACOG); the Endocrine Society; and Pharmaceutical Research Manufacturers of America (PhRMA))		
f) Health Advocacy Organizations (501c3) Nonprofit 501c3 patient or disease-specific health-advocacy organizations or foundations (e.g., National Women's Health Network, American Heart Association, National Osteoporosis Foundation, Alzheimer's Foundation)		
g) Coalition An organized group of multiple organizations or constituents (e.g., National Breast Cancer Coalition)		
h) Other (OTH) Any organization type not mentioned above, including non-U.S.-based international organizations that cannot be classified above.		

PV17: Types of Individuals Directly Quoted

For each individual who is directly quoted in the text, classify the individual into the category below that best describes the individual. Each category has a brief description next to it. A quoted individual can fall into more than one category if they are explicitly identified in more than one way. If an individual cannot be coded into the existing categories, select the “Other” category.

V17: Are any of the following types of individuals quoted in this release?

	Yes (1)	No (0)
a) Physician and/or Scientist		
b) Nurse Practitioner/Nurse/Other Clinicians		
c) CEO/Exec/Medical Director/PR Director/Official Spokesperson		
d) Attorney		
e) Celebrity		
f) Everyday affected woman		
g) Everyday family member of affected woman		
h) Other		

PV18: Pharmaceutical Funding of Individuals

This item captures explicit mentions of pharmaceutical funding or financial support of individuals. Below are examples of such explicit mentions:

“Wyeth named Dr. Utian a ‘Partner in Menopause Education’ (requiring a contribution of at least \$8,000) for the NAMS' 2007 Annual Meeting. Additionally, half of NAMS's Board of Trustees for 2007-2008 receives consulting fees or research support from Wyeth, including Dr. Utian.”

“The study is published in the journal Neurology. One author is a former employee of Wyeth, which sells Prempro.”

V18. Does the release explicitly mention pharmaceutical company funding of any individuals?

_____ 1 (Yes) _____ 0 (No)

PV19: Pharmaceutical Funding of Organizations

This item captures explicit mentions of pharmaceutical funding or financial support of organizations and their activities. Below are examples of such explicit mentions:

“The study was funded by the National Osteoporosis Foundation (NOF). NOF receives funding from Wyeth, which sells Prempro.”

“The National Association of Nurse Practitioners in Women's Health developed and launched the campaign with financial support from Upsher-Smith Women's Health.”

“The North American Menopause Society has created a comprehensive guidebook. Supported by an unrestricted educational grant from Berlex Laboratories, makers of Climara, the Menopause Guidebook is available on www.menopause.org. Berlex did not influence any of its contents.”

PV19. Does the release explicitly mention pharmaceutical company funding of any organizations?

_____ 1 (Yes) _____ 0 (No)

PV20: Pharmaceutical Funding of Research Studies

This item captures explicit mentions of pharmaceutical funding or financial support of research studies. Research studies can include unpublished clinical studies, published studies in scientific/medical journals, or a variety of consumer-oriented research studies (e.g., public opinion/survey studies). Below are examples of such explicit mentions:

"This study confirms what the medical community and the public already know about HRT and the treatment of heart disease," says Victoria Kusiak, M.D., Vice President, Global Medical Affairs and North American Medical Director for Wyeth Pharmaceuticals, the study's sponsor.”

“David F. Archer, M.D., professor of obstetrics and gynecology at EVMS' Jones Institute of Reproductive Medicine, was among a group of researchers in various parts of the United States who conducted the five-year study, which involved about 2,700 women and was funded by Wyeth-Ayerst Laboratories.”

“The New World of HRT study, sponsored by Pharmacia Corporation, was conducted by SRI Business Intelligence Center in April 2000.”

PV20: Does the release explicitly mention pharmaceutical funding of any research studies?

_____ 1 (Yes) _____ 0 (No)

CODE SHEET FOR PRESS RELEASES BEGINS ON NEXT PAGE

PV1: Coder #: _____ PV2: Press Release ID #: _____ PV3: Date: _____(Month)_____(Day) _____(Year)

PV4: Do any of the study search terms that were identified in the headline refer to hormone therapy (HT) for menopause or symptoms or conditions associated with menopause?

_____ (1) Yes _____ (0) No (IF NO, **ELIMINATE**)

PV5: Which of the following BEST describes this press release?

	Circle Code
Publicity <u>primarily</u> about the organization as opposed to HT (e.g. mergers/acquisitions/patent disputes/licensing and marketing agreements between firms/personnel news/quarterly financial earnings reports in which HT is <u>just briefly mentioned in passing</u>)	1
Publicity by industry/market forecasting firms (e.g. Report Linker market trend reports, etc.)	2
Publicity for film/television/book/theater/other entertainment products	3
Story about study conducted in animals only	4
None of the above	0

(IF SELECTED 1, 2, 3, or 4 ABOVE, **ELIMINATE**)

PV6: Organization Names/Produced Release:

PV7: Are any of the following types of organizations listed in the SOURCE field of the release?

Organization Types	Yes (1)	No (0)		Yes (1)	No (0)
a) Pharmaceutical Company			f) Health Advocacy Organizations (501c3)		
b) Other Company			g) Coalition		
c) U.S. Government			h) Medical/Scientific Journal Publishers		
d) Academic/Medical Institution			i) Other		
e) Medical Prof. /Trade Assoc. (501c6)					

PV8: Organization Names/Release Contact:

PV9: Are any of the following types of organizations listed in the CONTACT field of the release?

Organization Types	Yes (1)	No (0)		Yes (1)	No (0)
a) Pharmaceutical Company			f) Health Advocacy Organizations (501c3)		
b) Other For-Profit Company			g) Coalition		
c) U.S. Government			h) Medical/Scientific Journal Publishers		
d) Academic/Medical Institutions			i) Other		
e) Medical Prof. /Trade Assoc. (501c6)					

PV10. For each potential risk of HT below, check the relevant columns.

Potential Risks	Identified? (ID)		Quant? (QT)		Relative? (REL)		Absolute? (ABS)	
	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)
a) Breast cancer								
b) Cognitive (e.g., dementia, Alzheimer's)								
c) Gallbladder disease								
d) Heart attack/Heart disease/Cardiovascular disease								
e) Stroke								
f) Thrombosis/blood clots								
g) Uterine/endometrial cancer (includes ovarian cancer)								
h) Other1 (Specify):								
i) Other2 (Specify):								

PV11. For each potential benefit of HT below, check the relevant columns.

Potential Benefits	Identified? (ID)		Quantified? (QT)		Relative? (REL)		Absolute? (ABS)	
	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)
a) Cognitive Decline Reduced (e.g., dementia, Alzheimer's)								
b) Colon/Colorectal Cancer Reduced								
c) Heart Attack/Heart Disease/Cardiovascular Disease Reduced								
d) Hot Flashes/Night Sweats (vasomotor symptoms) Reduced								
e) Mood Problems Reduced (e.g., depression, irritability)								
f) Osteoporosis/Fractures Reduced								
g) Sex Life Improved (e.g., more libido/sexual activity)								
h) Skin Improved (e.g., less wrinkles, aging)								
i) Sleep Problems/Insomnia Reduced								
j) Vaginal Problems Reduced (e.g., atrophy, dryness)								
k) Other1 (Specify):								
l) Other2 (Specify):								

PV12. For each brand name below, check whether it appeared or not in any part of the release.

	Yes (1)	No (0)		Yes (1)	No (0)		Yes (1)	No (0)		Yes (1)	No (0)
Activella/Activelle			Divigel			Evamist			Prefest		
Alora			Elestrin			FemHRT			Premarin		
Angeliq			Enjuvia			Femring			Premphase		
Cenestin			Estrace			Femtrace			Prempro		
Climara/Pro			Estraderm			Menest			Prometrium		
CombiPatch			Estrasorb			Menostar			Provera		
Delestrogen			Estratab			Ogen			Vagifem		
Depo-Estradiol			Estratest			Ortho-Est			Vivelle/Vivelle-dot		
			Estring			Other1/(Specify):			Other2/(Specify):		

PV13. Does the release refer to a medical professional or scientific journal anywhere in the text?

_____ Yes (1) _____ No (0)

PV14: Journal Name: If any medical professional or scientific journals were mentioned in the release text, write them all below.

PV15: Organization Names/Mentioned in Body Text:

PV16: Are any of the following types of organizations mentioned in the BODY TEXT of the release?

Organization Types	Yes (1)	No (0)		Yes (1)	No (0)
a) Pharmaceutical Company			f) Health Advocacy Organizations (501c3)		
b) Other For-Profit Company			g) Coalition		
c) U.S. Government			h) Other		
d) Academic/Medical Institutions					
e) Medical Prof./Trade Assoc. (501c6)					

PV17: Are any of the following types of individuals directly quoted in this release?

	Yes (1)	No (0)
a) Physician and/or Scientist		
b) Nurse Practitioner/Nurse/Other Clinicians		
c) CEO/Exec/Medical Director/PR Director/Official Spokesperson		
d) Attorney		
e) Celebrity		
f) Everyday affected woman		
g) Everyday family member of affected woman		
h) Other		

PV18. Does the release explicitly mention pharmaceutical company funding of any individuals?

____(1) Yes ____ (0) No

PV19. Does the release explicitly mention pharmaceutical company funding of any organizations?

____(1) Yes ____ (0) No

PV20: Does the release explicitly mention pharmaceutical company funding of any research studies?

____(1) Yes ____ (0) No

Appendix D: Protocol and Codebook for News Stories

Coding Protocol/Instructions for News Stories

The protocol below describes each variable and demonstrates how the variable looks on the code sheet. The code sheet for news stories follows this protocol of instructions.

Each news story should be coded on a separate coding sheet.

NV1: Coder #

Please enter the coder # assigned to you in the blank.

NV1: Coder #: _____

NV2: News Story ID

Please enter the ID number that is written on the news story that you will code. You can find the number in the upper right hand corner of the first page of the story.

NV2: News Story ID: _____

NV3: Publication Date

Write-in the two digit month, two-digit day, and four-digit year that the news story was published. You will find the publication date at the top of the first page listed under the source.

NV3: Publication Date: _____(Month) _____(Day) _____(Year)

NV4: Primarily about HT

This study is focused on news stories primarily about menopausal hormone therapy (HT). Some stories may have qualified for inclusion based on the search terms appearing in the headline, but the search terms were really being used in the context of something different than menopausal HT. These releases should be eliminated. For example, some stories that use the term “hormone therapy” or “hormone therapies” refer to therapies given after a sex change or treatments for prostate cancer in men or breast cancer in women, not menopause. As another example, the term estrogen may come up in a range of news stories (e.g., stories about puberty, birth control pills) that have nothing to do with HT. Stories may also appear that discuss the role of declining estrogen in menopause, but never mention HT in any way. These news stories should all be eliminated based on the question below:

NV4: Do any of the study search terms that were identified in the headline refer to hormone therapy (HT) for menopause or symptoms or conditions associated with menopause?

_____(1) Yes _____(0) No – IF NO, ELIMINATE

If you indicated “no” above, you can stop coding the document. Place the document in the elimination file. Place this code sheet in the completed code sheet file. Code the next document. Make sure to use a new code sheet for each document, regardless of whether or not the document is eliminated.

NV5. Type of Document Description

This study is focused on news stories and features that are primarily about HT. Sometimes the study search terms may appear in the headline, but the document is not a news story or feature or is not focused on HT in a way that provides any substantive information about its use in the treatment of menopausal women. For example, stories that focus only on news about the organizations involved in the production or distribution of HT (and only mention HT briefly, in passing) should be eliminated. This may include stories that report on mergers, acquisitions, patent disputes, licensing and marketing agreements between firms, personnel news, or quarterly financial earnings. A news story that reports on a study about HT that was solely conducted in animals without discussion of any findings or implications for humans should also be eliminated.

Columns that are best described as editorial/opinion pieces, letters to the editor, and film/television/book/theater or other types of entertainment reviews should be eliminated from the study. Q&A-style health columns in which a columnist answers questions submitted by readers should be eliminated. If a Q&A text format is embedded within a typical news story just as a way of communicating information, however, the document should be included in the study. For example, a larger news story about the confusion surrounding HT might have a Q&A section within it that lists common questions about HT, and the answers to those questions based on the current evidence. In this case, this is not a Q&A *column*, but a presentation format within a *news story*, and this news story should be coded.

NV5: Is this document best described as any of the following?

	Circle Code
Story <u>primarily</u> about the organization as opposed to HT (e.g. mergers/acquisitions/patent disputes/licensing and marketing agreements between firms/personnel news/quarterly financial earnings reports in which HT is <u>just briefly mentioned in passing</u>) Story primarily about organization	1
Letter to the editor or editorial/opinion piece	2
Film/television/book/theater/other entertainment review	3
Story about study conducted in animals only	4
Q&A-style health advice column	5
None of the above	0

If you circled 1, 2, 3, 4, or 5 above, ELIMINATE and stop coding the document. Place the document in the elimination file. Place this code sheet in the completed code sheet

file. Code the next document. Make sure to use a new code sheet for each document, regardless of whether or not the document is eliminated.

NV6. Source

Please check which news source/newspaper this story appeared in.

NV6: Which source did this story appear in?

	Circle Code
<i>Associated Press</i>	1
<i>Los Angeles Times</i>	2
<i>The New York Times</i>	3
<i>The Wall Street Journal</i>	4
<i>The Washington Post</i>	5

NV7. Brand Name Mentions

NV7. For each brand name below, check whether it appeared or not in any part of the story.

	Yes (1)	No (0)		Yes (1)	No (0)
Activella/Activelle			Evamist		
Alora			FemHRT		
Angeliq			Femring		
Cenestin			Femtrace		
Climara/Pro			Menest		
CombiPatch			Menostar		
Delestrogen			Ogen		
Depo-Estradiol			Ortho-Est		
Divigel			Prefest		
Elestrin			Premarin		
Enjuvia			Premphase		
Estrace			Prempro		
Estraderm			Prometrium		
Estrasorb			Provera		
Estratab			Vagifem		
Estratest			Vivelle/Vivelle-dot		
Estring			Other1/(Specify):		
			Other2/(Specify):		

NV8: Medical/Scientific Journal Referenced

If the news story refers to or mentions a medical professional or scientific journal anywhere in the text, check “yes.” If not, check “no.” Examples of medical professional and scientific journals are: the *Journal of the American Medical Association* (JAMA), the *New England Journal of Medicine*, *Journal of Women’s Health*, and *Science*, etc.

NV8. Does the story refer to a medical professional or scientific journal anywhere in the text?

_____ Yes (1) _____ No (0)

NV9: Journal Name

NV9: If any medical professional or scientific journals were mentioned in the text of the release, write the full names of all of them below.

NV10: Risks

This coding activity on HT risks has 4 parts for each potential risk mentioned in the news story text.

Part 1

First, if the risk is identified as possible anywhere in the story text, put an X in the “yes” category in the “Identified?” column. If it is not identified in the text, put an X in the “no” category in the “Identified?” column.

You should code “Identified?” as “yes,” if the possibility of the risk of HT is mentioned in the text, even if the text says there is some uncertainty about the risk/science is not conclusive, etc. You should code based on what is being identified in the news story as a possible risk at the present time. You should not code “yes” if the story says that something is not a risk, or was thought be a risk in the past, but no longer is. A mark of “yes” indicates that the news story is making at least some suggestion that the risk is currently possible for some women who take HT.

For example, if a news story said:

“Hormone therapy has been linked to a greater risk of dementia and heart attacks when given to women after 65.”

Dementia and heart disease would both be coded as “yes” in the “Identified?” column.

For example, if a news story said:

“In the past, it was thought that hearing loss was a possible risk of HT, but current evidence indicates that this is not the case.”

Hearing loss would be coded as “no” in the “Identified?” category. The words hearing loss are present in the text, but the text is clearly suggesting this is not believed to be a risk of HT at the current time.

Part 2

For each risk that was checked as “yes” in the “Identified?” category, check whether the probability of the risk occurring was quantified in any way in the “Quantified?” column. Check “yes” if any numbers at all were used. Check no if no numbers were used at all.

Part 3

For each risk that was checked “yes” in the “Identified?” column, check whether the risk was presented in relative terms or not. Relative risk presentations present numbers that compare the chance of a risk occurring in individuals exposed to a risk factor vs. those not exposed. These numbers are often percents, but could also be in the form of rates or ratios.

For example, you would check “yes” in the “Relative?” column if the following text appeared in a news story.

“Among smokers, 3.4 percent of hormone users died of lung cancer, compared with 2.3 percent in the placebo group.”

You would also check “yes” in the “Relative?” column if the following text appeared in a news story.

“This part of the study was halted when researchers saw a 26 percent higher risk of breast cancer in women taking Prempro.”

Part 4

For each risk that was checked “yes” in the “Quantified?” column, check whether the risk was presented in absolute terms or not. Absolute risk presentations quantify a risk in terms of how many individuals in the population will actually experience the risk in terms of a given number of individuals or over a given period of time.

For example, the following passage would be coded as “yes” for the “Relative?” category above and “yes” for the “Absolute” category.

“Several experts stressed, however, that the absolute risk of dying from breast cancer was very low - in the new study 25 women died from breast cancer among those taking the hormones compared with 12 among those who took a placebo. The risk translates into about 1.3 additional deaths from breast cancer each year for every 10,000 women taking hormones, the study found.”

In the above text, the comparison of 25 women (taking hormones) vs. 12 women (placebo) is a relative risk comparison. The last sentence that translates how often the event will actually occur per 10,000 women per year is an absolute risk presentation.

Below is how the grid will look on the code sheet:

NV10. For each potential risk of HT below, check whether it was identified as possible or not in any part of the news story. If identified, check whether the probability of the risk was quantified in any way. If quantified, check if it was quantified in relative and/or absolute terms.

Risk	Identified?		Quantified?		Relative?		Absolute?	
	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)
a) Breast cancer								
b) Cognitive (e.g., dementia/Alzheimer's)								
c) Gallbladder disease								
d) Heart attack/Heart Disease/Cardiovascular disease								
e) Stroke								
f) Thrombosis/blood clots								
g) Uterine/endometrial cancer (includes ovarian cancer)								
h) Other 1 (Specify)								
i) Other 2 (Specify)								

NV11: Benefits

Follow the same rules as above (as outlined for NV10: Risks) for any of the following potential benefits mentioned in the story.

NV11. For each potential benefit of HT below, check whether it was identified as possible or not in any part of the news story. If identified, check whether the probability of the risk was quantified in any way. If quantified, check if it was quantified in relative and/or absolute terms.

Benefit	Identified?		Quantified?		Relative?		Absolute?	
	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)
a) Cognitive Decline Reduced (e.g., dementia, Alzheimer's, etc.)								
b) Colon/Colorectal Cancer Reduced								
c) Heart Attack/Heart Disease/Cardiovascular Disease								
d) Hot Flashes/Night Sweats (vasomotor symptoms) Reduced								
e) Mood Problems Reduced (e.g., depression, irritability)								
f) Osteoporosis/Fractures Reduced								
g) Sex Life Improved (more libido/sexual activity, etc.)								
h) Skin Improved (less wrinkling/aging, etc.)								
i) Sleep Problems/Insomnia Reduced								
j) Vaginal Problems Reduced (atrophy, dryness, etc.)								
k) Other1 (Specify)								
l) Other2 (Specify)								

NV12: Individuals Quoted

For each individual who is directly quoted in the text, classify the individual into the category below that best describes the individual. Each category has a brief description next to it. A quoted individual can fall into more than one category if they are explicitly identified in more than one way. If an individual cannot be coded into the existing categories, select the “Other” category.

NV12: Are any of the following types of individuals quoted in this news story?

	Yes (1)	No (0)
a) Physician and/or Scientist		
b) Nurse Practitioner/Nurse/Other Clinicians		
c) CEO/Exec/Medical Director/PR Director/Official Spokesperson		
d) Attorney		
e) Celebrity		
f) Everyday affected woman		
g) Everyday family member of affected woman		
h) Other		

NV13: Organization Names/Mentioned in Body Text

NV13: Write the full names of any organizations mention in the body text of the story.

NV14: Types of Organizations/Mentioned in Body Text

For each organization mentioned in the body text of the news story, classify it into the category below that best describes the type of organization it is. Each category has a brief description next to it. To determine nonprofit status (501c3 or 501c6) use the *GuideStar* database. If the organization cannot be found in the *GuideStar* database, review the organization’s website if available.

If an organization type appears more than once in the same story, you only need to mark its category in the grid below once.

NV14: Are any of the following types of organizations listed in the BODY TEXT of the news story?

Organization Types	Yes (1)	No (0)
<p>a) Pharmaceutical Company A company that manufacturers/sells prescription drugs (e.g., Wyeth, Duramed, Eli Lilly, Solvay Pharmaceuticals)</p>		
<p>b) Other For-Profit Company Any other for-profit company that is not a pharmaceutical company (e.g., Natural Products, Ltd., CVS, Walmart)</p>		
<p>c) U.S. Government Any federal government agency or entity (e.g., National Institutes of Health, Office of Women’s Health, National Heart, Lung, & Blood Institute, Food & Drug Administration, Centers for Disease Control & Prevention)</p>		
<p>d) Academic/Medical Institutions Universities, hospitals, medical centers, or other clinical centers involved in medical research and treatment (e.g., Harvard University, Emory University, Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center, University of Massachusetts Medical Center, Hospital of the University of Pennsylvania, Ralph Lauren Cancer Center, Memorial-Sloan Kettering Cancer Center)</p>		
<p>e) Medical Professional Societies /Trade Associations (501c6) Nonprofit 501c6 professional membership organizations (e.g., American Medical Association, AMA; American College of Obstetricians & Gynecologists (ACOG); the Endocrine Society; and Pharmaceutical Research Manufacturers of America (PhRMA)</p>		
<p>f) Health Advocacy Organizations (501c3) Nonprofit 501c3 patient or disease-specific health-advocacy organizations or foundations (e.g., National Women’s Health Network, American Heart Association, National Osteoporosis Foundation, Alzheimer’s Foundation)</p>		
<p>g) Coalition An organized group of multiple organizations or constituents (e.g., National Breast Cancer Coalition)</p>		
<p>h) Other Any organization type not mentioned above, including non-U.S.-based international organizations that cannot be classified above.</p>		

NV15: Pharmaceutical Funding of Individuals

This item captures explicit mentions of pharmaceutical funding or financial support of individuals. Below are examples of such explicit mentions:

“Wyeth named Dr. Utian a ‘Partner in Menopause Education’ (requiring a contribution of at least \$8,000) for the NAMS' 2007 Annual Meeting. Additionally, half of NAMS's Board of Trustees for 2007-2008 receives consulting fees or research support from Wyeth, including Dr. Utian.”

“The study is published in the journal Neurology. One author is a former employee of Wyeth, which sells Prempro.”

NV15. Does the news story explicitly mention pharmaceutical company funding of any individuals?

_____ 1 (Yes) _____ 0 (No)

NV16: Pharmaceutical Funding of Organizations

This item captures explicit mentions of pharmaceutical funding or financial support of organizations and their activities. Below are examples of such explicit mentions:

“The study was funded by the National Osteoporosis Foundation (NOF). NOF receives funding from Wyeth, which sells Prempro.”

“The National Association of Nurse Practitioners in Women's Health developed and launched the campaign with financial support from Upsher-Smith Women's Health.”

“The North American Menopause Society has created a comprehensive guidebook. Supported by an unrestricted educational grant from Berlex Laboratories, makers of Climara, the Menopause Guidebook is available on www.menopause.org. Berlex did not influence any of its contents.”

NV16. Does the news story explicitly mention pharmaceutical company funding of any organizations?

_____ 1 (Yes) _____ 0 (No)

NV17: Pharmaceutical Funding of Research Studies

This item captures explicit mentions of pharmaceutical funding or financial support of research studies. Research studies can include unpublished clinical studies, published studies in scientific/medical journals, or a variety of public opinion or survey studies. Below are examples of such explicit mentions:

"This study confirms what the medical community and the public already know about HRT and the treatment of heart disease," says Victoria Kusiak, M.D., Vice President, Global Medical Affairs and North American Medical Director for Wyeth Pharmaceuticals, the study's sponsor."

"David F. Archer, M.D., professor of obstetrics and gynecology at EVMS' Jones Institute of Reproductive Medicine, was among a group of researchers in various parts of the United States who conducted the five-year study, which involved about 2,700 women and was funded by Wyeth-Ayerst Laboratories."

"The New World of HRT study, sponsored by Pharmacia Corporation, was conducted by SRI Business Intelligence Center in April 2000."

NV17: Does the news story explicitly mention pharmaceutical funding of any research studies?

_____1 (Yes) _____0 (No)

CODE SHEET FOR NEWS STORIES BEGINS ON NEXT PAGE

NV1: Coder #: _____ NV2: News Story ID: _____ NV3: Date: _____(Month) _____(Day) _____(Year)

NV4: Does the headline refer to hormone therapy (HT) for menopause or symptoms or conditions associated with menopause?
 _____(1) Yes _____(0) No (IF NO, **ELIMINATE**)

NV5: Which of the following BEST describes this news story?

	Circle Code
Story <u>primarily</u> about the organization as opposed to HT	1
Letter to the editor or editorial/opinion piece	2
Film/television/book/theater/other entertainment review	3
Story about study conducted in animals only	4
Q&A-style health advice column	5
None of the above (0)	0

NV6: Which source did this story appear in?

	Circle Code
<i>Associated Press</i>	1
<i>Los Angeles Times</i>	2
<i>The New York Times</i>	3
<i>The Wall Street Journal</i>	4
<i>The Washington Post</i>	5

(IF SELECTED 1, 2, 3, 4, OR 5 ABOVE, **ELIMINATE**)

NV7. For each brand name below, check whether it appeared or not in any part of the news story.

	Yes (1)	No (0)		Yes (1)	No (0)		Yes (1)	No (0)		Yes (1)	No (0)
Activella/Activelle			Divigel			Evamist			Prefest		
Alora			Elestrin			FemHRT			Premarin		
Angeliq			Enjuvia			Femring			Premphase		
Cenestin			Estrace			Femtrace			Prempro		
Climara/Pro			Estraderm			Menest			Prometrium		
CombiPatch			Estrasorb			Menostar			Provera		
Delestrogen			Estratab			Ogen			Vagifem		
Depo-Estradiol			Estratest			Ortho-Est			Vivelle/Vivelle-dot		
			Estring			Other1/(Specify):			Other2/(Specify):		

NV8. Does the story refer to a medical professional or scientific journal anywhere in the text?

_____ Yes (1) _____ No (0)

NV9: Journal Name: If any medical professional or scientific journals were mentioned in the release text, write them all below.

NV10. For each potential risk of HT below, check the relevant columns.

Potential Risks	Identified? (ID)		Quant? (QT)		Relative? (REL)		Absolute? (ABS)	
	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)
a) Breast cancer								
b) Cognitive (e.g., dementia, Alzheimer's)								
c) Gallbladder disease								
d) Heart attack/Heart disease/Cardiovascular disease								
e) Stroke								
f) Thrombosis/blood clots								
g) Uterine/endometrial cancer (also includes ovarian cancer)								
h) Other1 (OTH1) (Specify):								
i) Other2 (OTH2) (Specify):								

NV11. For each potential benefit of HT below, check the relevant columns.

Potential Benefits	Identified? (ID)		Quantified? (QT)		Relative? (REL)		Absolute? (ABS)	
	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)	Yes (1)	No (0)
a) Cognitive Decline Reduced (e.g., dementia, Alzheimer's)								
b) Colon/Colorectal Cancer Reduced								
c) Heart Attack/Heart Disease/Cardiovascular Disease Reduced								
d) Hot Flashes/Night Sweats (vasomotor symptoms) Reduced								
e) Mood Problems Reduced (e.g., depression, irritability)								
f) Osteoporosis/Fractures Reduced								
g) Sex Life Improved (e.g., more libido/sexual activity)								
h) Skin Improved (e.g., less wrinkles, aging)								
i) Sleep Problems/Insomnia Reduced								
j) Vaginal Problems Reduced (e.g., atrophy, dryness)								
k) Other1 (Specify):								
l) Other2 (Specify):								

NV12: Are any of the following types of individuals directly quoted in this release? (CHECK ALL THAT APPLY)

Individuals Quoted	Yes (1)	No (0)		Yes (1)	No (0)
a) Physician and/or Scientist			e) Celebrity		
b) Nurse Practitioner/Nurse/Other Clinicians			f) Everyday affected woman		
c) CEO/Exec/Medical Director/PR Director/Official Spokesperson			g) Everyday family member of affected		
d) Attorney (ATTY)			h) Other		

NV13: Organization Names/Mentioned in Body Text:

NV14: Are any of the following types of organizations listed in the BODY TEXT of the release?

Organization Types	Yes (1)	No (0)		Yes (1)	No (0)
a) Pharmaceutical Company			f) Health Advocacy Organizations (501c3)		
b) Other For-Profit Company			g) Coalition		
c) U.S. Government			h) Other		
d) Academic/Medical Institutions					
e) Medical Prof./Trade Assoc. (501c6)					

NV15. Does the release explicitly mention pharmaceutical company funding of any individuals?

____(1) Yes ____ (0) No

NV16. Does the release explicitly mention pharmaceutical company funding of any organizations?

____(1) Yes ____ (0) No

NV17: Does the release explicitly mention pharmaceutical company funding of any research studies?

____(1) Yes ____ (0) No

Appendix E: Reliabilities for Content Analysis Variables

Table E1: Reliabilities for Content Analysis Variables

Variable Name/Description	Codebook ID number(s)	Fleiss' Kappa* κ
Date of press release or news story	PV3, NV3	
Month		.98
Day		.99
Year		.99
Headline refers to HT	PV4, NV4	.98
Press release/news story eliminated or not based on type	PV5, NV5	.94
Type of organization that produced/distributed release		
Pharmaceutical company	PV7a	.98
Other for-profit company (not a pharmaceutical)	PV7b	.82
U.S. government agency	PV7c	1.00
Academic/Medical institutions	PV7d	.83
Medical professional societies/trade assoc's. (501c6)	PV7e	.84
Health advocacy organizations (501c3)	PV7f	.81
Coalition	PV7g	0*
Medical/scientific journal publishers	PV7h	.84
Other	PV7i	.74
News source	NV6	.94
Potential Risks of HT		
Breast cancer identified	PV10a, NV10a	.93
quantified		.89
quantified in relative terms		.86
quantified in absolute terms		.81
Cognitive (e.g., dementia, Alzheimer's)	PV10b, NV10b	.93
quantified		.80
quantified in relative terms		.80
quantified in absolute terms		1.00
Gallbladder disease	PV10c, NV10c	.83
quantified		0*
quantified in relative terms		0*
quantified in absolute terms		0*
Heart attack/heart disease/cardiovascular disease	PV10d, NV10d	.86
quantified		.93
quantified in relative terms		.77
quantified in absolute terms		.87
Stroke	PV10e, NV10e	.92
quantified		.83
quantified in relative terms		.75
quantified in absolute terms		.81

*Fleiss' Kappa is an extension of Cohen's Kappa for more than two coders.

Variable Name/Description	Codebook ID number(s)	Fleiss' Kappa* κ
Thrombosis/blood clots	PV10f, NV10f	.90
quantified		.80
quantified in relative terms		.75
quantified in absolute terms		.75
Uterine/endometrial cancer (includes ovarian)	PV10g, NV10g	.88
quantified		.84
quantified in relative terms		.74
quantified in absolute terms		.75
Potential Benefits of HT		
Cognitive decline reduced (dementia, Alzheimer's)	PV11a, NV11a	.78
quantified		0*
quantified in relative terms		0*
quantified in absolute terms		0*
Colon/Colorectal cancer reduced	PV11b, NV11b	.84
quantified		1.00
quantified in relative terms		.86
quantified in absolute terms		.87
Heart attack/heart or cardiovascular disease reduced	PV11c, NV11c	.86
quantified		.94
quantified in relative terms		.84
quantified in absolute terms		.75
Hot flashes/night sweats/vasomotor symptoms	PV11d, NV11d	.87
quantified		.87
quantified in relative terms		.80
quantified in absolute terms		0*
Mood problems (e.g., depression, irritability)	PV11e, NV11e	.80
quantified		0*
quantified in relative terms		0*
quantified in absolute terms		0*
Osteoporosis/fractures reduced	PV11f, NV11f	.84
quantified		.80
quantified in relative terms		.81
quantified in absolute terms		.87
Sex life improved (e.g, more libido/sexual activity)	PV11g, NV11g	.86
quantified		0*
quantified in relative terms		0*
quantified in absolute terms		0*
Skin improved (e.g., less wrinkles, aging)	PV11h, NV11h	.75
quantified		1.00
quantified in relative terms		1.00
quantified in absolute terms		0*
Sleep problems/insomnia reduced	PV11i, NV11i	.85
quantified		0*
quantified in relative terms		0*
quantified in absolute terms		0*

*Fleiss' Kappa is an extension of Cohen's Kappa for more than two coders.

Variable Name/Description	Codebook ID number(s)	Fleiss' Kappa* κ
Vaginal problems reduced (e.g., atrophy, dryness)	PV11j, NV11j	.80
quantified		1.00
quantified in relative terms		0*
quantified in absolute terms		0*
HT Brand Names Mentioned	PV12, NV7	
Activella/Activelle		1.00
Alora		0*
Angeliq		.86
Cenestin		1.00
Climara/Climara Pro		.78
CombiPatch		0*
Delestrogen		0*
Depo-Estradiol		0*
Divigel		1.00
Elestrin		.80
Enjuvia		0*
Estrace		0*
Estraderm		0*
Estrasorb		0*
Estratab		0*
Estratest		0*
Estring		0*
Evamist		1.00
FemHRT		1.00
Femring		0*
Femtrace		1.00
Menest		0*
Menostar		1.00
Ogen		0*
Ortho-Est		1.00
Prefest		0*
Premarin		.89
Premphase		.75
Prempro		.90
Prometrium		0*
Provera		0*
Vagifem		0*
Vivelle/Vivelle-dot		0*

*Fleiss' Kappa is an extension of Cohen's Kappa for more than two coders.

Variable Name/Description	Codebook ID number(s)	Fleiss' Kappa* κ
Medical/Scientific Journal Referenced	PV13, NV8	.95
Organizations Mentioned in Body Text		
Pharmaceutical company	PV16a, NV13a	.93
Other for-profit company (not a pharmaceutical)	PV16b, NV13b	.74
U.S. government agency	PV16c, NV13c	.88
Academic/Medical institutions	PV16d, NV13d	.90
Medical professional societies/trade assocs. (501c6)	PV16e, NV13e	.74
Health advocacy organizations (501c3)	PV16f, NV13f	.85
Coalition	PV16g, NV13g	0*
Other	PV16h, NV13h	.82
Types of Individuals Directly Quoted		
Physician and/or scientist	PV17a, NV12a	.87
Nurse practitioner/nurse/other clinicians	PV17b, NV12b	0*
CEO/Medical Dir./PR Dir./Official Spokesperson	PV17c, NV12c	.72
Attorney	PV17d, NV12d	1.00
Celebrity	PV17e, NV12e	0*
Everyday affected woman	PV17f, NV12f	.87
Everyday affected family member of affected woman	PV17g, NV12g	0*
Other	PV17h, NV12h	0*
Pharmaceutical Industry Funding		
Explicit mention of funding individuals	PV18, NV15	1.00
Explicit mention of funding organizations	PV19, NV16	.76
Explicit mention of funding research studies	PV20, NV17	.78

*Fleiss' Kappa is an extension of Cohen's Kappa for more than two coders.

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