CONFLICTS OF INTEREST IN THE REPORTING OF BIOMEDICAL RESEARCH IN MAINSTREAM NEWSPAPERS IN CANADA

by

Steven Douglas Buist

August 2013

Conflicts of interest in the reporting of biomedical research in mainstream newspapers in Canada

by

Steven Douglas Buist

Dissertation in compliance with the requirements for the Master's Degree in Technology: Journalism in the Department of Media, Language and Communication, Durban University of Technology.

I declare that this dissertation is my own work and has not been submitted for any other degree or examination at any other institution.

Signed: [redacted] Date: 19/08/2013

Approved for final submission:
Supervisor : Professor D.D. Pratt

Signed: [redacted] Date: 19/08/2013

Abstract

Ethical behaviour by investigators is the cornerstone of scientific research. Recognizing, declaring and avoiding a conflict of interest are key responsibilities for biomedical researchers, particularly since commercial enterprises, such as pharmaceutical companies, have become major funding sources of research. Proactive disclosure of researchers' financial relationships is now a requirement for publication in most scientific journals. The question that arises is whether this same increased scrutiny of financial disclosure and potential for conflict of interest has extended to the mainstream press in Canada.

A content analysis of biomedical research articles that appeared in Canadian daily newspapers from 2001 to 2008 showed that 82 per cent of the articles failed to identify the financial connection that existed between the researcher(s) and the commercial funder, and nearly half of the articles did not even identify the commercial funding source of the research. A text analysis showed that 94 per cent of the articles were positive about the drug/device cited by the research, and positive, optimistic words such as “breakthrough”, “significant”, “hope” and “promising” were often used in the news articles. Reporters frequently frame biomedical research articles using a battle-like template that describes a fight between good and evil. Another common approach was to frame the article as a message of hope for the future. A genre analysis showed that the genre of medical research news articles published in newspapers is highly dissimilar to the genre of medical research articles published in scientific journals. It is likely these two genres have been constructed to appeal to very different target audiences.

The study results show overwhelmingly that readers are not provided with key information about potential financial conflicts of interest involving the researchers and the commercial sources of funding for the research. Such lack of transparency thwarts the reader’s ability to reach informed conclusions about whether or not the research has been either explicitly or implicitly influenced by the researcher’s potential conflict.

Acknowledgements:

To Dee, my thanks to you for your guidance and for taking me on as a student.

To Diana and my family, thanks for your unconditional love and support.

And to Jim, my mentor, thanks for your friendship.

Preface

The work contained in this thesis has not been previously submitted for a degree or diploma at any other higher education institution. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made or in prior publications by the candidate.

Prior publications by the candidate

Buist S (1999) The scientific method and how it works. *Hamilton Spectator*. May 8, 1999.

Buist S (2000) Irrationality in the midst of a techno world. *Hamilton Spectator*. August 23, 2000.

Buist S, Walters J and Muhtadie L (2005) Blind Faith newspaper investigative series. *Hamilton Spectator*.

DeLuca P, Buist S, Johnston N (2012) The Code Red Project: Engaging Communities in Health System Change in Hamilton, Canada. *Social Indicators Research,* 108 (2):317-327.

Table of contents

CHAPTER ONE: INTRODUCTION

1.1 Introduction

This chapter first looks in general at the importance of critical medical reporting in the mainstream press, particularly in respect of any conflicts of interest, and suggests the value of research into this issue. It then looks at the current Canadian newspaper "climate", suggesting that newspapers play a significant role in providing information for Canadian patients about new drugs. Next, a consideration of traditional newspaper structure and functions reveals the very tentative underpinning to properly informed as well as critical medical reporting, potentially putting the public at risk. An overview of scientific method and science ethics follows, as well as their significance in the reporting of medical discoveries. The chapter concludes with the aims and objectives of the study.

1.2 The importance of critical medical reporting in the mainstream press

Ethical behaviour by investigators is the cornerstone of scientific research. Recognizing, declaring and avoiding a conflict of interest are key responsibilities for biomedical researchers, particularly since commercial enterprises, such as pharmaceutical companies, have become major funding sources of research (Buist, Walters and Muhtadie, 2005). Proactive disclosure of commercial financial relationships of researchers has become an area of growing concern for scientific publications. Most reputable scientific publications, such as the *New England Journal of Medicine* (NEJM), now require the authors of scientific papers to make detailed disclosure of their commercial financial relationships as a prerequisite for publication (Drazen, Van Der Weyden, Sahni, Rosenberg, Marusic, Laine, Kotzin, Horton, Hébert, Haug, Godlee, Frizelle, de Leeuw and DeAngelis, 2009:1896).

The question that arises is whether this same increased scrutiny of financial disclosure and potential for conflict of interest has extended to the mainstream press, which is the focus of this research. The mainstream press plays an important role in informing the general public about advances in science (Cook, Boyd, Grossmann and Bero, 2007). Including information about potential financial conflicts of interest in news stories is an important service to readers, allowing them to be aware of any potential bias that may have consciously or unconsciously influenced scientific results (McComas and Simone, 2003:414).

Reporters are trained in the practices of journalism but they may not have any significant amount of scientific training. One hypothesis to be explored in this study is whether or not journalists at mainstream newspapers understand the scientific method and the importance of research ethics, which might be a possible explanation for any lack of reporting on potential conflicts of interest. Journalists may also not understand the complex relationships that now exist for biomedical researchers, who may be located at a public institution, such as a university, but receive funding from a variety of sources, both public and commercial. The value of such research would be to expose possible conflicts of interest in medical reporting and suggest ways in which readers might be better informed, and thus empowered in decision making about medical treatments.

1.3 The Canadian newspaper climate

Newspapers, both dailies and weeklies, remain an important source of information for Canadians about current events, particularly when the topics are related to science and, more specifically, biomedical research. As mentioned above, the mainstream press plays an important role in informing the general public about advances in science (Cook, Boyd, Grossmann and Bero, 2007). Indeed, newspapers trail only physicians and pharmacists as the top source of information for Canadian patients about new drugs (Cassels *et al.*, 2003:1133).

According to data from the Canadian Newspaper Association, there were 96 English- and French-language daily newspapers with paid subscriptions in Canada in 2009. Canada's paid circulation for daily newspapers averaged 4.1 million copies per publishing day in 2009 (Canadian Newspaper Association, 2010) in a country with approximately 12.4 million households, according to the 2006 national census. This figure does not include the distribution of 18 free daily newspapers in Canada, with daily circulation of almost 1.6 million copies in 2009. These publications are aimed primarily at rush-hour commuters in Canada's largest cities.

While the United States has experienced a gradual but steady decline in newspaper readership as a percentage of population over the past half of a century, the decline has been less pronounced in Canada, and newspaper circulation remains relatively robust. For example, Toronto, Canada's largest and most ethnically diverse city, boasts four large English-language daily newspapers, two free English-language daily newspapers aimed at commuters, an Italian-language daily newspaper and a Chinese daily newspaper.

1.4 Traditional newspaper structure and functions

The editorial department of a newspaper is hierarchical in structure, with three primary categories of staff: reporters, photographers (and other creative artists), and editors. Editors are responsible for directing news coverage, analyzing and editing the content of news articles, and the administration of the newsroom, including such areas as human resources issues, legal issues and the short-term and long-term strategic direction of a newspaper.

Reporters are responsible for the direct production of news content. The generation of newspaper content can be both top down (assignments handed out by editors to reporters) and bottom up (ideas generated by reporters that meet with the approval of editors). News reporters at daily newspapers fall into two main categories: general assignment reporters and beat reporters. General assignment reporters cover a wide variety of topics, depending on

the day-to-day needs of the newsroom. They may not have any specific expertise in a single area of coverage. Beat reporters cover specific subject matters, such as courts, health or education, and they are expected to have an in-depth knowledge of the subject matter encompassed in their beat.

But any in-depth knowledge about a subject matter that is acquired by a beat reporter may not come from any formal academic training in that particular field. When it comes to biomedical research and the sciences, the chances are even less likely that a daily newspaper reporter in Canada will have had formal academic training in the sciences to rely on when attempting to understand the complexities of the scientific world. Reporters and editors are trained in the practices of journalism, but they may not have any significant amount of scientific training upon which to rely when it comes time to make sense of both the complexities and the subtleties inherent in science.

This leads to two relevant and important questions:

- How do Canadian newspaper readers know that the science and biomedical research information they are reading is reliable and objective?
- More importantly, how do Canadian newspaper readers know that the reporters and editors responsible for assembling such stories fully understand the underpinnings of the scientific process so that readers are provided with the right type of information to make informed conclusions about the validity of the scientific outcomes being reported?

The short answer to both questions is simple: the readers cannot be sure this is the case.

1.5 Science and the scientific method

Science, and the coverage of science by newspapers, encompasses many areas of interest, from medicine and medical research, to physical sciences and chemistry, to environmental science and such topics as climate change.

Science is the process of gathering information through the ongoing application of critical thinking. At its simplest, science is the mechanism for putting ideas to the test via a rigorous protocol. Science, as has been noted by many, is not as much about proving what is true as disproving what cannot be true. For scientists of all disciplines, the foundation for putting ideas to the test is set out in the principles of the scientific method, a process of investigation that has been employed and refined for centuries. The scientific method is the framework for conducting an experiment to test an idea. The framework is made up of the following steps:

1. Observation. You observe something in the material world, using your senses or machines, which are basically extensions of those senses.
2. Question. You ask a question about what you observe.
3. Hypothesis. You predict what you think the answer to your question might be.
4. Method. You figure out a way to test whether the hypothesis is correct. The outcome must be quantifiable.
5. Materials. You must determine what substances and equipment are needed to test your hypothesis.
6. Result. You do the experiment using the method you came up with and record the results. You repeat the experiment to confirm your results.
7. Conclusion. You state whether your prediction was confirmed or not and try to explain your results.

For conclusions to be considered scientifically sound, the evidence gathered must satisfy six rules: falsifiability (a claim must be falsifiable), logic, comprehensiveness (all available evidence must be considered), honesty (all evidence must be evaluated objectively), replicability and sufficiency (Arneja, 2007:547). Journalists who are not specialists in science and the scientific method cannot be expected to assess the value and thrust of scientific discoveries in medicine, or weigh up their actual benefits so as to present a valid picture to members of the public.

1.6 Science and ethics

Clearly, the above framework of the scientific method suggests that ethics must play an important role in the soundness of scientific outcomes. According to the Merriam-Webster Dictionary, ethics, broadly, is the code of behaviour that distinguishes between right and wrong, good and bad. Being ethical is sometimes simplified as “doing the right thing when no one is watching you”. This is particularly pertinent in science, where self-regulation is a necessity for scientists. Scientific ethics encompass a number of areas in science, including such topics as the use of humans as research subjects, to the honest and accurate reporting of results, to freedom from bias when designing experiments or gathering evidence. Excellent science is thus dependent on excellent ethics. Ethical behaviour by investigators is the cornerstone of scientific research. This is particularly true in the area of biomedical research, where large sums of money are often required to conduct experiments (U.S. Department of State, 2006). The amounts of research funding that flow to a public institution from the private sector can be significant. At one Canadian university, for example, research funding from pharmaceutical companies in 2004 amounted to almost $130 million Cdn (Buist, Walters and Muhtadie 2005:1).

Once more, those journalists who do not specialise in the field of science ethics cannot be expected to weigh up the implications of medical research in terms of possible conflicts of interest with the public good.

1.7 Aims and objectives

This study specifically examines the tripartite relationship that exists between newspaper content, reporters' understanding of science and the scientific process, and the importance of ethical conduct in science. The specific scientific mechanisms being examined in this study are the relationships that exist between biomedical researchers and commercial funding sources, and the potential that exists for researchers to have financial conflicts of interest that may explicitly or implicitly affect scientific outcomes.

The aim of this study is to analyze the discourse of news media on biomedical discoveries to assess the extent of disclosure of potential financial conflicts of interest in the research. Specific objectives include a content, frame and genre analysis of articles related to biomedical discoveries in select Canadian daily newspapers from 2001 to 2008 to establish the following specific objectives, namely to establish:

1. To what extent disclosure is made of the principal researchers' financial backing.
2. To what extent disclosure is made of the funding sources of the biomedical research being reported.
3. What reasons might exist to explain why reporters might fail to note the financial connections of science researchers in news articles.
4. Whether the genre of medical research articles for newspapers differ from the genre of medical research articles for scientific journals
5. The implications of the answers to the above for readers/the public.
6. Recommendations which might be made to ensure that financial interests are disclosed.

It is hoped that recommendations might be made which will ensure that the public are better informed in assessing the value of any medical treatment based on new medical discoveries. The theoretical framework used to examine this issue is a combination of frame theory and genre analysis, which will compare the structure and functions of biomedical research articles published in scientific journals versus the structure and functions of biomedical research articles published in mainstream Canadian newspapers.

1.8 Conclusion

This chapter has touched on the main themes of the research. It has emphasised the importance of ethical medical reporting by the mainstream press, and has suggested that the value of the study lies in exposing the lack of reporting in Canadian newspapers of possible conflicts of interest in

medical research, and thus finding ways of empowering the public in decision making about medical treatments. It has shown how the key role of the press in reporting medical discoveries makes it necessary for reporters to be both informed and more critical of their researcher sources, while at the same time suggesting that most reporters are not likely to be well-informed about either scientific methods or science ethics.

Finally the aims and objectives given both pre-empt and provide the basis for the approach research methodology used in this study, as will be discussed in more detail in Chapter Three. However, first the literature informing this study will be examined in Chapter Two.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Scientific misconduct is widely recognized as a significant problem for contemporary science (Cook *et al.*, 2007; McComas and Simone, 2003:395). Recent examples, involving the withdrawn drugs rofecoxib (brand name: Vioxx) and valdecoxib (brand name: Bextra), and the controversy surrounding the whistleblowing case of Dr. Nancy Olivieri in Canada, shook the public's confidence in the trustworthiness of scientific research and raised questions about research ethics, control of clinical trial data and control of authorship (Harris, 2005; Buist *et al.*, 2005).

As Buist *et al.* noted in their *Blind Faith* series (2005), the growing reliance by researchers and institutions on funding from commercial sources raises questions about the potential for conflicts of interest when research at public institutions is carried out with private money. For example, at McMaster University in Canada, research funding from pharmaceutical companies quadrupled between 2002 and 2004 to $129 million.

Studies show a clear, direct connection between research results and funding sources (Bhandari, Busse, Jackowski, Montori, Schünemann, Sprague, Mears, Schemitsch, Heels-Ansdell and Devereaux, 2004:477; Lexchin *et al.*, 2003:1167; Lexchin, 2005:194). The research of Bhandari *et al.* (2004:477) shows that clinical trials on drugs and surgical instruments funded by the pharmaceutical industry are twice as likely to come to a positive conclusion about the product as those financed otherwise.

2.2 The drug discovery process

Ethical behaviour by investigators is the cornerstone of scientific research. This is particularly true in the area of biomedical research, where large sums of money are often required to conduct experiments (U.S. Department of

State, 2006). Take, for example, the process of bringing a new pharmaceutical product to market. The drug discovery and development process involves nine stages, according to a flow chart produced by Novartis (2010), a major global pharmaceutical company.

The process begins with the identification of targets that are involved in the disease process. The next stages are the testing of small molecules for effectiveness and the further refinement of these compounds. Once candidate compounds have been identified, they are tested for safety and effectiveness in the lab and in animal models. The fifth stage introduces human testing to determine safe dosages and to look for any side effects in small groups of patients. Two more stages of human testing are then introduced to test the compound against current standards of treatment for the same condition. The new compound is then put forward for approval from government regulatory agencies, and finally, the new drug is monitored post-approval to ensure there are no unexpected dangers or side effects (Novartis, 2010.)

This process is costly. According to a 2006 U.S. State Department document on intellectual property rights, the cost to a pharmaceutical company to develop one new drug from start to finish can range from $800 million US to $2 billion US.

2.3 Biomedical research and the clash between public and private interests

Pharmaceutical companies employ their own scientists during the drug development process. But these companies will also rely on the expertise of researchers based at public institutions, such as universities and hospitals. This is particularly useful to the pharmaceutical company when clinical trials with human patients are necessary.

Since the 1970s randomized double-blind controlled clinical trials have come to be viewed as the gold standard for testing new drug therapies (Sismondo,

2008:1910). In a randomized double-blind trial, neither the patients nor the clinical investigators know which patients are receiving the experimental drug and which patients are receiving a placebo (or in advanced trials, the currently accepted drug used to treat the disease in question). Such a regime reduces any potential bias that might lead to preferential care and treatment for those patients being prescribed the experimental drug.

Clinical trials are costly to organize and operate and require the specific competencies of medical doctors to monitor patient outcomes. Clinical trials are also frequently conducted at multiple sites at the same time, making it impractical for a pharmaceutical company to supply the necessary human resources. Such an arrangement between the public and private sectors provides symbiotic benefits to both sides.

The use of researchers at public institutions provides a pharmaceutical company with highly-skilled resources and reduces the manpower needed to be employed to gather evidence in support of a new product. Because of the positive reputations attached to public institutions, such as hospitals and universities, the use of researchers from these institutions also helps to provide an insulating layer of credibility to the pharmaceutical company for any results that are subsequently published in scientific journals.

For the researchers employed at public institutions, the relationship provides the benefit of research opportunities for the lab and for the researcher's associates and students. The relationship can also provide publication opportunities in scientific journals. For the public institution itself, the relationship with a pharmaceutical company provides research funding that helps retain staff members, attract new staff members and students, and can help improve the institution's prestige.

However, public institutions are not the only avenues available to pharmaceutical companies seeking to test new products. Contract research organizations – essentially, private-sector operators of clinical trials – have become a growing part of the drug development landscape. Between 1992

and 2001, contract research organization (CRO) revenues increased from $1 billion US to $7.9 billion US, and the number of their enrolled research subjects increased from seven million to 20 million (Mirowski and Van Horn, 2005:506). Unlike public institutions, CROs also make no publication demands on pharmaceutical companies when it comes to the data created from a clinical trial (Sismondo, 2008:1910).

With this financial interdependency that has developed between the public institution researcher and the pharmaceutical company, there comes the potential for conflict, particularly over the issues of data ownership and publication rights. As the Olivieri case in Canada highlights, this friction can prove to be highly damaging to both sides.

Olivieri, a haematologist, became concerned in 1996 that an experimental drug being used in a trial was causing serious side effects. The drug company disagreed with her conclusions. When Olivieri indicated she was going to tell the trial participants about her concerns, the drug company terminated the trial, invoked a confidentiality agreement in the research contract and threatened legal action if she made the findings public. Undeterred, Olivieri presented her results at a scientific meeting and submitted them for publication (Shuchman, 2005:976). Olivieri ultimately faced legal action and the case received widespread media coverage in Canada for a significant period of time, damaging the reputations of both the researcher and the company.

If public institutions must now compete with contract research organizations to attract clinical trials and research funding, issues related to data ownership and publication of results become an even more acute concern. It leads to the possibility, according to Sismondo (2008:1910), that academic researchers “may, consciously or not, feel pressure to cede more control over trials and publications to their sponsors”.

Pharmaceutical companies have responded by increasingly managing the data and planning the publications associated with a drug’s development.

“Companies have treated data as an important resource to be managed and marshalled,” Sismondo wrote. According to Sismondo:

> Publication planning is a form of ‘ghost-management’ of clinical research and publication when pharmaceutical companies and their agents help to shape multiple steps in the research, analysis, writing, and publication of articles, in ways unseen by readers. These companies not only fund clinical trials but also routinely design and shape them.

Pharmaceutical companies will also hire private-sector medical writers to prepare manuscripts and employ their own company statisticians to analyze trial data. Some academic journal papers will list company scientists and public institution researchers jointly as authors, further blurring the distinctions between the public and private sectors.

2.4 Biomedical research and scientific misconduct

In the midst of this potential confusion over data ownership rights and the responsibilities of each side – and with the financial stakes high – the potential for scientific misconduct is an area of concern and growing scrutiny. The high-profile withdrawal of the anti-inflammatory drug rofecoxib (brand name Vioxx) points to the importance of ethical behaviour and the dangers to the public of scientific misconduct. Clinical trial evidence of increased cardiovascular risks for patients taking rofecoxib was found to have been either suppressed by the pharmaceutical company, or by researchers at public institutions who conducted research on behalf of the company while at the same time having financial connections to the company. The damage to Merck, the company that manufactured rofecoxib, from the perceived unethical behaviour of its researchers was nearly catastrophic. The company has paid out nearly $5 billion US so far to settle lawsuits related to deaths from the drug and investors in the company lost a combined total of $28 billion when the share price of Merck stock plunged in the wake of the revelation of suppressed data (Associated Press, 2010).

The rofecoxib case was unusual but not unprecedented. However, determining the frequency of scientific misconduct with reliability is difficult.

A 2009 meta-analysis by Fanelli of 21 surveys showed that 2 per cent of scientists admitted to having fabricated, falsified or modified data or results at least once – a particularly serious form of scientific misconduct. One in three scientists admitted to other questionable research practices. However, in surveys where scientists were asked to report on the behaviour of their colleagues, the rates jumped significantly. Scientists reported their belief that 14 per cent of their colleagues had engaged in falsification of data, and 72 per cent engaged in other questionable research practices (Fanelli, 2009). It is interesting to note that researchers, in this example, are much more likely to believe that their colleagues are behaving unethically than to report that they themselves may have ethical lapses.

Scientific misconduct is not restricted to one specific type of action. It includes a range of behaviours, which have been summarized by the World Association of Medical Editors in an online policy guide titled "Publication Ethics Policies for Medical Journals" (2010):

1. **Falsification of data:** ranges from fabrication to deceptive selective reporting of findings and omission of conflicting data, or willful suppression and/or distortion of data.

2. **Plagiarism:** The appropriation of the language, ideas, or thoughts of another without crediting their true source, and representation of them as one's own original work.

3. **Improprieties of authorship:** Improper assignment of credit, such as excluding others, misrepresentation of the same material as original in more than one publication, inclusion of individuals as authors who have not made a definite contribution to the work published; or submission of multi-authored publications without the concurrence of all authors.

4. **Misappropriation of the ideas of others:** an important aspect of scholarly activity is the exchange of ideas among colleagues. Scholars can acquire novel ideas from others during the process of reviewing grant applications and manuscripts. However, improper use of such information can constitute fraud. Wholesale appropriation of such material constitutes misconduct.

5. **Violation of generally accepted research practices:** Serious deviation from accepted practices in proposing or carrying out research, improper manipulation of experiments to obtain biased results, deceptive statistical or analytical manipulations, or improper reporting of results.

6. **Material failure to comply with legislative and regulatory requirements affecting research:** Including but not limited to serious or substantial, repeated, willful violations of applicable local regulations and law involving the use of funds, care of animals, human subjects, investigational drugs, recombinant products, new devices, or radioactive, biologic, or chemical materials.

7. **Inappropriate behaviour in relation to misconduct:** this includes unfounded or knowingly false accusations of misconduct, failure to report known or suspected misconduct, withholding or destruction of information relevant to a claim of misconduct and retaliation against persons involved in the allegation or investigation.

8. Deliberate misrepresentation of qualifications, experience, or research accomplishments to advance the research program, to obtain external funding, or for other professional advancement.

As the World Association of Medical Editors policy statement notes, the deception can be deliberate, "by reckless disregard of possible consequences", or by ignorance.

2.5 Conflicts of interest in biomedical research

There are also ethical considerations that must be addressed in science that are not as obvious as the breaches that constitute scientific misconduct. One area that has attracted great scrutiny is the issue of conflict of interest. A conflict of interest has been defined as "a set of conditions in which professional judgment concerning a primary interest (such as patient welfare or the validity of research) can be influenced by a secondary interest (such as financial gain)" (Chaudhry, Schroter, Smith and Morris, 2002:1392). Murray (2002:1835) offered a definition of a conflict of interest as "a situation or set of circumstances that creates the possibility that a professional may provide a judgment or take an action motivated by something other than the interests or well-being of a patient, client, or the like — someone owed a professional duty".

In the scientific realm, a conflict of interest exists when a researcher makes a decision about a primary interest, such as academic publication, while under the influence of a secondary interest. These secondary interests may be personal, commercial, political, academic or financial, and they become an

issue when they have the potential to influence judgment inappropriately, whether or not the judgment is actually altered.

Financial interests include employment, research funding, stock or share ownership, payment for lecture or travel, consultancies and company support for staff (Sahu and Abraham, 2000:208). A financial conflict of interest "where the scientist stands to gain financially as a result of a particular research outcome", is the type of conflict most likely to affect the trust of the public" (Friedman, 2002:417). But there are also other possible conflicts of interest of a non-financial nature, such as bias in the planning, performance and analysis of the research. To guard against such conflicts, "research protocols must be scrutinized carefully, to eliminate as much as possible the flexibility that could allow bias to creep in, (along with) independent careful review of protocols, procedures, and statistics in the proposed research" (Friedman, 2002:419).

Recognizing, declaring and avoiding a conflict of interest are key responsibilities for biomedical researchers, particularly since commercial enterprises, such as pharmaceutical companies, have become major funding sources of research (Buist, Walters and Muhtadie, 2005). But how does one accomplish the first step – recognizing a potential conflict of interest – if the potential conflict is not explicit? Sismondo (2008:1911) identified this concern thus:

> (Clinical trial) sponsorship, then, creates subtle influences through the building of relationships that lead researchers to see the pharmaceutical companies with which they interact, and their products, in a more favourable light than they would otherwise. Undoubtedly, this not only inclines researchers to promote those companies' interests, but also facilitates the companies' ghost-management of research and publication to produce and publish positive results.

To deal with more explicit cases of conflicts of interest, the primary focus for improving transparency around potential conflicts for researchers has turned to the financial relationships that can exist between a researcher and commercial funding sources, such as pharmaceutical companies.

2.6 Conflicts of interest, disclosure policies and the role of the mainstream media

Proactive disclosure of commercial financial relationships of researchers has become an area of growing concern for scientific publications. Most reputable scientific publications, such as the *New England Journal of Medicine*, have developed detailed policies concerning proactive disclosure of financial connections for prospective authors and these journals now require the authors of scientific papers to make detailed disclosure of their commercial financial relationships as a prerequisite for publication (Drazen, Van Der Weyden, Sahni, Rosenberg, Marusic, Laine, Kotzin, Horton, Hébert, Haug, Godlee, Frizelle, de Leeuw and DeAngelis, 2009:4144). Prestigious Stanford University has decided to post the financial disclosures of its researchers online (Reuters, 2009).

In 2009, the *British Medical Journal* published details of its new financial disclosure policy for authors, which includes four categories of reporting by researchers relevant to a potential financial conflict:

1. Associations with commercial entities that provided support for the work reported in the submitted manuscript (the time frame for disclosure in this section of the form is the lifespan of the work being reported).
2. Associations with commercial entities that could be viewed as having an interest in the general area of the submitted manuscript (the time frame for disclosure in this section is the 36 months before submission of the manuscript).
3. Any similar financial associations involving a spouse or children under 18 years of age.
4. Non-financial associations that may be relevant to the submitted manuscript.

In light of the increased scrutiny by academic publications of researchers' financial relationships, the first question that arises is whether this same

increased scrutiny of financial disclosure and potential for conflict of interest has extended to the mainstream press in Canada and the U.S. Concerns about the accuracy of science and biomedical research reporting in mainstream newspapers are evident in past findings.

A 2000 study reported in the *New England Journal of Medicine* by Moynihan *et al.* stated that coverage of new medical treatments may be inaccurate and overly enthusiastic. Moynihan *et al.* concluded that news coverage of new medications "may include inadequate or incomplete information about the benefits, risks, and costs of the drugs as well as the financial ties between study groups or experts and pharmaceutical manufacturers" (Moynihan *et al.*, 2000:1645).

The second pertinent question that arises is whether or not readers care if they are presented with financial disclosure information when they consume science-related news. An experiment conducted by the *British Medical Journal* suggests that readers do, in fact, care (Chaudhry, Schroter, Smith and Morris, 2002:1391). To test whether the declaration of financial competing interests by researchers had an effect on readers' perceptions, readers were divided into two groups. One group received information about a medical advance listing the study authors as employees of a fictitious company who may also hold stock options in the company. The other group received the same information, except the study authors were listed as employees of a public institution with no competing financial interests. Readers in the first group reported the findings to be significantly less believable, important and valid than readers in the second group.

Ironically, it is the perception of science and scientists as cautious by nature and rigorous in approach that causes the media to overestimate their purity and underestimate the possibility of scientific misconduct. As Fanelli (2009) notes:

> A popular view propagated by the media and by many scientists sees fraudsters as just a 'few bad apples.' This pristine image of science is based on the theory that the scientific community is

> guided by norms including disinterestedness and organized scepticism, which are incompatible with misconduct. Increasing evidence, however, suggests that known frauds are just the 'tip of the iceberg,' and that many cases are never discovered.

In a similar way, mainstream newspapers are also infused with a layer of authority that can cause readers to overvalue the information they consume. Information about the financial connections of researchers is relevant and important to newspaper readers. Cook *et al.* (2007) observed that, as more scientific journals require financial disclosure, information about financial connections and potential conflicts of interest is becoming increasingly available to reporters. But studies also show that, even with tightened standards for financial disclosure, there are still significant omissions and inaccuracies related to disclosure by researchers in scientific journals, suggesting that the potential for conflicts of interest is even higher than already noted (Okike, Kocher, Wei, Mehlman, and Bhandari, 2009:1466; Weinfurt, Seils, Tzeng, Lin and Schulman, 2008). Okike *et al.* (2009) also demonstrated that just over 20 per cent of direct financial payments and 50 per cent of indirect financial payments were not disclosed by researchers.

The mainstream print media are an important source of science information for the general public (McComas and Simone, 2003:395). But one major content analysis of science news articles taken from leading U.S. newspapers showed significant omissions related to the identification of funding sources, the financial ties of researchers and study limitations. The content analysis showed that just slightly more than 10 per cent of the articles reported the financial ties of researchers (Cook *et al.*, 2007). In another case, an analysis of 207 news stories on new drug therapies revealed that 85 cited experts with financial ties to the drug manufacturer, but that only 33 of those stories reported the financial relationship (Moynihan, Bero, Ross-Degnan, Henry, Lee, Watkins and Soumerai, 2000:1645).

2.7 The clash of journalists and scientists

We must now consider hypotheses that might explain this apparent disconnect between increased reporting of financial disclosure by scientific

journals and the reluctance of mainstream newspaper articles to report these same financial connections.

Health and science reporters are particularly dependent upon sources (Moriarty *et al.*, 2008:5). One study by Seo (1988) shows that sources for science-related articles are overwhelmingly organizational sources. The sources may have their own direct or indirect bias. Reporting of clinical trial results, for example, is generally positive in tone, and rarely negative. Articles about clinical trials that were positive in tone were significantly influenced by pharmaceutical companies and medical journals (Moriarty *et al.*, 2008). One content analysis of cancer news coverage showed that news articles in leading U.S. newspapers focused heavily on cancer treatment, including pharmaceuticals and clinical trials, but paid scant attention to cancer prevention and detection, despite the fact that a significant number of deaths could be avoided through better detection and prevention efforts (Moriarty *et al.*, 2008:2).

It is evident that there are times when the goals of scientists and the goals of journalists clash when it comes to the public dissemination of scientific discoveries. Both groups strive for accuracy, but journalists are also highly interested in accessibility and audience appeal (Reed, 2001:291). It is important to note that the motivation for the creation of the content of biomedical research news stories and scientific journal articles is significantly different. Scientists create content for journal articles to explain and justify specific experiments and to present the results uncovered during such research. Journalists create content to appeal to readers and to explain how the scientific research can have an impact on the reader directly or indirectly. This can also help explain why news stories are overwhelmingly skewed towards research findings with positive outcomes rather than those with neutral or negative outcomes. Positive outcomes are more likely to appeal to readers.

Reed's (2001) interviews with scientists and journalists revealed that scientists fear that techniques used by journalists to simplify complex

information for a general audience might lead to inaccuracies and misinterpretation. Scientists may also believe that their findings should appear as written and they may object to the reporter's role of asking questions and re-writing the scientific findings in a different voice (Reed, 2001:289). In some cases, the clashes between journalists and scientists lead to hostility. In one noteworthy example, more than 100 researchers collaborated to co-author a journal article that was highly critical of a Los Angeles Times series about a certain class of pharmaceuticals. The scientists were defending the honour of one of their colleagues, whose ethics, they believed, were under attack in the newspaper series (Anaissie *et al.*, 2006:1031).

2.8 News framing and the "gatekeepers"

Moriarty, Jensen and Stryker (2008), amongst others, describe journalists as "gatekeepers" in the process of transmitting information. Due to the hierarchical nature of news organizations, there are a number of these gatekeepers in the path from information discovery to publication, and these gatekeepers shape the content and influence its importance for the reader (White, 1950:383). As White (1950:383) noted in his seminal research on this topic, due to the hierarchical structure of news organizations, many people can act as gatekeepers and decide which information is in, and which is out.

What readers may not recognize, either explicitly or implicitly, is that the reporters creating the news control the content by deciding what information is excluded and what information is included. Kosicki (1993:113) summed it up in this manner: "Media gatekeepers do not merely keep watch over information, shuffling it here and there. Instead, they engage in active construction of the messages, emphasizing certain aspects of an issue and not others."

In Canada, the United States and other developed countries, it is taken as a given by the public that "good" journalism is the same as "objective"

journalism, and people now "come to see news as a value-free presentation of the facts" (Haskell, 2009:87). Haskell offers up a useful plain-language description of what contributes to objective journalism:

> To be considered objective, a story had to be written in a detached fashion – that is, the reporter writing the story had to let the facts speak for themselves and keep (his/her) personal opinions on the matter to (his/her)self. Objectivity was also said to be enhanced if the reporter offered 'both sides' of the story in a non-partisan way, used eyewitness accounts when possible and corroborated (his/her) facts with multiple sources (Haskell, 2009:87).

This common acceptance by the public of the mainstream media's supposed objectivity provides an important lens by which news is viewed by the reader. If it is objective news, this lens suggests, it must mean that it presents both sides of the story. By extension, if it is objective and presents both sides of the story, it must be free of bias. And by further extension, since this objective news satisfies all of these conditions, it must be the truth.

There is one flaw with this model, however. News is constructed by people – journalists – and even though these people are trained in the practices of the profession, they are still people who bring with them their own subjective biases and social constructs. As Haskell (2009:89) notes: "It is impossible for journalists to reproduce events and issues for the public without first filtering them through a host of internal socio-cultural influences." But reporters bring with them their subjective biases, which can implicitly direct the content of news coverage. "The best the news-consuming public can hope for is that the journalists who bring them their information will act in accordance with the ideal of objectivity and thereby endeavour to keep their personal biases in check when covering news events" (Haskell, 2009:89).

Mainstream media sets an agenda through media framing (Cheng, 2009). To frame, Cheng notes, "is to select some aspects of a perceived reality and make them more salient in a communicating text, in such a way as to promote a particular problem definition, causal interpretation, or moral evaluation for the item described" (2009:6). Riffe (2006:2) notes that framing

is an implicit part of the storytelling process. “In reporting a story,” Riffe states, “journalists select aspects of an event or issue and organize or emphasize them in ways that may characterize the issue, suggest who or what is responsible for it, and perhaps even suggest solutions or changes.”

The framing of news helps tell the reader what needs to be known and what should be known (Tuchman, 1978:1). As Gitlin (1980:7) argued, “media frames, largely unspoken and unacknowledged, organize the world both for journalists who report it and, in some important degree, for us who rely on their reports.” The reporter's frames in constructing an article serve four functions: to define problems, to diagnose causes, to make moral judgments, and to suggest remedies (Entman, 1993:52). Frames, then, are different broad concepts which help to simplify an issue, but which can influence, in turn, what the public thinks about the issue. The frame, or lens, by which reporters view biomedical discoveries can be shaped significantly by the sources consulted (Billgen, 2006:7). According to Entman (1991:7), the initial interactions between journalists and their sources sets the framing process in motion.

2.9 Science, newspapers and news framing

As noted previously, the rigours of the scientific method imbue scientists with a layer of authority and near-infallibility in the minds of the public. Similarly, the accepted notion that reporters in Western society strive to produce objective news content imbues that content with a layer of authority.
This allows mainstream media to act as an agenda-setting device.

Science writing, particularly that pertaining to biomedical research, is a small specialized subset of journalists. According to Hotz (2002:6), only two-thirds of the members of the U.S.-based National Association of Science Writers are actually journalists, and about one-half of those journalists are actually freelance reporters, “not staff writers, making them dependent on corporate and university assignments. They are not in a position to easily bite the hand that feeds them”. “In part, this situation reflects the economic realities of any

21st century newsroom," Hotz noted, "especially those of most broadcast outlets and many mid-sized or small newspapers where no one can afford to specialize. Fewer staff reporters are stretched to cover increasingly complex science stories" (Hotz, 2002:6).

As is the case with other specialized newspaper beats, science/biomedical research beat reporters are expected to cultivate and maintain a network of sources. Much like the symbiotic relationship that has developed between pharmaceutical companies and public research institutions, a symbiotic relationship exists between science/biomedical reporters and their sources.

This raises a subtle but important point. Symbiotic relationships by definition mean that each side stands to gain – which means the source side in the journalist-source equation can expect to realize a benefit from the relationship, just as much as the reporter side of the equation expects to realize a benefit. According to Palmer (2000:4):

> Without news sources, there is no news. While this principle may be obvious, it is worth stressing because the dependence of journalists upon sources does not only explain the fact that a story is covered at all: it may well explain *how* the story is covered, or at least some elements of the way in which coverage occurs.

Beats, then, come to be defined in particular ways according to a number of factors, "which include the way editors and their reporters conceive of the beat; the kinds of news stories reporters thereby seek; the journalists' own relevant knowledge base; the institutions they frequent in their search for news; and the contacts they make with sources of information" (Gasher, Hayes, Hackett, Gutstein, Ross and Dunn, 2007). As Gasher *et al.* also noted: "A beat as vast as health, for example, compels newspapers to make decisions about which subtopics of health – medical research, the health care system, public policy, lifestyle, alternative healing methods – will be covered" (2007:561).

The potential biases – explicit or implicit – of the sources used by reporters for biomedical research stories thus become relevant when contemplating the content of biomedical research articles. As Hotz (2002:6) argued:

> Science writers are no more or less vulnerable to the occupational hazard of any beat reporter - that of adopting the point of view of the people they cover. In this case, it means that reporters can come to identify with the enterprise of science itself.

Gasher and his colleagues examined the health literacy of Canadian newspapers in a 2007 paper and they offered this concise description of media framing:

> Communication theory maintains that the media do not simply mirror or reflect reality. Instead, through the use of words and images, the media represent, or depict in particular ways, the people, places, events, ideas, and institutions that constitute our world. . . Media content is produced or constructed through a series of complex choices about precisely how to depict a given topic—what to include, what to exclude, what to emphasize, what to minimize (Gasher *et al*, 2007:558).

These "complex choices" are not always made in isolation by the reporter. These choices are influenced by editors at a variety of levels in the editorial hierarchy. Not surprisingly, the greater the importance of the story, the greater the number of editors who are likely to seek input on the story and the higher those editors will be in the hierarchy.

2.10 Biomedical research reporting and the lay audience

While newsrooms are hierarchical in nature, traditional news articles are also hierarchical in nature. The standard news article employs what is known as the inverted pyramid, where the bulk of the important new information is placed at the top of the article, generally in the lead and the first few paragraphs, with each subsequent paragraph revealing less and less new and important information.

Van Dijk (1988) proposes a so-called "superstructure" that acts as a framework for a news product. The superstructure consists of a list of "ever-

present” categories such as the headline and the lead, which, together, form what he calls the Summary. The Background is formed by the main events, context and history. The Verbal Reactions and Comments category is comprised of quotations and the types of sources used in the news product. This kind of structure allows for the most important details to come ahead of other not so important details, which van Dijk(1988:43) describes as "a top-down strategy, which assigns a so-called relevance structure to the text". By its nature, this article structure lends itself to quick and simple dramatizations of information to capture the reader’s attention.

Biomedical research articles typically apply common reporting shortcuts and omit standard pieces of information. This reporting shorthand helps turn scientifically dense material into easy-to-comprehend texts for the reader. For example, biomedical discoveries as described in scientific journals are almost never definitive when it comes to the success of experimental treatments. (It is perhaps ironic that those discoveries that are most definitive are actually those that report a negative or harmful outcome rather than a positive one.) Successes are determined by complicated statistical processes. There are virtually no full “cures” identified from biomedical research, and certainly none of the breakthroughs identified in this study resulted in “cures” that had a 100 per cent success rate. Instead, successes are measured by incremental improvements compared to the previous gold standard of treatment. For experimental cancer treatments, for example, improvements are often measured in years, months or perhaps even as little as weeks of added survival time.

Biomedical research articles in mainstream newspapers consistently omit details of the statistical processes used in evaluating the effectiveness of the pharmaceutical products. Biomedical research articles will also typically omit the complicated scientific underpinnings that explain the effectiveness of the newly-discovered process. In other words, the specific physiological mechanics of the new treatment will be put aside in favour of a more general and simpler explanation that can be understood by a lay audience.

This is not unexpected. When crafting a newspaper article, the reporter must balance between providing enough information to make the article informative and useful to the reader and providing an excessive amount of information that makes the article difficult for the reader to comprehend.

Many factors can influence how the reporter arrives at the decision about what to include and what information to omit: the amount of time available to produce the text, the amount of space allotted to the article in the newspaper, the reporter's own understanding of science and the scientific concepts involved. Faced with these competing factors, it is easy to see that the types of sources involved in information gathering and the bias of the sources can play a key role in the information inclusion and exclusion process.

2.11 Journalists and ethics

There has been discussion earlier about the important connection between scientists and scientific ethics, particularly the necessity for scientists to engage in ethical behaviour in their pursuit of scientific discoveries. It is important to note that there must also be a connection between journalists and journalistic ethics. In this case, however, there is less clarity in a common understanding of precisely what constitutes ethical journalistic practices. When questions are raised about the accuracy of news, some journalists are unable to cite their news values and ethics, and even if they can, there is a lack of consistency in articulating a common code of ethics (Corrigan, 1990:653).

Borden and Pritchard provide a useful definition of conflict of interest as the concept applies to journalists. Conflicts of interest in journalism arise in "circumstances in which there is reason to be concerned that the judgment and performance of journalists might be unduly influenced by interests that have that lie outside their responsibilities as journalists" (Borden and Pritchard, 2001:74).

The public depends on journalists to gather and disseminate information "that enables us to make meaningful decisions about our lives" (Borden and Pritchard, 2001:75) and conflicts of interest jeopardize this trust.

As Borden and Pritchard noted:

> "If people cannot trust a journalist to 'give it to them straight,' they are stripped of their ability to make well-informed choices. They will not know whether the information provided is a reliable basis for decision-making; their options are curtailed" (2001:76).

There have been attempts made to create standardized ethical journalistic practices. Some organizations, such as the International Federation of Journalists, the American Society of News Editors, and the Society of Professional Journalists have established their own codes of ethics. However, participation in these organizations is not mandatory for journalists, adherence to each of these codes is not universal and there is no enforcement mechanism in place to keep journalists accountable to these essentially voluntary standards.

In Canada, there is no licensing body that provides accreditation for journalists, there are no government-regulated ethical standards that must be adhered to, nor are there any regulations that specifically govern journalists aside from the broader laws that govern criminal and civil offences, such as libel and slander. In general, Canadian journalists are expected to adhere to what could best be referred to as "common industry practices". Newspapers in Canada typically would expect their journalists to abide by in-house ethical standards. These in-house standards may or may not be explicitly spelled out in writing and the journalists may or may not be aware of their existence.

2.12 Conclusion

Thus, there are three "trip-wires" that need to be considered in the chain that extends from the production of news concerning biomedical research advances by the reporter, to its consumption by the reader:

1. The reader may not be aware that both the reporter and the reporter's sources may have subjective biases that have influenced how the content has been created and manipulated.
2. The reporter may not be aware of his/her own subjective biases and the biases of the sources consulted to create the content.
3. The researcher sources that were consulted may not realize that they have subjective biases that have been influenced explicitly or implicitly through their financial connection with the commercial funding source of the research.

If any of these trip-wires are set off, it presents a barrier that can distort the value of the information being reported.

CHAPTER THREE: METHODOLOGY

3.1 Introduction

Reporters write stories. They start with an idea – or an assignment is handed to them – they ask questions and collect information, then they assemble the pieces of information they have obtained like a jigsaw puzzle, in an attempt to make sense of whatever issue is being addressed. Rarely, however, do reporters analyze the underlying structure of discourse when they are writing these stories. What conscious or unconscious decisions were made to group certain words together in a question? Why did Question A lead to Question B? What conditioned the respondent to group certain words together in an answer? How was the reporter pre-conditioned from previous experiences to view the issue? How was the reporter pre-conditioned to interpret the respondent's answers? This is where critical discourse analysis can be a useful tool. As Fairclough (2002:14) states: "The question of discourses is the question of how texts figure (in relation to other moments) in how people represent the world, including themselves and their productive activities." This chapter, then, deals with the analytical frameworks applied to the texts comprising the data, namely discourse analysis, framing and genre analysis. It concludes with the specific methods used

3.2 Texts, discourse and discourse analysis

Discourses do not just reflect or represent social entities and relations, they construct or "constitute" them (Fairclough, 2002:14). Discourse analysis is "a qualitative methodology that acknowledges that language is a form of social interaction and focuses on its meaning based on the cultural and social contexts in which it is used" (Trimble and Sampert, 2009). Discourse analysis challenges us to move from seeing language as abstract to seeing our words as having meaning in a particular historical, social, and political condition (McGregor, 2003:1). A strength of discourse analysis is its ability to

examine not only individual phrases or sentences but also to explore the larger issues represented or excluded from the text (Richardson, 2007:1).

In discourse analysis, the term “text” encapsulates more than just the written word. Text can also mean written, oral, visual, non-verbal language. In this study, texts are represented by the words that make up newspaper reports. “Texts can bring about changes in our knowledge (we can learn things from them), our beliefs, our attitudes, values and so forth . . . texts have causal effects upon, and contribute to changes in, people (beliefs, attitudes, etc.), actions, social relations, and the material world” (Fairclough, 2003:8).

3.3 Frames and framing

Frames are “basic cognitive structures which guide the perception and representation of reality. On the whole, frames are not consciously manufactured but are unconsciously adopted in the course of communicative processes” (Konig, 2009:1). Framing “essentially involves selection and salience. To frame is to select some aspects of a perceived reality and make them more salient in a communicating text” (Entman, 2003:52). Frames highlight pieces of information in ways that make them more noticeable and meaningful to the audience. By making the information more meaningful and noticeable, it “enhances the probability that receivers will perceive the information, discern meaning and thus process it, and store it in memory” (Entman, 2003:52).

Entman lays out the function of frames in this manner. Frames, he states (2003:52):

1. Define problems (determine what a causal agent is doing with what costs and benefits, usually measured in terms of common cultural values);
2. Diagnose causes (identify the forces creating the problem);
3. Make moral judgments (evaluate causal agents and their effects);

4. Suggest remedies (offer and justify treatments for the problems and predict their likely effects).

Frames are exclusive as well as inclusive. “Most frames are defined by what they omit as well as include, and the omissions of potential problem definitions, explanations, evaluations, and recommendations may be as critical as the inclusions in guiding the audience” (Entman, 2003:54).

As Scheufele and Tewksbury (2007:12) note:

> The term "framing" refers to modes of presentation that journalists and other communicators use to present information in a way that resonates with existing underlying schemas among their audience. This does not mean, of course, that most journalists try to spin a story or deceive their audiences. In fact, framing, for them, is a necessary tool to reduce the complexity of an issue, given the constraints of their respective media related to news holes and airtime.

3.4 Frame analysis as a method of textual analysis

The analysis of frames in media content is the analysis of the way issues are presented (Stonbely, 2011:2). Frames are “central organizing ideas that provide coherence to a designated set of idea elements” (Ferree, Gamson, Gerhards and Rucht, 2002:105) Frame analysis looks for key themes within a text, and shows how cultural themes shape our understanding of events. In studies of the media, frame analysis shows how elements of the language and structure of news items emphasize certain aspects and excludes other aspects. As Hall (2008:46) notes, “Framing merges quite fluidly with critical discourse analytical methods and theory; for one, framing itself is discursive, and, arguably frame analysis is indeed a kind of discourse analysis.” Unlike discourse analysis, which is qualitative in nature, frame analysis usually takes the form of quantitative content analysis, where the instances of different, pre-determined frames are counted, and then the prominence of frames is connected to the ideological function they perform (Stonbely, 2011; Entman, 1991).

3.5 Framing and agenda-setting

Agenda-setting is defined as "focusing the public's attention on a particular object or issue over another object or issue" (Kuypers, 2002:6). This can be achieved by presenting articles about a particular person or issue repeatedly or by simply covering certain people and issues from the same angle every time. While most newspaper journalists today might be offended by any suggestion they engage in agenda-setting, it is instructive to remember the words of newsman Walter Lippmann, who once described the news media as the audience's window to the outside world.

With respect to agenda-setting, Van Dijk (1995:14) notes that each time people read a news report, "they form a new (or update an already existing) model of that event." An event model describes a mental representation of an experience which is determined by the commonly shared knowledge and attitudes of the social group of the reader. The model's structure can be influenced by manipulating the significance of certain events, their causes or consequences. According to this agenda-setting theory, by focusing on certain issues and neglecting others, media shape people's decision-making processes by telling them what to think about (Berger, 1995). As Hester and Gibson (2007:13) noted, "the press may not be successful much of the time in telling people what to think, but it is stunningly successful in telling its readers what to think about".

3.6 Genre analysis

Genres have been defined by Swales (1990:58) as particular forms of discourse with shared "structure, style, content, and intended audience," which are used by a specific discourse community to achieve certain communicative purposes. Genre analysis examines the use of language to achieve communicative goals. Bhatia identifies a number of goals that can be achieved through genre analysis, which include "to represent and account for the seemingly chaotic realities of the world; to understand and account for the private intentions of the author, in addition to socially recognized communicative purposes; to understand how language is used in and shaped

by socio-critical environment; and to offer effective solutions to ... applied linguistic problems" (Bhatia, 2002:5).

In Swales' (1990) framework, the structure of a genre is broken down into moves, where a move is defined as a functional unit in a text used for some identifiable purpose, and is often used to identify the textual regularities in certain genres of writing and to describe the functions which particular portions of the text perform in relationship to the overall task. A move can be obligatory or optional. It can also be repeated or unique.

For the purposes of this study, two genres will be compared: the genre of medical news articles created for mainstream newspapers and the genre of medical texts created for scientific journals. There are three different approaches to genre analysis: English for Specific Purposes (ESP), Systemic Functional Linguistics and the New Rhetoric. For the purposes of this study, the ESP approach will be used.

3.7 The English for Specific Purposes approach to genre analysis

Swales (1981, 2000) proposes three key notions which are central to the ESP approach of genre analysis: discourse community, genre and schema. A group of individuals are identified as a discourse community when they share the following six characteristics:

- shared goals of members (informing the public, for example, in the case of journalists);
- the presence of mechanisms for communication among members to achieve their shared goals (such as attending press conferences, for journalists, or attending academic conferences in the case of scientific researchers);
- active participation by members;

- common acceptance of a genre(s) possessed by the discourse community;
- acquisition of specialized terminologies by members;
- a mixture of the level of members' expertise.

As already mentioned, a genre is viewed as a class of communicative events with a set of goals that are shared by members of a discourse community (Swales, 2000:24). A communicative event refers to an event in which language plays a significant and indispensible role (Swales, 1990:58).

Thirdly, there is the notion of schema. According to Swales (1990:58) a schema is a psychological concept that is used to refer to the organization of knowledge in the memory which is influenced by previous experience and prior texts. According to Suhardja (2008:36), there are two types of schema that contribute to an identification of genre: content schema and formal schema. As Suhardja states, “knowledge of facts and concepts contribute to content schema, while knowledge of text structure, rhetoric, style and procedures contribute to formal schema. Therefore, an understanding of genre requires an understanding of both content and formal schema” (Suhardja, 2008:36).

3.8 Structure of medical research articles published in scientific journals

Convention requires a rigid structure for texts published in medical journals when research results are being brought to light. Journal articles follow a format of Introduction – Methods – Results – Discussion. It is also customary to include an abstract, which summarizes the findings, as well as references, tables, images and diagrams, the funding source of the research, and a description of the authors, their affiliations and any financial connections they may have to the funders. A Conclusion may also follow the Discussions section.

Skelton (1994:456-457) has constructed a move structure for medical research texts published in scientific journals that will be used as the template for this study. Using Skelton's template, medical research texts in scientific journals can be divided into the following moves:

The Introduction section:

Move 1: Stating the relevance of the research

Move 2: Contextualizing the research in the literature

Move 3: Claiming the novelty of the research

Move 4: Stating the purpose of the research

The Methods section:

Move 5: Identify the population being studied

Move 6: Describe the research procedures

Move 7: Name the statistical tests

The Results section:

Move 8: Adjustment and exclusion from the general population stated in Move 5

Move 9: Representation of the results

Move 10: Discussion of the data

Move 11: Assessment of the data

The Discussion section:

Move 12: State the limitation and defend the success of the research finding

Move 13: Present what the study has achieved

Move 14: Contextualize the research procedures and findings

Move15: Offer recommendations

What is evident from Skelton’s structure is that medical research texts in scientific journals follow a near chronological progression, as follows. The

existing research landscape is summarized, the rationale for new research is explained and the goals are outlined. The methods for conducting the research are explained along with the methods used to quantify the collected data. The results are then presented and assessed. Finally, there is a discussion of the significance of the research findings and forward-looking suggestions of future implications.

3.9 Structure of medical research news articles for mainstream newspapers

Convention has also led to a rigid format for news articles that are created for mainstream newspapers. As discussed earlier, conventional news articles employ an inverted pyramid format that packs the most important, and generally the most recent, developments at the beginning of the article.

Suhardja (2008) has constructed a move structure for medical research news articles published in mainstream newspapers. Her move structure is appropriate for the purposes of this study. In Suhardja's format, moves can be further subdivided into steps. Steps are specific actions or devices that advance the move. Steps can be obligatory or optional.

Suhardja's (2008:75) move structure for medical research news articles:

Move 1: Attracting the readers' attention

Step 1: Headline

Step 2: Subhead

Step 2A: indicating the implication of the research or

Step 2B: indicating the debate surrounding the research or

Step 2C: comparing present research with past research

Move 2: Providing attribution

Step 1: Specifying the name of the journalist and/or

Step 2: Specifying the title of the journalist and/or

Step 3: Specifying the contact detail

Move 3: Summarizing the news report (the lead paragraph)

Move 4: Presenting the main event

Step 1: presenting the main and specific research finding and

Step 2: specifying the research method

Step 2A: describing the research process and/or

Step 2B: specifying the type and size of data collected

Move 5: Indicating the significance of the event

Step 1: referring to intrinsic qualities of the research articles and/or

Step 2: referring to the implication of the research and/or

Step 3: referring to the local relevance

Move 6: Presenting background information

Step 1: comparing the present research with past, present and/or other related research and/or

Step 2: explaining the technical terms and concepts used and/or

Step 3: indicating the funder of the research

Move 7: Indicating the source of information

Step 1: referring to the scientists and

Step 2: referring to the journal

Move 8: Showing balanced reporting

Step 1: indicating the reaction of other scientists and/or

Step 2: indicating the reaction of other users

What is most evident with Suhardja's move structure is that the news article does not follow a chronological progression, as seen in the format of medical research articles published in scientific journals. Instead, the medical research news article closely follows the conventional format of a news story, with an inverted pyramid structure that places the most important and most recent developments at the beginning of the report.

3.10 Texts used in this study

3.10.1 Source of texts

The units of analysis for this study were English-language newspaper articles selected from a database known as Canadian Newsstand, which is a comprehensive, full-text archive of approximately 300 of Canada's leading newspapers. The archive dates back to 1977 and it is updated daily. Keyword searches of the entire database, as well as date range searches, can be performed quickly and easily. Article entries include the date the article appeared, author (if identified), the publication, the headline that appeared with the article, a short abstract, the full text of the article and its word count. Editorials, letters to the editor and news briefs less than 200 words in length were omitted from consideration. The date ranges used in this study were newspaper publication dates from January 1, 2001 to December 31, 2008.

3.10.2 Identification of texts suitable for inclusion

Various keywords and keyword combinations were used to identify articles for inclusion. Examples of keywords included, but were not limited to: drug, discovery, pharmaceutical, breakthrough, advance, medical, research, scientific. In some cases, the general scientific names and/or brand names for certain drugs were used as keyword searches in cases where those drugs had been linked to scientific advances to ensure that all articles about the drug in question were captured.

3.10.3 Inclusion criteria

For inclusion in the study, an article must have satisfied all of the following criteria:

- articles must be over 200 words in length, to eliminate what are known as "news briefs" in the newspaper industry;
- articles must discuss research related to a drug or medical device; the research described in the article must have been conducted by a researcher or researchers who are affiliated with public institutions, such as a university, college, teaching hospital, or government agency, such as the National Cancer Institute of Canada;
- the research described in the article must have been funded in whole or in part by a commercial funding source, such as a pharmaceutical company or a medical device manufacturer;
- the principal investigator(s) of drug or medical device, and/or the investigators cited in the article must have a financial connection to the commercial funding source of the research.

A financial connection to a commercial funding source is defined as the receipt of honoraria, speaking fees, consultant's fees, stock ownership, stock options, royalty or patent payments and research funding.

3.10.4 Final selection of texts

Potential article candidates were then cross-referenced with the appropriate scientific publication where the research was published. The scientific journal articles were then analyzed to establish if the research was funded by a commercial source and, where applicable, if there was a financial connection between the investigator(s) and the commercial funding source. The journal articles were then saved for reference. In cases where the article was produced by a wire service and appeared in multiple newspapers, the newspaper publication with the longest, most complete version of that particular wire service article was selected for inclusion.

3.11 Procedure for textual analysis

The following types of textual analysis were carried out to generate data which might be useful in achieving the first three objectives of the research, namely, to establish:

1. To what extent disclosure is made of the principal researchers' financial backing.
2. Whose financial interests are involved in each case.
3. What reasons might exist to explain why reporters might fail to note the financial connections of science researchers in news articles.

3.11.1 Content analysis

Articles identified for inclusion were then analyzed for content. Three principal questions were examined:

1. Does the article identify the financial connection between the researcher(s) and the commercial funding source?
2. Does the article identify the source of the research funding?
3. Does the article identify the amount of the research funding?

A spreadsheet was created to tabulate the results. The spreadsheet included such categories as article publication date, author, word count, investigator(s), scientific journal and journal article title, commercial funding source, funding amount, keywords and any additional comments about the newspaper article or scientific journal article.

3.11.2 Analysis of tone

Newspaper articles identified for inclusion were then further examined for tone. Four principal questions were asked about tone:

1. Was the article positive, neutral or negative in its coverage of the drug or medical device?

2. Did the article report any possible side effects and/or dangers associated with the drug or medical device?
3. Did the article include comment from a neutral third party?
4. Did the article include an opposing view from a third party to balance the article?

A text analysis was then carried out on the newspaper articles to identify the types of words used by the authors when describing these scientific advances.

3.12 Genre analysis

A genre analysis was carried out on a case study involving one biomedical research discovery which took place in October 2003 and was the subject of six newspaper articles included in this study. The intention was to compare the structure and functions of the medical journal article announcing the biomedical advance for a breast cancer drug called letrozole with the structure and functions of the six newspaper articles published in Canadian newspapers which that covered the research findings in the journal article. While the genre analysis was aimed at providing data to answer research objective 3. (i.e. to establish "What reasons might exist to explain why reporters might fail to note the financial connections of science researchers in news articles"), it could also offer further insights into research objectives 1. and 2 (i.e. in showing how various elements were accommodated – or not – in the genre/s involved).

3.13 Interviews with Journalists

Interviews with Journalists were aimed at eliciting possible reasons as to why reporters "might fail to note the financial connections of science researchers in news articles" (i.e. to provide further insights into answering research objective 3). Contact information was gathered for each of the reporters who authored an article included in the study. Three questionnaires were then assembled. The questions were designed to obtain general information about the reporter, including amount of experience and areas of expertise.

The questions were also designed to obtain more specific information about the reporter's understanding of science, the scientific process and scientific ethics. One questionnaire was assembled specifically for reporters who authored articles that did not identify financial connections between researchers and the commercial funding sources. One questionnaire was assembled for reporters who authored articles that did identify such a financial connection. One questionnaire was assembled for the rare cases of reporters who authored both types of articles.

The reporters were contacted either by electronic mail, telephone or in person. Those who responded positively were told the purpose of the study and then asked if they would agree to answer the questionnaire. Completed questionnaires were then tabulated and analyzed.

3.14 Conclusion

In this chapter different frameworks for analyzing texts have been put forward for discussion. Frames, as Ferree *et al* (2002:105) note, are “central organizing ideas that provide coherence to a designated set of idea elements”. As discussed in this chapter, frame analysis looks for key themes within a text, and shows how cultural themes shape our understanding of events. A third layer is the framework of genre analysis, where a genre is a particular form of discourse with shared ‘‘structure, style, content, and intended audience,’’ which is used by a specific discourse community to achieve certain communicative purposes (Swales 1990:58). This study will compare two distinct genres: the genre of medical research articles published in scientific journals and the genre of medical research news articles published in mainstream newspapers.

The structures of these two genres are distinctly dissimilar. Medical research articles published in scientific journals are structured to proceed in chronological fashion, with background material placed at the beginning, followed by the methodology, followed by the results and the forward-looking implications of the results. Medical research news articles published in

mainstream newspapers are structured in reverse fashion. They typically begin with the highlights of the results and the forward-looking implications of the results, with background material placed closer to the end of the story. The specific methodology of the research may not even be included in the news article. However, medical research news articles will typically include reaction to the results with direct quotes from scientists, third-party agencies and patients, a move that is absent from the move structure of medical research articles published in scientific journals.

CHAPTER FOUR: RESULTS OF THE TEXTUAL ANALYSIS

4.1 Introduction

A textual analysis of the newspaper articles was conducted to help satisfy the objectives of this study, as laid out in the opening chapter. To recap, the six objectives include ascertaining the following:

1. To what extent disclosure is made of the principal researchers' financial backing.
2. To what extent disclosure is made of the funding sources of the biomedical research being reported.
3. What reasons might exist to explain why reporters might fail to note the financial connections of science researchers in news articles.
4. Whether the genre of medical research articles for newspapers differs from the genre of medical research articles for scientific journals
5. The implications of the answers to the above for readers/the public.
6. Recommendations which might be made to ensure that financial interests are disclosed.

4.2 Sample obtained for analysis

By applying the methods for selection of texts described in the previous chapter, a total of 87 newspaper articles were identified for inclusion in this study, representing an average of about one article per month over the eight-year study range. Twenty-six different Canadian newspapers are represented among the 87 articles identified. The average word count was 588 words per article, with a high of 1,760 words and a low of 222 words.

4.3 Analysis as per questions identified in the methodology

The results are broken down as per the questions identified in the methodology. Table 4.1 gives an overview of the results obtained, which are then dealt with per question.

Table 4.1 Overview of results as per questions identified in the methodology

	The article…	**YES**	**NO**	
1.	…identifies connection between researcher(s) and funding source	18.4%	81.6%	
2.	…identifies source of research funding	50.6%	49.4%	
3.	…identifies amount of research funding	4.6%	95.4%	
5.	…reports possible side effects and/or dangers	49.4%	50.6%	
6.	…includes comment from a neutral third party	52.9%	47.1%	
7.	…includes opposing view from a third party	21.8%	71.2%	
		Neutral	**Positive**	**Negative**
4.	…is positive, neutral or negative in its coverage	2.3%	94.3%	3.4%

4.3.1 Connection between the researcher(s) and the commercial funding source

These results answer the question: “Does the article identify the financial connection between the researcher(s) and the commercial funding source?”

- 16 of 87 articles (18.4 per cent) identified the connection between the researcher(s) and the commercial funding source.
- 71 of 87 articles (81.6 per cent) did not identify the connection between the researcher(s) and commercial funding source.

An overwhelming proportion of the news articles failed to identify that there was a financial connection between the researcher(s) and the commercial entity that was funding the research in question. In nearly 82 per cent of the articles, readers were not provided with the most critical piece of information that would identify a potential conflict of interest for the researcher(s).

It is important to note that the financial connections between the researcher(s) and the commercial funding source were present in 100 per cent of the scientific journal articles that matched the research reported in the newspaper articles. Information about the potential financial conflicts for the researchers was available to be reported.

4.3.2 Source of research funding

These results answer the question: “Does the article identify the source of the research funding?”

- 44 of 87 articles (50.6 per cent) identified the funding source.
- 43 of 87 articles (49.4 per cent) did not identify the funding source of the research.

Roughly half of the articles failed to even acknowledge that a commercial entity, such as a pharmaceutical company, was the source of funding for the research.

The source of research funding could be considered one of the most basic pieces of information that would help readers identify potential conflicts, as well as whose interests are being served by the dissemination of research results. The source of funding for the research was present in 100 per cent of the scientific journal articles that matched the research reported in the newspaper articles. Information about the potential financial conflicts for the researchers was available to be reported.

4.3.3 Amount of research funding

These results answer the question: “Does the article identify the amount of the research funding?”

- 4 of 87 articles (4.6 per cent) identified the amount of funding for the research.
- 83 of 87 articles (95.4 per cent) did not identify the amount of funding for the research.

Nearly all of the newspaper articles failed to mention the amount of funding provided by the commercial entity. This can be a key piece of information as well in helping readers understand what is at stake for both the commercial source and the researchers. It is not unusual for large clinical trials to require millions, if not tens of millions of dollars in funding. In nearly all articles, that important context was absent.

4.3.4 Positive, neutral or negative coverage of the drug/medical device

These results answer the question: “Is the article positive, neutral or negative in its coverage of the drug or medical device?”

- 82 of 87 articles (94.3 per cent) were positive about the drug/device cited by the research.
- 2 of 87 articles (2.3 per cent) were neutral.
- 3 of 87 articles (3.4 per cent) were negative.

As noted in the introduction to chapter 2, a bias already exists with respect to articles published in scientific journals. A landmark study by Bhandari et al (2004) showed that clinical trials funded by the pharmaceutical industry are twice as likely to come to a positive conclusion about the product than trials financed otherwise.

The bias with newspaper articles is even more staggeringly one-sided. Nearly 95 per cent of the articles were positive about the drug or medical

device research, which was funded by the commercial entity. Potential motivations for the one-sided reporting of positive outcomes in newspaper articles will be explored in chapters 5 and 6.

4.3.5 Reporting of possible side effects or dangers of treatments

These results answer the question: “Does the article report any possible side effects and/or dangers associated with the drug or medical device?”

- 43 of 87 articles (49.4 per cent) point out the dangers and/or side effects of the drug/device cited in the research.
- 44 of 87 articles (50.6 per cent) did not point out the dangers and/or side effects of the drug/device cited in the research.

Half of the articles failed to identify possible dangers and side effects of the drug or device cited in the research. This is an important piece of context to help balance a news article for readers. It is important to note that side effects and possible dangers of treatment were present in 100 per cent of the scientific journal articles that matched the research reported in the newspaper articles. Information about the potential financial conflicts for the researchers was available to be reported.

4.3.6 Comment from a neutral third party

These results answer the question: “Does the article include comment from a neutral third party?”

- 46 of 87 articles (52.9 per cent) included neutral comment of the research from a third party.
- 41 of 87 articles (47.1 per cent) did not include neutral comment of the research from a third party.

Nearly half of the articles failed to include a comment from a neutral third party to help provide balance to the newspaper reporting for the reader.

It is important to note that neutral third parties refers to experts in the field who were not associated with the research being reported. However, because many researchers in the field have overlapping financial connections with multiple commercial entities it is possible that the third parties who were quoted may have been neutral with respect to the specific research cited but they themselves may have had a potential financial conflict with the funder relating to other work. So in fact, some may have been neutral to the research but not at all neutral with respect to the funder. The financial connections of neutral third parties was not explored in this study.

4.3.7 Opposing view from a third party

These results answer the question: “Does the article include an opposing view from a third party to balance the article?”

- 19 of 87 articles (21.8 per cent) included an opposing view of the research to balance the story.
- 68 of 87 articles (78.2 per cent) did not include an opposing view of the research to balance the story.

An overwhelming proportion of articles did not include an opposing view of the research. This, however, is perhaps not unexpected. Given that the research results being reported were, by nature, new findings, it is not unexpected that there might not be enough opinions formed about the discovery to elicit opposing views.

An interesting sequel to this study would be to re-examine the products reported positively in these articles to see if the positive outcomes have been maintained once the products have either entered the marketplace or been subjected to more rigorous clinical trials.

4.3.8 Summary

A statistical examination shows that an overwhelming majority of the newspaper articles failed to inform readers about potential financial conflicts

of interest that existed between the researcher(s) and the funders. Only half of the articles identified the source of funding, and almost all of the articles failed to include the amount of funding provided. Key pieces of context were frequently withheld from readers.

4.4 Results of the text analysis

Table 4.2 shows some of the most common terms used in the newspapers articles to describe the militaristic approach to reporting on biomedical discoveries and / or optimism for the future.

Table 4.2 Overview of results of the text analysis

Texts contain the terms:	**%**
breakthrough	36.8%
significant/significantly	23.0%
hope	20.7%
promising	14.9%
important	14.9%
major	11.5%
huge	11.5%
exciting	8.1%
dramatic	6.9%
landmark	4.6%
tremendous	4.6%
groundbreaking	3.4%
weapon	3.4%

An overview of the results of the text analysis is given in Table 4.2, showing the prevalence of terms indicating that the medical research reported on represents a breakthrough or that science is prevailing in the battle against disease. The term “breakthrough” tops the list, with words such as “significant”, “hope” and “promising” suggesting that medical research is prevailing in the battle against evil (i.e. the disease), although the term “weapon” has one of the lowest scores. Interestingly claims that the

“breakthrough” is “huge” or a “landmark” victory are less common, suggesting that hyperbole is to be avoided.

4.5 Improvement in the reporting of funding connections

The results also suggest that reporting of the funding connections between the principal researcher(s) and the commercial funding source improved over the eight-year period covered by this study. Half of the articles that cited such a connection (n=8) have been published since September 2006, which puts them among the 20 most recent articles identified for inclusion. That represents an identifying rate of 40 per cent, more than twice as high as the overall rate that financial connections were identified.

4.6 Frame analysis

As discussed previously, power relationships and power imbalances are central to critical discourse analysis. In this case, there are several strata of power relationships at play, creating a hierarchy. The pharmaceutical companies have economic power over the researchers, who depend to greater or lesser extent on money from the companies to conduct research. That ability to conduct research and produce results enhances the researcher's own power among his or her peers. The researchers have power over journalists through knowledge ownership. Journalists are dependent on the knowledge of the researchers to provide them with the information necessary to produce their work. Journalists have power over their readers through the process of information control. Readers are dependent on journalists to provide them with the information necessary to help them make sense of the world around them.

As noted earlier, journalists are the "gatekeepers" in the process of transmitting information. They engage in the active construction of the messages of news articles by emphasizing certain aspects of issues and not others (Kosicki, 1993). The construction of these messages is done through the use of frames, different broad concepts that help to simplify an issue, but that can influence, in turn, what the public thinks about the issue. As noted

earlier, according to Entman (1993), frames serve four functions – to define problems, to diagnose causes, to make moral judgments, and to suggest remedies – although not all articles include all four functions.

As Haskell (2009) notes, news framing is a process of information selection and emphasis. "When they create a news story," Haskell said, "journalists must use interpretive judgment selecting and emphasizing some facts and leaving others out." In the case of biomedical research reporting, the information selection and framing process is influenced by the reporter's pre-existing training and knowledge (or lack thereof) of the subject, choice of sources and pre-conditioned views of the issue.

The structural framework of the articles included in this study is remarkably similar, particularly given that the framework is consistent across different reporters, different publications and across the eight years of the study period.

4.6.1 The "triumph of good over evil" frame

The overwhelmingly common approach across the articles was to frame the biomedical research advance as a triumph of good over evil. Often there was an accompanying quantification of the good that will be achieved, sometimes extrapolated to a global level to inflate the numbers of people who could benefit from the advance being reported.

4.6.2 The "hope for the future" frame

Another common approach was to frame the article as a message of hope for the future. It was also common for the articles to frame a quote from one of the lead researchers early in the article, with the researcher's message intended to reinforce the good that will be achieved by the advance, or to offer a message of hope, or, in some cases, both. In this way, the articles quickly condition the reader to view the researcher as being on the side of good in the fight against evil. But by choosing this frame, the articles also condition the reader to view the researcher favourably, making it less likely

for both the reporter and the reader to question the motives or ethical underpinnings of the scientist.

Here are 10 examples of the leads from news articles identified in this study, showing the consistency of approach to biomedical research advances:

1. A blood thinner already used after angioplasty has been shown to be a highly effective treatment for people with ominous chest pain or mild heart attacks, and could potentially prevent 100,000 heart emergencies a year in the United States. A major study released Monday found that the drug, called Plavix, reduced the risk of death, strokes and new heart attacks in these people by 20 per cent, making it probably the most significant advance in their treatment since the introduction of Aspirin. "This is a breakthrough," said Dr. Valentin Fuster of Mount Sinai School of Medicine in New York. "It will change the practice of medicine.

2. A potential life-saving heart drug discovered in Hamilton will soon undergo its first testing in humans. The anti-thrombotic medication, known only as GH9001, is intended to be used in patients who have suffered a heart attack or stroke, or developed a blood clot after surgery. Should it make it into the global drug market, it could become a windfall for its investors, which include Hamilton Health Sciences and McMaster University. The worldwide market for anti-thrombotics is projected to grow to over $9 billion by 2005, significantly higher than in 1999 when sales reached $7.9 billion. "GH9001 has tremendous potential," said Dr. Jack Hirsh.

3. For the first time, a new class of anti-cancer drugs has been shown to be even more effective than the "gold-standard" tamoxifen in keeping postmenopausal breast cancer patients alive, according to groundbreaking research doctors say will "revolutionize" treatment of the second-leading cancer killer of women. "This is not a run-of-the-mill drug company trying to make noise about something rather irrelevant. This is a complete shift in the treatment of breast cancer," said Dr. Paul Goss, a medical oncologist at Princess Margaret Hospital in Toronto.

4. Breast cancer survivors have an important new weapon in their long-term treatment arsenal, researchers revealed yesterday as they announced the dramatic findings of a clinical trial into the drug letrozole. The principal investigator said the significance of the findings is on a par with the earlier discovery that chemotherapy fights breast cancer. "I think this is a sea change in the treatment of the disease," said Dr. Paul Goss, a breast cancer clinician and researcher from Toronto's Princess Margaret Hospital. "I think that no doctor will

go to the clinic or to his patient office tomorrow and feel the same about treating breast cancer again.

5. Jubilant Canadian researchers have announced a major breakthrough in the treatment of breast cancer in post-menopausal women. The results of a large international trial released yesterday found that a drug called letrozole virtually cut in half the risk of disease recurrence and death in female breast-cancer survivors who had first taken the drug tamoxifen for five years. The findings were so dramatic that the Canadian-led international trial was halted early so more women could benefit immediately.

6. A new vaccine could do for cervical cancer what immunization did in the fight against polio, scientists said Tuesday. "This is the greatest breakthrough since the implementation of Pap (smear) tests 55 years ago," said Alex Ferenczy, head of gynecologic pathology and cytopathology at Montreal's Jewish General Hospital.

7. Study results of more than 8,000 women worldwide who took the breast-cancer drug Herceptin are "simply stunning" and suggest the treatment is a potential cure for the disease, according to an editorial published today in the New England Journal of Medicine. Treatment must change today so that all patients who would benefit from the drug, also known as trastuzumab, can receive it, according to the editorial written by Gabriel Hortobagyi, director of the Breast Cancer Research Program at the M. D. Anderson Cancer Center of the University of Texas. "This observation suggests a dramatic and perhaps permanent perturbation of the natural history of the disease, maybe even a cure," Dr. Hortobagyi wrote.

8. A drug that targets only diseased cells has proved astonishingly effective against an aggressive form of early breast cancer -- a long-sought breakthrough that has doctors talking about curing thousands of women each year in the U.S. alone. The drug, Herceptin, is already used for advanced cancer. But in three studies involving thousands of women with early-stage disease, it cut the risk of a relapse in half. Several experts used words like "revolutionary," "stunning" and "jaw-dropping" to describe the findings. "In 1991, I did not know that we would cure breast cancer, and in 2005, I'm convinced we have," exulted Dr. Jo Anne Zujewski, head of breast cancer therapeutics at the government's National Cancer Institute.

9. A drug that reduces cholesterol has for the first time been found to "turn the clock back" in narrowed arteries, a discovery that could prevent heart attacks and strokes in thousands of people. A British doctor who contributed to the study said that reducing the build-up of fatty deposits in arteries was the "Holy Grail" in the fight to combat heart disease.

10. A highly anticipated study has produced powerful evidence that a simple blood test can spot seemingly healthy people who are at increased risk for a heart attack or stroke and that giving them a widely used drug offers potent protection against the nation's leading killers. In findings that could transform efforts to prevent cardiovascular disease, the study of nearly 18,000 volunteers in 26 countries found that a cholesterol-lowering statin slashed the risk of those flagged by the test by about half -- even if their cholesterol was normal. "The potential public health benefits are huge," said Paul Ridker of the Brigham and Women's Hospital in Boston.

The leading paragraphs of the examples cited follow a template. Typically, there is an announcement of the significance of the findings, with the potential benefits often quantified at a national or even international scale. Optimistic words are frequently used to highlight the significance. The positive findings are typically followed with a quotation from a scientist that further conditions the reader to see the results in a positive, hopeful frame.

The appeal of a hopeful, forward-looking article, of course, is that the claims being made escape harsh scrutiny from the reader. Futuristic predictions of benefits cannot be tested in the present. An interesting exercise would be to explore biomedical advances that have advanced beyond the experimental stage and retrospectively examine the claims that were made in news articles to see if the benefits were realized. This is, however, beyond the scope of this study.

4.6.3 The “battle against disease” frame

Another popular approach by reporters was to frame the articles with a militaristic theme, which helped reinforce the message of good triumphing over evil. Words such as “battle”, “weapon”, “arsenal” and “fight” provide easy-to-understand analogies for the reader and, again, cement in place a positive image of the researcher. The militarization of biomedical research terminology is best exemplified by the late U.S. President Richard Nixon’s well-publicized declaration of a “war on cancer”. Nixon announced in his 1971 State of the Union address that he would seek $100 million to find a cure for cancer, and he used militaristic words such as “campaign” and “conquering” to frame the biomedical challenge he perceived to be facing the

nation. In an odd irony, a U.S. Army biological warfare facility in Maryland was converted to a national cancer research centre (U.S. National Cancer Institute, 2004).

4.7 Conclusion

The content and frame analysis showed how certain key elements of content were included or omitted in the series of [number] medical news articles. The textual analysis also revealed common recurring themes and motifs. The genre analysis in the next chapter will show how these terms fitted into the genre structures used in medical news reports in terms of their purpose and audience, which are different from those of medical research journal articles. The inclusions, omissions, tone and imagery used in medical news reporting are not the result of personal or random choices, not necessarily a deliberate (or accidental) omission to deal with ethical concerns, but an inherent feature of that specific news genre itself.

CHAPTER FIVE: GENRE ANALYSIS

5.1 Introduction

This chapter will present findings of a genre analysis on a case study involving one biomedical research discovery that took place in October 2003 and which was the subject of six newspaper articles included in this study. The intent is to compare the structure and functions of the medical journal article announcing the biomedical advance for a breast cancer drug called letrozole with the structure and functions of the six newspaper articles published in Canadian newspapers that covered the journal article's research findings.

5.2 Content of medical research journal article and six related newspaper articles

Here is the full journal article, published Oct. 9, 2003 in the *New England Journal of Medicine.* Using Skelton's Move structure for medical research articles published in scientific journals identified in chapter 3, the specific moves will be highlighted in the body of the journal article, identified in bold capitals within square brackets at the conclusion of the move. (Example: **[MOVE 1]**).

> **TITLE: A Randomized Trial of Letrozole in Postmenopausal Women after Five Years of Tamoxifen Therapy for Early-Stage Breast Cancer**
> **INTRODUCTION**
> The risk of a recurrence of breast cancer continues for an indefinite period after surgery, radiation, and medical therapy.1,2 Since the growth of breast cancer depends on the action of estrogen,3 long-term reductions in the risk of recurrence have been achieved by antagonizing the activity of estrogen with the selective estrogen-receptor modulator tamoxifen in women with hormone-receptor–positive tumors.1,2 [**MOVE 1]** The postoperative administration of tamoxifen for five years reduces the risk of recurrence by 47 percent and reduces the risk of death by 26 percent.2,4 However, in a trial conducted by the National Surgical Adjuvant Breast and Bowel Project

(NSABP), women who continued to receive tamoxifen therapy after five years had worse outcomes than women in whom it was discontinued at five years.[5,6] On the basis of these results, the National Cancer Institute has recommended that, outside of a clinical trial, tamoxifen treatment should be limited to five years.[7] **[MOVE 2]** Tamoxifen is both an antagonist and a partial agonist of the estrogen receptor.[8] Over time, its agonist action may become exaggerated and thereby impair its potential anticancer activity. It is known that resistance to tamoxifen and dependence on its estrogen-agonist effects develop in breast-cancer cells that are cultured in the presence of tamoxifen.[9-17] In women with metastatic disease that progresses despite tamoxifen therapy, aromatase (estrogen synthetase) inhibitors, including letrozole, have demonstrated efficacy.[18,19] **[MOVE 3]**
In this study of postmenopausal women who had been treated for early-stage breast cancer, we investigated whether letrozole would have antitumor effects after 4.5 to 6 years of tamoxifen therapy had been completed. We report the results of our first planned interim analysis. **[MOVE 4]** After reviewing the information presented here, the data and safety monitoring committee recommended that, in the interest of patient care, the study be discontinued early, and the participants informed of the results. These actions were taken immediately before this article was published.

METHODS

Study Design

We conducted a phase 3, randomized, double-blind, placebo-controlled trial of letrozole in postmenopausal women with primary breast cancer who had completed approximately 5 years (range, 4.5 to 6) of adjuvant tamoxifen therapy. **[MOVE 5]** Women were randomly assigned to receive letrozole (2.5 mg) or placebo orally daily for five years. Women were stratified according to the tumor hormone-receptor status (positive or unknown), lymph-node status (negative, positive, or unknown), and receipt or nonreceipt of previous adjuvant chemotherapy. **[MOVE 6]** The primary end point was disease-free survival, defined as the time from randomization to the recurrence of the primary disease (in the breast, chest wall, or nodal or metastatic sites) or the development of a new primary breast cancer in the contralateral breast. Secondary cancer and death without a recurrence or a diagnosis of contralateral breast cancer were not included as events in this analysis.
The secondary end points included overall survival (defined as the time to death from any cause), quality of life, and long-term safety. Adverse events were assessed according to the Common Toxicity Criteria of the National Cancer Institute (version 2.0). Quality of life was assessed by means of the Medical Outcomes Study 36-Item Short Form General Health Survey (SF-36) and the Menopause-Specific Quality of Life (MENQOL) questionnaire.[20,21] Companion studies assessed the lipid profile and the bone mineral density annually. **[MOVE 7]**
The institutional review board of each participating institution approved the study protocol. All patients gave written informed consent.

Study Population

Women were eligible if they were at least 50 years of age at the start of adjuvant tamoxifen therapy, if they were younger than 50 years but were postmenopausal at the initiation of tamoxifen therapy, if they were younger than 50 years at the start of tamoxifen therapy but had undergone bilateral oophorectomy, if they were premenopausal and younger than 50 years of age at the start of tamoxifen therapy but became amenorrheic during chemotherapy or treatment with tamoxifen, of if they had postmenopausal levels of luteinizing hormone or follicle-stimulating hormone. Other criteria for eligibility included the following: previous adjuvant tamoxifen therapy lasting 4.5 to 6 years; histologically confirmed primary breast cancer; a tumor that was positive for estrogen receptors, progesterone receptors, or both (defined by a level of 10 fmol per milligram of protein or a positive result on immunohistochemical analysis or estrogen-receptor or progesterone-receptor immunocytochemical analysis); discontinuation of tamoxifen therapy less than 3 months before enrollment; an Eastern Cooperative Oncology Group performance status of 0, 1, or 2 (scored on a scale of 0 to 5, with lower scores indicating better function); and a life expectancy of more than 5 years. Imaging studies were performed to rule out metastatic disease only in women who were symptomatic or had abnormal blood tests.

Criteria for exclusion were the concurrent use of investigational drugs and a history of or the presence of another type of cancer other than skin cancer or carcinoma in situ of the cervix. Concomitant systemic hormone-replacement therapy or concomitant treatment with a selective estrogen-receptor modulator was contraindicated. Intermittent treatment with vaginal estrogens was permitted. **[MOVE 5]**

Study Procedures

Women were randomly assigned to treatment groups with the use of the minimization method.[22]They were assessed at one month, through telephone interviews, for compliance and toxic effects. Clinical evaluation, routine blood work, and evaluation of toxic effects were performed semiannually during year 1 and annually thereafter; mammography was performed annually throughout the study. At base line, women reported previous diagnoses of bone fractures, osteoporosis, or cardiovascular disease. Subsequently, new diagnoses were reported by women at follow-up visits. Treatment was discontinued if there was serious intercurrent illness, unacceptable toxic effects, or a recurrence of disease or at the request of the patient. SF-36 and MENQOL questionnaires were completed by a subgroup of women. Recurrence of disease was defined pathologically or on the basis of clinical or radiologic findings, and recurrences were dated at the time they were first detected. **[MOVE 6]**

Interim safety analyses were reviewed twice yearly by the data and safety monitoring committee. Funding was provided by the Canadian Cancer Society, the U.S. National Cancer Institute, and Novartis Pharmaceuticals. Data were collected, managed, and analyzed by the National Cancer Institute of Canada Clinical Trials Group. The trial committee made the decision to publish the results.

Statistical Analysis

The sample size was calculated under the assumptions of a four-year disease-free survival rate of 88 percent in the placebo group and the detection of a difference of 2.5 percent in the four-year disease-free survival rate (hazard ratio for local or metastatic recurrence of the disease or the diagnosis of contralateral breast cancer, 0.78), with 80 percent power at a two-sided alpha level of 0.05. These assumptions necessitated the enrollment of 4800 women over a four-year period with two years of follow-up, accounting for 515 events. **[MOVE 7]**

Two interim analyses were to be conducted, after 171 and 342 events had occurred. Early termination would be considered at the time of the interim analyses if the P value of the stratified log-rank test was below a nominal significance level calculated with the use of the Lan–DeMets alpha spending function, with O'Brien–Fleming boundaries that maintained the overall significance of the study at a two-sided alpha level of 0.05. 23 **[MOVE 7]**

The required minimal number of events for the first interim analysis (171) had occurred by March 2003. This report is based on the results presented to the data and safety monitoring committee on August 22, 2003; it includes data on efficacy through August 19, 2003, and data on adverse events through February 28, 2003. Disease-free survival and overall survival were the two efficacy end points considered in the interim analysis. For the analysis of disease-free survival, data for the women who died without a recurrence of breast cancer or a new diagnosis of contralateral primary breast cancer were censored at the date of death. The stratified log-rank test, taking into account the stratification factors used for randomization, was used for the comparison of the treatment groups in terms of disease-free and overall survival. 24 The chi-square test was used for the comparison of the groups in terms of the rates of toxic effects. All reported P values are two-sided. **[MOVE 7]**

RESULTS

Study Population

Between August 1998 and September 2002, 5187 women underwent randomization; 2593 were assigned to the letrozole group, and 2594 to the placebo group. In order to complete accrual to a substudy focused on effects on bone, enrollment exceeded the planned 4800 women. Thirty women (18 in the letrozole group and 12 in the placebo group) who did not have investigation forms at base line were excluded from the analyses. Thirty-nine women (19 in the letrozole group and 20 in the placebo group) were deemed ineligible because they had received adjuvant tamoxifen therapy for too long, too much time had elapsed since their discontinuation of such therapy, their menopausal status did not meet the eligibility criteria, they had had a previous recurrence, they currently had or had previously had another type of cancer, their primary surgery had been inadequate, they had a hormone-receptor–negative tumor, they had inadequate investigations at base line, or they were receiving simultaneous hormone therapy. These women were included in the analysis according to the intention-

to-treat principle. The two groups were balanced in terms of all relevant base-line characteristics (Table 1). **[MOVE 8]**

Study Outcome

At a median follow-up of 2.4 years in this first analysis, 207 events (40 percent of the events required for the final analysis) had occurred. With this number of events, the O'Brien–Fleming boundary was 0.0008. Figure 1A shows the Kaplan–Meier curves for disease-free survival in the two groups. The estimated four-year disease-free survival rate was 93 percent in the letrozole group and 87 percent in the placebo group. The hazard ratio for a local or metastatic recurrence or new contralateral breast cancer in the letrozole group as compared with the placebo group was 0.57 (95 percent confidence interval, 0.43 to 0.75; P=0.00008). We also performed a sensitivity analysis in which we counted the deaths of women who did not have a recurrence or contralateral breast cancer as events in the estimation of disease-free survival, instead of censoring the data for these women. In this analysis, the hazard ratio for death, recurrence, or contralateral breast cancer in the letrozole group as compared with the placebo group was 0.61 (95 percent confidence interval, 0.47 to 0.79; P≤0.001). **[MOVE 9]**

In an unplanned subgroup analysis, the effect of letrozole was at least as great among women with node-negative disease (hazard ratio for recurrence or contralateral breast cancer, 0.47; P=0.005) as among those with node-positive disease (hazard ratio, 0.60; P=0.003). Table 2 shows the sites of recurrence; there were fewer locoregional and distant recurrences and fewer new primary tumors in the contralateral breast in the letrozole group than in the placebo group. **[MOVE 9]**

Among the 25 women who had only local recurrences in the ipsilateral breast, 4 had ductal or lobular carcinoma in situ (all in the placebo group), and among the 40 women in whom new primary tumors developed in the contralateral breast, 6 had ductal or lobular carcinoma in situ (1 in the letrozole group and 5 in the placebo group). Seventy-three deaths have been reported (31 in the letrozole group and 42 in the placebo group) (Table 3 and Figure 1B). The estimated four-year overall survival rate was 96 percent in the letrozole group and 94 percent in the placebo group. The hazard ratio for death from any cause in the letrozole group as compared with the placebo group was 0.76 (95 percent confidence interval, 0.48 to 1.21; P=0.25). Table 4 shows the rates of disease-free survival and overall survival through year 4. **[MOVE 9]**

Safety

Table 5 shows data on safety and toxic effects in the first 4299 women enrolled in the study. Toxic effects were primarily of grade 1 or 2. Hot flashes, arthritis, arthralgia, and myalgia were more common in the letrozole group than in the placebo group (P<0.05 for all comparisons). Vaginal bleeding was more common in the placebo group (P=0.01). A total of 4.5 percent of the women in the letrozole group discontinued the study treatment because of toxic effects, as compared with 3.6 percent of the women in the placebo group; the difference was not significant (P=0.11). Approximately equal numbers

of women in the letrozole group (256) and the placebo group (254) chose to discontinue treatment. **[MOVE 10]**
There was a trend toward a higher rate of reports of newly diagnosed osteoporosis in the letrozole group than in the placebo group (P=0.07). Slightly more women in the letrozole group had at least one cardiovascular event or new bone fracture, but neither difference between the groups was significant (P=0.40 and P=0.24, respectively).**[MOVE 10]**

DISCUSSION

We compared therapy with letrozole, an aromatase inhibitor, with a placebo in healthy women with previously treated early breast cancer. The study treatment was given from years 5 through 10 after the diagnosis — a period when further tamoxifen therapy is not beneficial but when relapses of breast cancer occur. 5,6 Several other trials comparing aromatase inhibitors with tamoxifen as adjuvant therapy for the first five years after diagnosis or studying aromatase inhibitors used in sequence with tamoxifen are under way.25 Preliminary results from the Arimidex, Tamoxifen, Alone or in Combination (ATAC) trial show that disease-free survival is longer with anastrozole than with tamoxifen,26 although tamoxifen therapy is still considered an acceptable standard of care.27,28 **[MOVE 12]**
We found a significant improvement in disease-free survival, including a substantial reduction in the rate of distant metastasis in the letrozole group as compared with the placebo group; the rate of death due to breast cancer was almost halved. Letrozole was equally effective in women with node-negative disease and those with node-positive disease. The reduction in the rates of recurrent and new disease in the letrozole group confirms the continuous dependence of hormone-receptor–positive breast cancer on estrogen. **[MOVE 13]**
The data and safety monitoring committee concluded that the results concerning disease-free survival would in themselves have necessitated the unblinding of the study. In addition, the trend toward a reduction in overall mortality in the letrozole group, albeit not statistically significant, influenced the members of the committee to recommend that this information be made available expeditiously. This step was taken immediately before the publication of this article. **[MOVE 12]**
The reduction in the frequency of new primary tumors in the contralateral breast (a relative reduction of 46 percent), a secondary end point of our trial, is compatible with the reduction in the frequency of contralateral disease among women who received adjuvant tamoxifen therapy in earlier studies, 2as well as the reductions among women in the NSABP tamoxifen prevention trial29 and those in the ATAC trial.26 **[MOVE 13]**
Tamoxifen provides protection against bone fractures and lowers serum cholesterol levels.30-32 In contrast, aromatase inhibitors, by decreasing estrogen levels, may reduce bone mineral density and cause hypercholesterolemia. Studies of the effects of letrozole on plasma lipids have had conflicting results.33,34 We found a nonsignificant difference in the rate of cardiovascular events between

the letrozole group (4.1 percent) and the placebo group (3.6 percent), and there were no reports of drug-related hypercholesterolemia. Longer follow-up is needed to rule out the possibility that letrozole has adverse cardiovascular effects. Ongoing monitoring for toxic effects in women receiving letrozole therapy and analysis of our lipid substudy are planned. **[MOVE 14]**

Estrogen deficiency is associated with menopausal osteoporosis.35 Both anastrozole and letrozole have been shown to increase bone resorption,26,36,37 but they have not been associated with osteoporosis. In our study, more women in the letrozole group than in the placebo group reported diagnoses of new-onset osteoporosis, and fractures occurred in a few more women in the letrozole group than in the placebo group (3.6 percent and 2.9 percent, respectively). Because of the early discontinuation of our study, however, these data may underestimate the long-term effects of letrozole on bone metabolism. **[MOVE 14]** The effectiveness of adding bisphosphonates to aromatase inhibitors is under evaluation. Until the results of this evaluation become available, we recommend that women receiving long-term letrozole therapy take calcium and vitamin D according to the guidelines for the prevention of osteoporosis and that their physicians consider monitoring their bone mineral density. **[MOVE 15]**

Hot flashes, arthritis, arthralgia, and myalgia, although more common with letrozole, were generally low-grade. Few women discontinued the study treatment because of toxic effects. The consequences of these effects should be clarified by analyses of our data on quality of life, but because of the early termination of our study, we could not present these data here. Endometrial cancer is in part an estrogen-dependent cancer and represents a rare complication of tamoxifen therapy that may occur even after the discontinuation of treatment with the drug.29,38,39 Vaginal bleeding was significantly less frequent in the letrozole group than in the placebo group in our study, and future studies to determine whether letrozole reduces the risk of endometrial cancer will be of interest. **[MOVE 12]**

Letrozole therapy resulted in a significant improvement in disease-free survival, which included a reduction in the frequency of new primary tumors in the contralateral breast; this reduction accounted for 21 percent of the difference in events between the treatment groups (12 of 57 events). The rates of distant recurrence of disease and death due to breast cancer were also lower in the letrozole group than in the placebo group. **[MOVE 13]**

On the basis of these findings, postmenopausal women with hormone-receptor–positive tumors who have completed about five years of adjuvant tamoxifen therapy should be considered for letrozole treatment. **[MOVE 15]** However, our results, which necessitated the discontinuation of the study, leave the optimal duration of treatment undefined and the question of long-term toxicity unanswered. Data from other, ongoing aromatase-inhibitor trials will contribute information regarding toxic effects, but the question of the optimal duration of treatment will not be answered by the current trials. Our

study did not address the efficacy of letrozole therapy in women in whom tamoxifen therapy had been discontinued more than three months earlier, but because there was an ongoing reduction in the hazard of recurrence in the letrozole group, the use of the drug in such women should be considered. **[MOVE 12]** Consequently, our trial committee has recommended that women in the placebo group in our study discuss their personal risk profile with their oncologist and be considered for letrozole therapy. **[MOVE 15]** Our results do not apply to premenopausal women, since therapy with aromatase inhibitors alone does not suppress estrogen production adequately in women who are still ovulating.40 These results show that in postmenopausal women, letrozole therapy significantly improves disease-free survival.

We now move to the six newspaper articles, all published Oct. 10, 2003, that reported on the findings of the letrozole study in the *New England Journal of Medicine.*

Using Suhardja's Move structure for medical research news articles published in newspapers identified in chapter 3, the specific moves will be highlighted in the body of the journal article, identified in bold capitals within square brackets at the conclusion of the move. (Example: **[MOVE 1-STEP 2A]**).

Newspaper article 1:

Headline: Drug halves repeat of breast cancer **[MOVE 1-STEP 1]**
Subhead: Canadian researchers call letrozole a 'sea change' in the treatment of post-menopausal women **[MOVE 1-STEP 2A]**
By Helen Branswell, Canadian Press [MOVE 2-STEP 1]
Breast cancer survivors have an important new weapon in their long-term treatment arsenal, researchers revealed yesterday as they announced the dramatic findings of a clinical trial into the drug letrozole. **[MOVE 3]**
The principal investigator said the significance of the findings is on a par with the earlier discovery that chemotherapy fights breast cancer. "I think this is a sea change in the treatment of the disease," said Dr. Paul Goss, a breast cancer clinician and researcher from Toronto's Princess Margaret Hospital. **[MOVE 7-STEP 1]**
"I think that no doctor will go to the clinic or to his patient office tomorrow and feel the same about treating breast cancer again." **[MOVE 5-STEP 2]**
The Canadian-led study, which involved 5,000 women in a host of countries, found the risk of a breast cancer recurrence was nearly halved for post-menopausal women who took the drug after five years of treatment with tamoxifen. **[MOVE 4-STEP 1]**
Letrozole is not an appropriate treatment for premenopausal breast cancer patients.

The benefits were so striking, in fact, the researchers had to end the study mid-way through the planned five-year period.
It had reached the point where it would have been unethical to withhold letrozole from the women in the control arm who were receiving a placebo. **[MOVE 5-STEP 2]**
"The results of this study unquestionably offer new hope to hundreds of thousands of breast cancer patients and their families," Goss said at a news conference held shortly before the study was published online by the prestigious New England Journal of Medicine. **[MOVE 7-STEP 2]**
The Canadian Cancer Society, which helped fund the study, estimates 21,200 Canadian women will be diagnosed with breast cancer this year and 5,300 will die from it. **[MOVE 6]**
After a woman receives treatment for breast cancer -- be that surgery, radiation, chemotherapy or some combination of the three -- doctors recommend a five-year course of tamoxifen, a drug that inhibits the estrogen that fuels the majority of breast cancer tumours.
Tamoxifen has been a crucial weapon against breast cancer. But studies have shown it "runs out of steam" after about five years, Goss noted. It's believed tumours develop a resistance to it and that taking tamoxifen for longer might actually increase the risk of recurrence.
Up till now, breast cancer patients who survived five years were then left without any additional tools to decrease the chance of a recurrence. **[MOVE 6-STEP 1]**
Kathy Anderson found herself in that boat. Anderson, a Toronto woman who was diagnosed with breast cancer 8 1/2 years ago, was invited to enrol in the study when she reached the end of her five- year course of tamoxifen.
She was delighted when she learned she had been taking letrozole, not a placebo, for the past 2 1/2 years.
"It's scary at the end of tamoxifen, at the end of five years and you think you have nothing to move onto," she said. **[MOVE 8-STEP 2]**
Breast cancer experts hailed the findings, supporting Goss's claim that letrozole will become an important part of breast cancer treatment.
"This is the first study that shows that continuing treatment beyond the five years that we have always done has beneficial effects," said Dr. Pamela Goodwin, a renowned breast cancer researcher at Toronto's Mount Sinai Hospital.
"It's going to eventually be seen as a watershed trial." **[MOVE 8-STEP 1]**

Newspaper article 2:
Headline: Drug cuts return of cancer by half **[MOVE 1-STEP 1]**
Subhead: Breast cancer test halted to rush product to patients **[MOVE 1-STEP 2A]**
By Joanne Laucius, Ottawa Citizen [MOVE 2-STEP 1]
A groundbreaking Canadian-led study on letrozole, a drug to reduce the reappearance of early-stage breast cancer, found that the estrogen-inhibiting drug cut the risk of recurrence almost in half. **[MOVE 3]**

The five-year study was terminated before its midway point. And, in a rare move, the results were published electronically yesterday in the New England Journal of Medicine. **[MOVE 7-STEP 2]**

The study results will offer new hope to hundreds of thousands of breast cancer patients and their families, said lead researcher Dr. Paul Goss, a medical oncologist and director of the breast cancer prevention program at the Princess Margaret Hospital in Toronto. **[MOVE 3 / MOVE 7-STEP 1]**

An interim analysis found that there were 75 cases of recurrent breast cancer in patients taking letrozole compared to 132 cases in the placebo group. **[MOVE 4-STEP 1]**

Women who had been on a placebo will now be offered the option of treatment with letrozole. Continuing the trial would "imperil women on the placebo," said Dr. Goss in an interview yesterday.

"This result directly affects 50 per cent of breast cancer patients," he said. **[MOVE 5-STEP 1]**

Five years of tamoxifen therapy is standard for preventing recurrence of breast cancer for post-menopausal women with hormone-dependent breast cancer. Tamoxifen inhibits the estrogen that fuels breast cancer tumours. But there has been a disturbing suggestion of negative effects if tamoxifen is taken for more than five years. **[MOVE 6-STEP 2]**

Dr. Goss's study involved more than 5,000 post-menopausal women -- about 20 per cent of them in Canada with the remainder in the U.S, and Europe -- and looked at the effectiveness of letrozole to follow up tamoxifen treatment. **[MOVE 4-STEP 2B]**

Letrozole, produced by Novartis Pharmaceuticals and sold under the name Femara, is an "aromatase inhibitor" that blocks the production of estrogen. It is not appropriate to use for pre- menopausal women with breast cancer. **[MOVE 6-STEP 1]**

Normally, it would take nine or 10 months for study results to appear in the New England Journal of Medicine, said Dr. Goss. These results, which will be published in the journal next month, were released on the website within three and a half weeks, he said.

There were a small number of side effects, including hot flashes, night sweats and arthritis. But few women reported them -- only 4.5 per cent quit taking letrozole because of the side effects compared to 3.6 per cent who stopped taking the placebo.

However, two editorials published in the same online journal of the New England Journal of Medicine expressed some caution.

One noted that halting the study early would cut off findings about the long-term effectiveness of letrozole. **[MOVE 8-STEP 1]**

But Dr. Goss said yesterday he didn't have any reservations about ending the study early. The decision to halt the study was made according to a protocol, he said. The results of the study exceeded those boundaries by ten-fold.

"We're not in the business of experimenting on patients," he said.

Another editorial by medical oncologist Dr. Harold Burstein of Dana-Farber Cancer Institute pointed out that the absolute benefits of letrozole therapy are "limited." **[MOVE 8-STEP 1]**

The number of recurrences has been reduced by about one event for every 100 women per year, he wrote in the editorial.
But Dr. Goss called that "a mischievous statement that should be refuted." He said as the years pile up, more women will benefit. Within four years, for example, one in 16 women would benefit from letrozole therapy, he estimated. **[MOVE 5-STEP 2]**
One out of every eight women will be diagnosed with breast cancer in her lifetime. **[MOVE 6]**
About 68 per cent of women with hormone-dependent breast cancer survive at least 15 years after diagnosis, said Dr. Goss. With tamoxifen, that is increased to 78 per cent. **[MOVE 6-STEP 1]**
Meanwhile, it is not clear how long women will remain on this drug, although Dr. Goss believes it is likely to be a minimum of three years.
Dr. Elaine Jolly, an associate professor of obstetrics and gynecology at the University of Ottawa and a menopause and hormone replacement therapy researcher called the news "very exciting."
Many women who take tamoxifen to prevent recurrence of breast cancer often drop the drug because of the side effects. Letrozole has a better side-effect profile than tamoxifen, and it will give women an alternative to extend treatment, she said. **[MOVE 8-STEP 1]**

Newspaper article 3:
Headline: Drug cuts breast cancer relapse **[MOVE 1-STEP 1]**
Subhead: Clinical trials end early so patients on placebos can receive letrozole treatment **[MOVE 1-STEP 2]**
By Allan Woods, National Post [MOVE 2-STEP 1]
A new drug to battle the recurrence of breast cancer has been so successful that doctors stopped clinical trials two years early in order to put thousands of patients taking a placebo on the therapy. **[MOVE 3]**
The drug, letrozole, offers hope to the tens of thousands of women diagnosed with breast cancer in Canada who live under the "dark cloud" of a possible recurrence.
"No doctor will go to the clinic tomorrow and feel the same about treating breast cancer again," said Dr. Paul Goss, the head of the research team and a leading oncologist at Toronto's Princess Margaret Hospital. **[MOVE 7-STEP 1]**
In the trials, letrozole almost cut in half the recurrence of breast cancer in post-menopausal women who had exhausted all other forms of treatment, the Canadian-led research team found. **[MOVE 5-STEP 2]**
Because of the results, a safety committee ruled it unethical to withhold the drug from the patients taking placebos. **[MOVE 5-STEP 2]**
The Canadian Cancer Society estimates more than 21,000 women will be diagnosed with breast cancer this year and more than 5,000 are expected to die of it. Breast cancer usually strikes again in one out of two women five or more years after diagnosis. **[MOVE 6]**
"This becomes a dark cloud that hangs over patients and their families for many years after the primary diagnosis," Dr. Goss said.
"I can now tell patients that, yes, we are doing something. The fight

against breast cancer is progressing."
However, other doctors warned that more tests still need to be done and women should not regard letrozole as a wonder drug.
The clinical trial of letrozole, produced by Novartis Pharmaceuticals under the name Femara, was prompted by the absence of a drug to take over for the standard tamoxifen drug therapy. Tamoxifen, which has been used for two decades, prevents estrogen from binding to breast cancer cells and proliferating. **[MOVE 6-STEP 2]**
But after five years, tumours develop a resistance to the drug and tamoxifen becomes "a potent fertilizer for breast cancer development," Dr. Goss said.
Until this study, Dr.Goss said, oncologists had two treatments -- chemotherapy and tamoxifen -- to stop breast cancer from coming back. "I think this result means we have a third tool," he said. **[MOVE 4-STEP 1]**
The study involved 5,187 breast cancer survivors from Canada, the United States and Europe who had gone through menopause or had stopped ovulating early because of their cancer treatments. On average, they participated in the planned five-year study for almost 2.5 years. **[MOVE 4-STEP 2B]**
The drug was found to reduce the risk that breast cancer will return in post-menopausal women by 43%. Of the women involved in the trial, cancer returned in 207. Of those, 132 had received a placebo pill made to look like letrozole and 75 took the real drug. **[MOVE 4-STEP 2B]**
Dr. Goss said the "dramatic results" prompted doctors to halt the trial so that nearly 2,600 women in the placebo group could start taking the once-daily pill immediately. **[MOVE 5-STEP 2]**
Letrozole belongs to a class of drugs known as aromatase inhibitors. The drugs, of which letrozole is the strongest, limit the body's ability to produce estrogen. **[MOVE 6-STEP 2]**
The implications of the findings have prompted the New England Journal of Medicine to publish the results, along with two editorials, a month early on its Web site. **[MOVE 7-STEP 2]**
The research team involved Princess Margaret Hospital, the Canadian Cancer Society, the National Cancer Institute of Canada, the Mayo Clinic in Rochester, Minn., and the U.S. National Cancer Institute. **[MOVE 7-STEP 1]** The drug was distributed to patients at 413 sites including hospitals in all 10 Canadian provinces.
While the researchers were buoyed by the results of the test, they and other experts counselled caution. "New data always bring up new questions," said Dr. James Ingle, a medical oncologist at the Mayo Clinic who handled the U.S. portion of the study. **[MOVE 8-STEP 1]**
Because the drug trial was stopped early, there are no definitive results and further trials will be required to back up these initial findings. Future studies will need to determine whether tumours can develop a resistance to letrozole, as they can to tamoxifen. They must also examine the side-effects of long-term use of the drug.
Researchers note that the estrogen-blocking drug could reduce bone density and elevate the risk of osteoporosis. Bone fractures were

slightly more frequent in women taking the drug than in those receiving a placebo. **[MOVE 6-STEP 1]**
Women taking the drug reported experiencing hot flashes, arthritis, muscle pain and joint pain -- effects similar to those in menopause. But there was less vaginal bleeding in women taking the drug, which could point to uses for the drug in treating endometrial cancer, which occurs in the inner layer of a woman's uterus.
"If we are to make clinically appropriate treatment decisions, we need data on adverse events to support risk-benefit analyses," reads an editorial in the New England Journal of Medicine.
Dr. John Mackey, a medical oncologist at the Cross Cancer Institute in Edmonton, said the study "doesn't answer as many questions as it raises." **[MOVE 8-STEP 1]**
He said he was concerned breast cancer survivors would see letrozole as a wonder drug and demand their doctor put them on it.**[MOVE 8-STEP 1]**
Apart from the unknown side-effects, he said the drug is not approved by Health Canada except in advanced-stage cases, where the disease has already recurred or has spread to other parts of the body.
Funding and regulatory approval for the drug will rely on the results of future trials and could be years away.
For the women around the world who learned this week they had been taking letrozole, the reportedly mild side effects associated with the drug were a small price to pay for the piece of mind that there is now additional treatment to prevent cancer from coming back.
"The results have provided women with hope," said Kathy Anderson, 50, who was diagnosed with breast cancer more than eight years ago.
The elementary school principal, who is one of Dr. Goss's patients, said she was struck with anxiety when she ended the tamoxifen drug regimen 3 1/2 years ago. **[MOVE 8-STEP 2]**
With no other treatment available, she joined the clinical trial group and learned in a phone call last week she was among the more than 2,000 who'd been taking the drug. "It does relieve one's mind." **[MOVE 8-STEP 2]**
For Dr. Goss, who has treated more than 5,000 patients in 22 years, the results are also rewarding. "I understand what the dark cloud is like," he said.
"I understand what it feels like to wake up each morning waiting for the other shoe to drop."

Newspaper article 4:
Headline: Breast cancer drug 'extraordinary **[MOVE 1-STEP 1]**
By Ann Lukits, Kingston Whig-Standard [MOVE 2-STEP 1]
An international clinical trial led by Kingston researchers was abruptly halted six weeks ago after the breast cancer drug under investigation produced extraordinary early results. **[MOVE 3]**
Those results, published yesterday in an advance online edition of the New England Journal of Medicine, offer a potentially exciting new treatment - and new hope - for older women with hormone- receptive tumours. **[MOVE 7-STEP 2]**

Dr. Joe Pater, director of the National Cancer Institute of Canada's Clinical Trials Group at Queen's University, said the statistician working on the trial showed him the astonishing preliminary findings on Aug. 22. **[MOVE 7-STEP 1]**

The drug's performance in stopping the spread of breast cancer was so dramatic that Pater promptly shut down the trial and contacted researchers and participants.

The international trial was supposed to continue for another four years. In a career that has involved 150 cancer drug investigations, Pater said he has seen similar trials halted early only two or three times. **[MOVE 6-STEP 1]**

"It's extraordinary," he told The Whig. "It doesn't happen very often."

The drug, called letrozole, was being tested on more than 5,000 women in Canada - including 29 from the Kingston area - the United States, Switzerland and Belgium. **[MOVE 4-STEP 2B / MOVE 5-STEP 3]** All the participants were post- menopausal survivors of early stage breast cancer who had undergone surgery, radiation and, in some cases, chemotherapy plus completed five years of treatment on a drug called tamoxifen. **[MOVE 4-STEP 2A]**

The trial was investigating letrozole's effectiveness in suppressing the production of estrogen in women with tumours classed as hormone-receptor-positive. **[MOVE 4-STEP 2A]**

Letrozole blocks the conversion of sex hormones into estrogens, reducing the overall amount of estrogen in the body. In so doing, it reduces the chances of estrogen stimulating the growth of new cancer cells. **[MOVE 6-STEP 2]**

Researchers, to their surprise, found that letrozole significantly increased a woman's chances of remaining free of cancer. Of the 5,187 women enrolled in the trial, 207 suffered recurrences of cancer. Of these, 75 were taking letrozole and 132 were taking a placebo. Deaths from breast cancer were also reduced in the women taking letrozole. Seventeen women taking the placebo died of breast cancer compared to nine taking letrozole. **[MOVE 4-STEP 2B]**

Pater said the early findings are exciting for both researchers and breast cancer survivors. About half of the 20,000 women who are diagnosed with breast cancer every year are post-menopausal and have estrogen-receptive tumours. **[MOVE 6-STEP 1]**

"Many people thought that women who'd gone through menopause and had tamoxifen, that there shouldn't be any more chance of estrogen driving the cancer," he said.

"But it's not true. There still is [estrogen]. The fundamental thing that is exciting about this is that now we see that suppressing estrogen production, even after all this long time in women, has a benefit to them." **[MOVE 4-STEP 1]**

Pater said that researchers anticipate receiving calls from women who are not enrolled in the international trial but may want to take letrozole to increase their chances of long-term survival.

Until the trial was launched four years ago, letrozole was given to women whose breast cancer had recurred or spread. Whether the drug should be prescribed to all breast cancer survivors is a subject of

debate, Pater said. **[MOVE 5-STEP 2]**
Letrozole is one of three drugs available in Canada called aromatase inhibitors. The drugs block a chemical process called aromatisation in which androgens, or sex hormones produced by the adrenal glands, are converted into estrogens. **[MOVE 6-STEP 2]**
Even before the letrozole investigation was started, cancer doctors were tending to favour the use of aromatase inhibitors over tamoxifen to treat cancer patients, Pater said. **[MOVE 6-STEP 1]**
Tamoxifen, an anti-estrogen drug that acts in a different way than letrozole, is widely used to treat breast cancer, both after the initial operation and after a recurrence, but tumours eventually become resistant to it. **[MOVE 6-STEP 1]**
The drug has also proven to suppress the development of breast cancer in healthy women considered at high risk to develop the disease because of genetic reasons.
A downside of letrozole is that it appears to accelerate the development of osteoporosis, or bone thinning. Of the women taking letrozole, 5.8 per cent developed osteoporosis compared to 4.5 per cent on a placebo. The fracture rate was about the same for both groups. **[MOVE 5-STEP 2]**
Researchers will continue to monitor the letrozole patients and collect long-term data on the number who develop fractures but Pater said there are reasons to think the other aromatase inhibitors may not trigger the same bone loss.
The study was funded by the Canadian Cancer Society, the U.S. National Cancer Institute and Novartis Pharmaceuticals. **[MOVE 6-STEP 3]** The Canadian society released the preliminary results yesterday at a news conference in Toronto that was attended by the trial's physician co- ordinator, Dr. Lois Shepherd of Kingston.
The findings will be published in the Nov. 6 issue of The New England Journal of Medicine. As of yesterday, they were available at www.nejm.org. **[MOVE 7-STEP 2]**

Newspaper article 5:
Headline: Breakthrough in treatment of breast cancer announced **[MOVE 1-STEP 1]**
Subhead: Drugs cut risk of recurrence and death in half for female cancer survivors **[MOVE 1-STEP 2A]**
By Torstar News Service [MOVE 2]
Jubilant Canadian researchers have announced a major breakthrough in the treatment of breast cancer in post-menopausal women. **[MOVE 3]**
The results of a large international trial released yesterday found that a drug called letrozole virtually cut in half the risk of disease recurrence and death in female breast-cancer survivors who had first taken the drug tamoxifen for five years. **[MOVE 4-STEP 1]**
The findings were so dramatic that the Canadian-led international trial was halted early so more women could benefit immediately. Half of the more than 5,000 women worldwide -- 1,404 of them in Canada -- taking part in the trial had, until now, been given a placebo. Neither

they nor their doctors knew for the past 21/2 years whether they were taking the drug or a placebo. **[MOVE 4-STEP 1 / MOVE 4-STEP 2B]**
The study was published yesterday in an advance on-line edition of The New England Journal of Medicine. **[MOVE 7-STEP 2]**
"I think this is a sea change in treatment, this is a new discussion that is going to take place now," said Dr. Paul Goss, director of breast-cancer research at Princess Margaret Hospital who conceived and chaired the international trial. **[MOVE 7-STEP 1]**
"Literally hundreds of thousands of women will be affected by this," Dr. James Ingle of the Mayo Clinic in Rochester, Minn., told a news conference at Toronto's Intercontinental Hotel. **[MOVE 7-STEP 1]**
Tamoxifen, developed more than 20 years ago, is used widely to treat breast cancer in early and advanced stages. The drug blocks the effects of estrogen, a female hormone that contributes to the growth of breast cancer. Letrozole, which also leads to the reduction of estrogen in the body, is used to treat breast cancer in post-menopausal women. **[MOVE 6-STEP 2]**
Until now, there has been no effective treatment for post- menopausal women with breast cancer who have taken tamoxifen for five years. At that point, tamoxifen stops being effective for these women because, researchers believe, tumours become resistant to it and it can actually cause more cancer. **[MOVE 6-STEP 1]**
The study was designed to see if letrozole could pick up where tamoxifen left off.
More than half of women who have a recurrence of breast cancer do so more than five years after their initial diagnosis, Goss said. **[MOVE 6]**
"This is a dark cloud that hangs over our patients and their families," he said. "Our study ushers in a new era of hope by cutting these ongoing recurrences and deaths from breast cancer after tamoxifen by almost one-half."
More than 21,000 women in Canada will be diagnosed with breast cancer this year and more than half of them may be eligible for the new treatment. **[MOVE 6]**
One of those patients is 50-year-old Kathy Anderson, who was diagnosed with breast cancer 81/2 years ago, had two surgeries, radiation and chemotherapy and found out this week that she had been taking letrozole and not the placebo for the past 21/2 years.
She had taken tamoxifen for five years and "it's scary when you think you have nothing to move on to," she said at the news conference.
"Knowing this drug has cut the recurrence rate in half is very important. It does relieve one's mind."
Anderson said she only learned the study results two days ago and until now hasn't told anyone except her husband.
"We celebrated that night with a special glass of wine," Anderson said.
"The results are so important, the word has to get out. Women need to know they can go to their doctor because there is a drug." **[MOVE 8-STEP 2]**
Overall, letrozole reduced the risk of cancer recurring by 43 per cent.
After four years of the trial, 13 per cent of the women on the placebo,

but only 7 per cent of those on letrozole, had a recurrence. **[MOVE 4-STEP 1]**
Seventeen women taking the placebo died of breast cancer during the trial, compared to nine taking letrozole.
In the study, one in 100 women benefited from letrozole -- a figure that rose to six in 100 after four years. **[MOVE 4-STEP 1]**
"It's a bit like watching Tiger Woods hit a golf ball -- it looks good at first, but it gets better as it goes along," Goss said.
The findings were even more "remarkable" because many anticipated that the benefits of letrozole would be modest, John Bryant and Dr. Norman Wolmark, two independent experts, said in an editorial in The New England Journal of Medicine. **[MOVE 8-STEP 1]**
But because the study was stopped early, many questions have been left unanswered, such as how long women should take letrozole and what the long-term side effects might be.
During the trial, the drug produced relatively minor side effects, including increased bone loss, hot flashes, sweating, sore muscles and fatigue. **[MOVE 5-STEP 2]**
The trial was to run for five years, but when an independent safety and monitoring committee saw the first dramatic results after just under 21/2 years, it recommended the trial be stopped so women on the placebo could be offered the drug.
"The estimated magnitude of the benefit ... was substantially greater than expected," Bryant and Wolmark wrote in the journal editorial. **[MOVE 8-STEP 1]**
Patients in any drug trial sign a consent form and this one specified, "If new side effects or information about my disease or treatment are discovered during the study, I will be told."
That's normally built in for the safety of the patients in case the drug has adverse effects, said Dr. Lois Shepherd, trial co- ordinator of the study for the National Cancer Institute of Canada clinical trials group. **[MOVE 8-STEP 1]**
But in this case, the benefits of the drug were "so extreme," the independent monitoring group decided the trial should be halted so more women could benefit.
"That doesn't happen very often," she said. **[MOVE 8-STEP 1]**
The journal editorial commends the study as a "well-conceived and well-conducted clinical trial," and concedes "perhaps reluctantly" that the recommendation to halt the study was justified.
But many things were lost because the study was stopped, the editorial adds.
The trial was to determine the effect of taking letrozole for five years, yet none of the women took it that long. **[MOVE 5-STEP 2]**
As well, concerns about the long-term side effects of the drug remain, including a possible increased risk of osteoporosis and cardiovascular disease. **[MOVE 5-STEP 2]**
"It would have been of great value to have been able to follow the women over a period of years in comparison with a blinded placebo group," the editorial says.
Moreover, other long-term trials involving aromatase inhibitors like

letrozole "are virtually certain to be modified or terminated" because of the early release of the study results.
That includes a trial Bryant and Wolmark are involved in that "is in peril" because of these results, they say. **[MOVE 8-STEP 1]**
But after asking rhetorically what they would have done in the same situation, they conclude they would have "disclosed the data in exactly the same manner."
"An inescapable truism of randomized trials is that we are condemned to bear the burden and limitations of our incremental successes," the editorial says.
Dr. Shepherd said the investigators plan to keep the women in the study on letrozole for five years and will follow them afterwards to see the long-term effects. **[MOVE 8-STEP 1]**
"We just won't have a placebo group to compare them to any more," she said. "The issue is we have lost a little bit of information."
Most studies take the full five years to produce the results researchers are looking for, she said.
"No one really expected the results to be this dramatically different at such an early time point. It was really exciting.
"You conduct these trials and you put these studies together in the hopes you will advance knowledge and help people with cancer," Shepherd said. "It's such a lot of work, a lot of people power -- a lot of patients and organizational effort goes into these studies." **[MOVE 8-STEP 1]**
The study was conducted by researchers from the Canadian Cancer Society, Princess Margaret, the U.S. National Cancer Institute, the Mayo Clinic and the National Cancer Institute of Canada's clinical trial group at Queen's University in Kingston. **[MOVE 7-STEP 1]**
More information is available from the cancer society at 1-888- 939-3333 or at its Web site, www.cancer.ca.

Newspaper article 6:
Headline: Experts hope findings will let more women live cancer-free **[MOVE 1-STEP 1]**
By Andre Picard, Globe and Mail [MOVE 2-STEP 1]
The chances of postmenopausal women living long after a bout of breast cancer have been bolstered with Canadian researchers' discovery that a new drug can reduce the recurrence of cancer in survivors by almost half. **[MOVE 3]**
The data were so impressive that the Canadian-led study was halted early and rushed into print so physicians and women could be notified immediately about the new treatment possibility. **[MOVE 4-STEP 1]**
The drug, letrozole, is prescribed only after another popular drug has been taken for five years. If the research holds true in the real world, the vast majority of breast-cancer survivors should now be able to live cancer-free for a decade or more. **[MOVE 5-STEP 2]**
"This is a significant finding that's going to give breast-cancer survivors a better hope of a life without cancer," Barbara Whylie, director of cancer-control policy for the Canadian Cancer Society, said

yesterday. **[MOVE 8-STEP 1]**
Kathy Anderson, a 50-year-old elementary school teacher whose breast cancer was diagnosed eight years ago, was invited to enrol in the study when she reached the end of her five-year course of tamoxifen.
She jumped at the chance and was delighted when she recently learned she had been taking letrozole, not a placebo, for the past 2½ years.
"It's a big step. Women who have taken tamoxifen now have another medication to take," she said.
"There is anxiety about recurrence," Ms. Anderson said. "It's scary at the end of tamoxifen, at the end of five years and you think you have nothing to move on to." **[MOVE 8-STEP 2]**
There are more than 250,000 postmenopausal survivors of breast cancer in North America, and researchers estimated that up to half of them could benefit from the new treatment. **[MOVE 6-STEP 1]**
To date, the only treatment available has been tamoxifen, a drug prescribed to postmenopausal women who have suffered early-stage breast cancer. The drug is effective in the short term, but after five years it can actually increase the risk of recurrence. Tamoxifen also has serious side effects, such as greatly increasing the risk of cancer of the endometrium, the lining of the uterus. **[MOVE 6-STEP 2]**
In the new study, letrozole was prescribed to women after five years of tamoxifen therapy.
Four years later, 7 per cent of women who took letrozole had a recurrence of cancer, compared with 13 per cent who took a placebo. Put another way, for every 16 women who took the drug for four years, one recurrence of breast cancer was prevented. **[MOVE 4-STEP 1]**
"This is a sea change in the treatment of breast cancer," said Paul Goss, a cancer specialist at Toronto's Princess Margaret Hospital and the lead researcher. **[MOVE 7-STEP 1]** He said recurrence is one of the greatest fears of breast-cancer survivors, and women have been clamouring for new treatments.
"A dark cloud hangs over patients and their families," and that cloud has now been lifted, at least partly, Dr. Goss said.
Because the results were so promising, the study was stopped early on ethical grounds. It was felt that women given the placebo were being placed at undue risk because they were not receiving the effective treatment.
The research was published yesterday in the on-line edition of the New England Journal of Medicine. **[MOVE 7-STEP 2]**
James Ingles, a medical oncologist at the Mayo Clinic in Rochester, Minn., cautioned that there is still much to learn about letrozole. "How long should one take it? What are the long-term toxicities?" he wondered aloud.
Dr. Ingles said the research does not address whether letrozole will work after women have stopped tamoxifen for more than three months, or whether it can work as an alternative. **[MOVE 8-STEP 1]**
(None of the women in the study had stopped taking tamoxifen for more than three months before they began taking letrozole.)

When tamoxifen was introduced, it was with similar fanfare, but the lustre soon came off as serious side effects emerged. By halting the study early, researchers were denied the opportunity to learn whether letrozole, which alters women's hormone levels, poses a risk to cardiovascular health and bone density. **[MOVE 5-STEP 2]**
Letrozole, sold under the brand name Femara, is a form of hormone therapy. It works by limiting the ability of an enzyme called aromatase to produce estrogen, a major risk factor for breast cancer.
Tamoxifen does not affect estrogen production; it prevents estrogen from binding to tumours. **[MOVE 6-STEP 2]**
There is another aromatase inhibitor on the market -- Arimidex, a product of AstraZeneca -- but it was not used in the research, so it is unclear whether it would be as effective. **[MOVE 6-STEP 1]**
Novartis, the maker of Femara, provided $12-million (U.S.) of the $20-million cost of the study, in which 5,187 breast-cancer survivors participated. **[MOVE 6-STEP 3** / **MOVE 4-STEP 2B]** Of that number, 75 who were prescribed letrozole had a recurrence of cancer, compared with 132 who were taking a placebo. Nine women who were taking letrozole died, compared with 17 who were taking the placebo. **[MOVE 4-STEP 2B]**
In 2003, breast cancer will be diagnosed in an estimated 21,200 Canadian women and 211,300 U.S. women. **[MOVE 6-STEP 1]**

5.3 Analysis of letrozole article in *New England Journal of Medicine*

Skelton's move structure (1994:456-457) for medical research articles published in scientific journals proposes four moves in the Introduction section: 1. Stating the relevance of the research; 2. Contextualizing the research in the literature; 3. Claiming the novelty of the research; 4. Stating the purpose of the research. The NEJM article concerning letrozole satisfied all four of the moves. The authors used a minimal amount of technical language to frame the existing research landscape and state the purpose of their own project.

There are three moves contained in Skelton's structure for the Methods section: 1. Identify the population being studied**;** 2. Describe the research procedures**;** 3. Name the statistical tests. Again, all three moves have been satisfied with the content of the letrozole article's Methods section. The language in the Methods section becomes more technical and specific to its

intended audience, which would include breast cancer researchers. The Methods section also comprises a significant proportion of the overall article. About one-third of the article's length is devoted to the methodology of the experiment.

There are four moves in Skelton's Results section structure: 1. Adjustment and exclusion from the general population stated in Move 5; 2. Representation of the results; 3. Discussion of the data; 4. Assessment of the data. Three of the four moves are present in the letrozole article. Only the Assessment of the data move is absent. The language in the Results section remains highly technical, including very technical descriptions of the statistical analyses conducted on the data. The Results section of the article comprises less than a quarter of the article's overall length.

In Skelton's framework, the structure for the Discussion section contains four moves: 1. State the limitation and defend the success of the research finding; 2. Present what the study has achieved; 3. Contextualize the research procedures and findings; 4. Offer recommendations. All four of the moves are addressed in the letrozole NEJM article. The language in the Discussion is technical, although not beyond the comprehension level of a layperson with a knowledge of advanced high school or university-level biology.

In summary, the content of the letrozole journal article addressed 14 of the 15 moves found in Skelton's framework for medical research journal articles. The article follows a near-chronological progression that begins with a description of the existing landscape, followed by a description of the experiment and the measures that would be used to assess the data, by the results of the experiment, and a forward-looking discussion of the implications raised by the results.The headline accompanying the article is simply a description of the clinical trial (“A Randomized Trial of Letrozole in Postmenopausal Women after Five Years of Tamoxifen Therapy for Early-Stage Breast Cancer”) and it offers no suggestion about the results of the trial.

Several of the common devices employed in a news text published in a mainstream newspaper are not found in the letrozole journal article. There are no direct quotes from the authors or any other scientists who might have an interest in the trial's outcomes. There are no direct quotes from the trial's sponsors or from third-party cancer agencies, such as the Canadian Cancer Society, and there are no direct quotes from trial participants or cancer patients who might be affected by the trial's outcome.

It should also be noted that the letrozole NEJM article indicated that the trial had been discontinued prematurely ("After reviewing the information presented here, the data and safety monitoring committee recommended that, in the interest of patient care, the study be discontinued early, and the participants informed of the results.") but did not explicitly explain the reason for the premature conclusion or the implications for patients. In this case, such an explanation would have been deemed unnecessary because the target audience for the journal article – breast cancer researchers – would have inherently understood the rationale for the trial's premature conclusion.

5.4 Analysis of the six newspaper articles related to the letrozole research findings

An analysis was carried out of the six newspaper articles related to the letrozole research findings using Suhardja's move structure for medical research news articles.

5.4.1 Move 1: Attracting the readers' attention

The opening move in Suhardja's (2008) structure (Attracting the readers' attention) includes the steps of a headline and subhead. All six articles include a headline and four of the six include a subhead. A headline, with its larger type size and bolder print, is typically the reader's first text-based entry point to a newspaper article. A subhead, with smaller type size than the headline but larger than the type size of the body text, typically provides additional explanation that can expand on the headline's message.

While the headline of the letrozole NEJM trial is a simple description of the trial, the headlines attached to the six newspaper articles focus on the results of the trial or the forward-looking implications of the trial's outcome. Three of the headlines focused on the main finding in the Results section of the trial ("Drug halves repeat of breast cancer;" "Drug cuts return of cancer by half;" "Drug cuts breast cancer relapse"). One headline offered an optimistic interpretation of the trial's outcome ("Breakthrough in treatment of breast cancer announced"), another conveyed an optimistic opinion of the trial's outcome ("Breast cancer drug 'extraordinary'"), and another focused on an optimistic forward-looking implication of the trial ("Experts hope findings will let more women live cancer-free").

Of the four articles that included a subhead, two focused on the trial's premature conclusion ("Breast cancer test halted to rush product to patients", "Clinical trials end early so patients on placebos can receive letrozole treatment"). Headlines and subheads for the newspaper articles were optimistic, forward-looking messages, using words such as "extraordinary", "hope", breakthrough" and "sea change".

5.4.2 Move 2: Providing attribution

Five of the six articles provided the name of the reporter and the name of the news outlet. One provided just the name of the news organization.

5.4.3 Move 3: Summarizing the news report (the lead paragraph)

Lead paragraphs were split evenly between those that focused on the trial's results and their implications, and those that looked forward optimistically to the future. The lead paragraphs included words such as "groundbreaking", "dramatic findings", "jubilant", "major breakthrough" and "extraordinary" to summarize the benefits. One lead employed a militaristic theme to engage readers ("Breast cancer survivors have an important new weapon in their long-term treatment arsenal…")

Four of the lead paragraphs focused on the trial's potential benefits for breast cancer patients or postmenopausal women in general. Statements included: “The chances of postmenopausal women living long after a bout of breast cancer have been bolstered . . .,” and “Jubilant Canadian researchers have announced a major breakthrough in the treatment of breast cancer in post-menopausal women.” Two of the lead paragraphs reported on the premature conclusion of the trial (“. . . was abruptly halted six weeks ago after the breast cancer drug under investigation produced extraordinary early results” and “. . . so successful that doctors stopped clinical trials two years early in order to put thousands of patients taking a placebo on the therapy.”)

By comparison, none of the words “breakthrough”, “groundbreaking”, “jubilant”, “dramatic findings” or “extraordinary” appear in the letrozole NEJM article. The strongest descriptor in the letrozole NEJM article is “significantly improves”.

5.4.4 Move 4: Presenting the main event

This move can include two steps that are intended to specify the research findings, the research methods and the type and size of data collected. Each of the six articles summarized the main results of the letrozole trial, focusing on the reduction in death rates for those patients receiving letrozole versus the control group. Each of the stories included a description of the trial size, either by providing the precise number of participants or rounding the number to approximately 5,000.

Examples include this paragraph from article 1: “The Canadian-led study, which involved 5,000 women in a host of countries, found the risk of a breast cancer recurrence was nearly halved for post-menopausal women who took the drug after five years of treatment with tamoxifen.” From article 3: “The drug was found to reduce the risk that breast cancer will return in post-menopausal women by 43%. Of the women involved in the trial, cancer returned in 207. Of those, 132 had received a placebo pill made to look like letrozole and 75 took the real drug.”

None of the six articles referred to the statistical methods used by the researchers to assess the data and establish its quality, even though this received significant attention in the NEJM article that reported on the letrozole trial. Each of the articles noted that the trial was halted prematurely. Article 6 provided the clearest explanation: “Because the results were so promising, the study was stopped early on ethical grounds. It was felt that women given the placebo were being placed at undue risk because they were not receiving the effective treatment.” Each of the six articles provided only cursory descriptions of the research protocol and the biological explanation for the research. The term “estrogen” appears in all six articles

Article 4 provided a concise two-paragraph description of the biological basis for the letrozole trial: “The trial was investigating letrozole's effectiveness in suppressing the production of estrogen in women with tumours classed as hormone-receptor-positive: “Letrozole blocks the conversion of sex hormones into estrogens, reducing the overall amount of estrogen in the body. In so doing, it reduces the chances of estrogen stimulating the growth of new cancer cells.” Five of the six articles included the term “aromatase”, the class of enzyme inhibited by letrozole. Only article 4 provided a further explanation of the significance of aromatase inhibition and the process of aromatization.

Five of the six articles included direct quotes from Dr. Paul Goss, the lead scientist for the letrozole trial. Three of the five articles quoting Goss used the same quote: “A dark cloud hangs over patients and their families.” Three also used this same Goss quote: “I think this is a sea change in the treatment of the disease.” Two used the Goss quote “No doctor will go to the clinic or to his patient office tomorrow and feel the same about treating breast cancer again.” The quotes selected from the lead scientist are used as emotional devices rather than quotes that include scientific terminology or scientific explanations.

Three of the six articles provided a quote from one of the trial's researchers before a summary of the trial's findings were presented. Employing such a

structure could act as a device to condition the reader to accept the legitimacy of the findings by giving an active voice to the main players.

5.4.5 Move 5: Indicating the significance of the event

Suhardja's move structure provides for three steps within this move: referring to the intrinsic qualities of the research articles; referring to the implication of the research; referring to the local relevance.

Each of the six articles highlighted the implications of the letrozole research. All of the articles made reference to the numbers of women who are diagnosed annually with breast cancer, and there were also references to the number of women who die annually from breast cancer. Three of the six articles noted that only half of postmenopausal breast cancer survivors could benefit from the letrozole treatment.

Five of the six articles included negative implications of the research by reporting on letrozole's side effects and/or the rates of participants who dropped out of the trial. All of the references to the trial's negative implications were located in the bottom half of the article's content, suggesting that the negative implications of the trial's findings were deemed less important than the trial's positive findings.

Five of the six articles noted that the letrozole trial was led by Canadian researchers. Interestingly, the one article that did not include the term “Canadian-led” was published in the Kingston Whig-Standard newspaper. Kingston is the site of Queen's University. The Whig-Standard article highlighted the contributions of a local Queen's researcher who was part of the letrozole trial group and noted the trial was international in scope. While the author's motivation is unknown, it is possible she sought to highlight the international scope of the research to inflate the importance of the local contribution to the research.

5.4.6 Move 6: Presenting background information

Three steps are possible within this move: comparing the present research with past, present and/or other related research; explaining the technical terms and concepts used; indicating the funder of the research.

Each of the six articles presented background information, typically by framing letrozole's effectiveness in context with the previous standard of treatment, tamoxifen. From article 1: “Tamoxifen has been a crucial weapon against breast cancer. But studies have shown it ‘runs out of steam’ after about five years, Goss noted. It is believed tumours develop a resistance to it and that taking tamoxifen for longer might actually increase the risk of recurrence.” From article 3: “Tamoxifen, which has been used for two decades, prevents estrogen from binding to breast cancer cells and proliferating. But after five years, tumours develop a resistance to the drug and tamoxifen becomes ‘a potent fertilizer for breast cancer development,’ Dr. Goss said.” From article 4: “Even before the letrozole investigation was started, cancer doctors were tending to favour the use of aromatase inhibitors over tamoxifen to treat cancer patients, Pater said. Tamoxifen, an anti-estrogen drug that acts in a different way than letrozole, is widely used to treat breast cancer, both after the initial operation and after a recurrence, but tumours eventually become resistant to it.”

As discussed, none of the six articles provided detailed discussion of the scientific terms and biological pathways that were commonly found in the letrozole NEJM article. There may be one or more explanations for this deficiency. It is possible that the authors of the newspaper articles determined that detailed scientific explanations were unwanted or unnecessary for the target audiences – in these cases, the general public. It is possible that the space constraints of a daily newspaper required the authors to exclude detailed scientific explanations so that other content could be included. It is also possible that the authors may have omitted detailed scientific explanations because the authors themselves may not have

adequately comprehended the detailed scientific jargon and opted to self-exclude the information.

Only two of the six articles noted that Novartis Pharmaceuticals was one of the funders of the letrozole trial. Only one of the two articles included the total cost of the letrozole trial and the amount funded by Novartis. Two additional articles noted that Novartis is the maker of letrozole but did not note that Novartis was one of the trial sponsors.

None of the six articles identified the fact that the letrozole researchers quoted in the articles had declared financial connections to Novartis, even though the financial connections were easily obtained from the NEJM article.

5.4.7 Move 7: Indicating the source of information

All six of the articles correctly identified the letrozole researchers and each article indicated that the research had been published in the *New England Journal of Medicine*.

5.4.8 Move 8: Showing balanced reporting

Four of the six articles included direct quotes from a breast cancer patient who had participated in the letrozole trial. Interestingly, it was the same patient in each of the four articles, suggesting that the patient had been pre-selected by either the researchers or the trial sponsors to attend a press conference. The selection of quotes used in the articles from the patient provide positive comment on the letrozole findings and forward-looking optimism directed generally at other women who might benefit from letrozole in the future.

Four of the six articles included direct quotes from researchers who were not part of the letrozole trial group. These voices were intended to act as neutral commentators on the letrozole findings. Three of the articles contained positive remarks about the letrozole trial by the neutral commentators, one contained a negative comment from the neutral source and one article

contained a positive and a negative comment from separate commentators. One of the articles also noted that a cautionary editorial accompanying the letrozole trial results had been published simultaneously in the *New England Journal of Medicine*.

5.5 Conclusion

The results of the genre analysis are summarised as follows. The letrozole article in the *New England Journal of Medicine* closely adhered to the move structure proposed by Skelton for the genre of medical research journal articles. The article followed a chronological progression, beginning with background material and context of the research landscape, followed by the methodology of the experiment, followed by the findings and the implications of the findings for the present and the future.

The letrozole article did not contain direct quotes from the trial group researchers, other scientists or patients. The headline of the journal article contained no optimistic commentary or forward-looking statements, and the headline did not summarize any of the trial's outcomes. Descriptors such as “extraordinary”, “jubilant”, “hope” “breakthrough” and “groundbreaking” were absent from the journal article. The Methods and Results sections contained scientific jargon and detailed statistical assessments of the data.

Meanwhile, the six newspaper articles reporting on the letrozole trial closely adhered to Suhardja's proposed move structure for the genre of medical research news articles. None of the articles followed a chronological progression. Instead, headlines, subheads and the lead paragraphs focused on the trial's results, often with optimistic language and forward-looking statements. Positive descriptors of the trial outcomes (“extraordinary”, “jubilant”, “hope”, “breakthrough” and “groundbreaking”) were commonly used. Statistical references were absent from the news articles and scientific jargon was minimal. Direct quotes from the trial group researchers, other scientists and a trial patient were featured prominently in the news articles, and the quotes were overwhelmingly positive about the trial's findings and

implications. Five of the six articles did report negative implications from the trial, such as side effects of the drug, but the negative implications were always found in the second half of the news article.

All six of the articles identified the *New England Journal of Medicine* as the publication source of the trial's results, however none of the six articles identified the financial connections that existed between the trial group researchers and Novartis, the commercial sponsor of the trial, even though information about the financial connections was readily available from the NEJM article. Only two of the six articles identified Novartis as the funder of the trial.

As this case study illustrates clearly, the genres of medical research journal articles and medical research news articles are highly dissimilar. It is likely these two genres have been constructed to appeal to very different target audiences. Scientists, the intended audience of scientific journal content, expect texts to follow a familiar science template of an Introduction followed by Methods, Results and Discussion. Scientific jargon, statistical assessments and the absence of direct quotes or hyperbole are expected. In the case of medical research news articles published in mainstream newspapers, the target audience – the general public – has been conditioned to receive news texts in a familiar format that follows the inverted pyramid model. In this model, the most important and salient information is placed at the top of the text and background information is placed closer to the bottom of the text. For news articles related to medical research, mainstream newspaper readers expect journalists to interpret and translate complicated scientific jargon into plainer language, even though journalists often do not possess detailed scientific knowledge. This significant difference in the genres of their texts could be another source of friction between scientists and reporters.

CHAPTER SIX: AUTHOR INTERVIEWS

6.1 Introduction

To better understand the results of the article search conducted for this study, it is necessary to better understand the reporters who wrote the articles, their level of scientific training, their comprehension of the scientific process and the motivating factors that led to the articles' content. These issues were addressed through a comprehensive voluntary questionnaire. Respondents reported a wide range of journalistic experience, from less than five years reporting experience to more than 20 years.

6.2 Journalists' background and experience of medical reporting

Three respondents self-reported that more than 75 per cent of the articles they wrote focused primarily on health and/or science topics, one reported between 26-50 per cent and two reported less than 25 per cent. The respondents' specific health and medical reporting experience also varied greatly, from a general assignment reporter with no specific health and medical reporting experience to reporters with more than 11 years of such experience. The range of respondents' highest level of academic scientific education achieved showed a similar spread, from high school courses only to a Bachelor's degree. Four of six respondents self-reported their level of understanding of science and biomedical concepts as "above average", one reported as "average", and one reported as "below average". None of the respondents self-reported their level of understanding as "excellent" or "poor".

When asked: "Does your publication have any written policies or guidelines that pertain specifically to the writing of health and/science topics?" one respondent reported yes, three reported no and two were unsure. The results were similar when respondents were asked if their publication had

unwritten or informal policies pertaining specifically to the writing of health and/or science topics.

When asked: “Does your publication have any written policies or guidelines that specifically govern a potential conflict of interest for a reporter when writing about a topic?” four respondents reported yes, one reported no and one was not sure. All six respondents reported yes when asked if their publication had any unwritten or informal policies that govern a potential conflict of interest for a reporter. Three respondents reported that their level of understanding of clinical research ethics was “above average”, two reported “average” and one reported “poor”. Three of the six respondents were unaware that most scientific journals now require authors of research papers to declare potential conflicts of interest as a prerequisite for publication. When asked, “When writing about medical or scientific research, how often do you report all funding sources of the research?” one respondent self-reported “always”, one reported “most of the time”, three reported “some of the time” and one reported “rarely/never”.

And finally, the key question was asked: “When writing about medical or scientific research, how often do you report, when applicable, that a researcher may have a financial connection to a commercial funding source of the research?” Two respondents self-reported “most of the time”, one reported “some of the time”, one reported “occasionally” and two reported “rarely/never”.

6.3 Issues related to biomedical research ethics

To then explore the reporters’ motivations further and to better understand the content of the news articles, a series of open-ended questions were asked to seek comment about general issues related to biomedical research ethics, as well as specific issues related to the news articles in question.

6.3.1 The reporting of potential financial conflicts of interest in biomedical research

Journalist A has more than 11 years of experience as a health reporter at a large daily newspaper. Journalist A made the following general observations about the media and the reporting of potential financial conflicts of interest in biomedical research:

> "As a health reporter, I have watched the research community itself try to come to terms with this. However, I haven't seen the media critically examine how it reports these stories. I do not think it's even on the radar of many editors or reporters. It should be. Each newsroom should have written guidelines for reporters and more education and training about how to cover these stories. If this information is left out, copy editors should call reporters to make sure the question (about potential financial conflicts of interest) was asked and make sure the proper information gets in.
>
> "There should be a set group of facts that is expected to be in every research story that includes who paid for the research and whether the researcher has any ties or financial interest to that funder. It's an area we need to do a better job at because the public gets a lot of its health information from the media and looks to us as a reliable source of information. We should make sure that the information we provide is a more full account with links to the actual (journal) article itself or other reliable sources of information."

Journalist B has more than 20 years of experience, including more than seven years' experience as a health reporter. Journalist B made these general observations on the same topic of reporting of potential financial conflicts of interest in biomedical research:

> "I use the famous line from *All The President's Men* as my mantra in medical and health reporting: 'Follow the money.' Knowing who paid

for research or a press release will often tell me an enormous amount about the newsworthiness of a study or a pitch.

"Industry funding doesn't negate the findings of a study or the expertise of someone I would ask to assess a study for me. But it's important for readers to know who paid for the generation of the data, and whether the 'unbiased expert' is unbiased."

Journalist F has more than 20 years of experience, including more than seven years as a health reporter. More than 75 per cent of the articles written by Journalist F relate to health topics and Journalist F self-reported an above average understanding of science and biomedical concepts:

"Much university science/medical research relies on some funding from special interest groups. The potential for conflict of interest is major but it's not a fait accompli. I think (perhaps mistakenly) that the potential for conflict lessens in double-blind randomized controlled studies/trials that are held at several sites, have thousands of participants and are then published in respected, peer-reviewed journals. That said, respected journals are not infallible. The Lancet withdrew the Wakefield autism study many years after publication."

6.3.2 The importance of being aware of funding sources and financial connections

The reporters were questioned more closely on the importance of being aware of funding issues and financial connections between researchers and funding sources.

a. The importance of being aware of all funding sources

The following question was posed to the reporters:

Is it important or is it not important for readers of mainstream newspapers to be made aware of all funding sources in an article about medical and/or scientific research?

Journalist C was a reporter with more than 11 years of experience as a health reporter. Journalist C observed:

> "The disclosure of funding sources is always important to scientists and researchers and I usually included such information in my stories, though generally at the end. I do not think readers are necessarily interested in the funding sources of scientific research but I believe this type of information adds credibility to stories."

Journalist D has more than 11 years of experience as a reporter. Journalist D observed:

> "If it is a university-sponsored study, than I do not think it is as important. But if it is a private, or publicly-funded company sponsoring their own study than yes, the public should definitely be aware."

Journalist E is a general assignment reporter with less than five years of experience. Journalist E observed:

> "It is important so readers understand any potential conflict of the researcher and/or potential influence on results."

Journalist B said:

> "It is at times impractical to list all sources of funding for a study. Many have multiple direct sources and indirect sources – the work of individual authors may be supported by various granting institutions. We have word limits and devoting 50+ words to the source of the funding (and it could sometimes take that many words) would mean other key information would need to be left out. All funding is not equal. Is it important for a reader to know that one of the authors holds a Canada Research Chair? Maybe not. Is it important that readers know that the research into a controversial drug was funded

by the maker? Absolutely. Is it important that we tell readers that Expert X who is defending the drug has had funding from that drug maker in the past? Yes."

Journalist A noted:

> "It is crucial to publish the funding sources within a story. It helps readers determine the credibility of the research and whether any of the funders have a vested interest in the outcome of the research. It's also important for readers to get an idea of who is paying for the research being done in their area – government, charities, private sources etc. And it's good for readers to know what type of research is being funded by certain agencies. That way, readers know what research government is supporting or where the dollars they give to a specific organization, like the Canadian Cancer Society, are going."

b. The importance of being aware of financial connections between researchers and funding sources.

Journalists were then asked:

> Is it important or is it not important for readers of mainstream newspapers to be made aware that a researcher may have a financial connection to a commercial funding source of the research?

Journalist C observed:

> "Yes, it's very important. Readers (and reporters) should be skeptical of scientists who stand to gain by investing in the company that funds their research."

Journalist B stated:

> "It is important. Knowing who paid for the research helps readers put

study results in context. It doesn't mean the results are wrong or overhyped, but it does imply caution needs to be taken in interpreting them."

Journalist A observed:

"It's important for readers to know if the researcher has a vested interest in the outcome of the research or if the researcher has connections to companies that have a vested interest in the outcome of the research. It helps readers judge the credibility of the research. It's also important for accountability, honesty and transparency. A connection doesn't mean the research is not good quality but it flags readers to be aware there could be a conflict that could impact the research. As a result readers may want to be a little more critical in examining how the research was done or seek out research that backs up these findings."

Journalist F stated:

"Readers should know who is backing the research – especially if it's the commercial funding source. I do not know that it's always important for readers of mainstream papers to know about speaking fees when the researcher involved is presenting results of a major study at an international conference of scientist/doctors."

6.3.3 Limitations faced by mainstream newspapers and their reporters when dealing with medical reporting

The limitations faced by mainstream newspapers and their reporters – both in terms of time, resources and skill levels - were hinted at in the following question:

In your opinion, are readers of mainstream newspapers provided with enough information in articles concerning biomedical advances to understand the benefits and limitations of biomedical research?

Journalist C stated:

> "Small newspapers like (the one I worked at) are putting out the paper with shockingly few staff and virtually no copy editors (my paper is 'edited' in a call-centre setup in (a small town)). Reporters are under enormous pressure to simply fill space and as a result a lot of important information gets dropped or simply ignored, including an explanation of the significance of a particular investigation. While small papers are struggling to survive, the large papers can still afford true beat reporters and as such, do a much better job of informing readers about health and science issues."

Journalist B observed:

> "This question is almost impossible to answer because the calibre of and standards for reporting vary quite a bit from outlet to outlet and even reporter to reporter. Some outlets/reporters do a good job keeping research news in context and not overhyping findings. Others do not."

Journalist A said:

> "Some newspapers are better at this than others and some reporters are better at this than others. Papers also have different levels of resources and expertise that make some better equipped to do this than others. It also depends on the day. Some days as a reporter, I have more space and time to get in a wider variety of sources and detail than I do on other days. So I would say even in my own reporting, I do a better job of this on some days than others. Of course, reporters always have the limitation of having to turn the story

around very quickly with limited space to provide the information. I think that means reporters can provide a broad overview of the benefits and limitations of the findings but not a detailed account of the benefits and limitations of how the study was done."

Journalist D stated:

"As a reader, my impression is that the media tends to overhype advances that are not necessarily that significant. In other words, just because we've cured cancer in mice doesn't mean we can do it in humans."

6.3.4 Possible reasons for omitting the financial connection between the researcher and the commercial funding source

In cases where an article failed to identify the financial connection between the researcher and the commercial funding source, the authors were also asked to recall as best as possible why that information was not included.

Because of the long time lag since the articles were written, three of the respondents could not recall the exact circumstances. However, two of the respondents indicated that it did not occur to them to ask for that information. It is also worth noting that some of the articles included in this survey were produced by reporters at a wire service, where the demands are somewhat different than those at a daily newspaper. As one of the respondents rightly noted, wire service articles are often modified one or more times during the course of a news cycle. Earlier versions of the article are intended to satisfy the immediacy of getting news content to members of the service and later versions of the article are intended to add more depth and detail as that information becomes available. A newspaper may choose to publish an earlier, less-complete version of a wire article.

Journalist B, a reporter at a wire service, pointed out that this indeed was the case with one article included in this survey. In email correspondence,

Journalist B forwarded a later, more complete version of a wire article that was included in this study, which provided additional details pertaining to the funding sources of the drug study in question.

6.4 Conclusion

Interviews conducted with a small cross-section of reporters who produced some of the articles included in this study reveal a surprising disconnect between the experience and beliefs of the reporters and their actions when producing texts. Five of six respondents described their level of understanding of science and biomedical concepts as either above average or average. Five of six respondents reported that their level of understanding of clinical research ethics was above average or average. Yet the study results show that nearly 82 per cent of the articles about biomedical research failed to identify the financial connection between the principal researcher(s) and the commercial funding source of the research. In their interviews, most of the respondents supported the belief that readers should be made aware of researchers' financial connections yet half of the respondents were not aware that scientific journals require these financial connections, to be declared as a prerequisite for publication.

CHAPTER SEVEN: CONCLUSIONS AND RECOMMENDATIONS

7.1 Introduction

Mainstream newspapers not only convey news to the public, they also perform a valuable service by providing the context that helps frame a better understanding of the news. There is an implicit trust between a newspaper and its readers. Readers trust that the news they are absorbing is accurate, objective, fair and balanced, and, to a lesser extent, appropriate in scale. To fulfill these benchmark criteria, readers place their trust in journalists, on the assumption that journalists have the training and skill necessary to act as the reading public's proxy when it comes time to collect and synthesize information.

This study began with two rather straightforward questions:

- How do Canadian newspaper readers know that the science and biomedical research information they are reading is reliable and objective?

- More importantly, how do Canadian newspaper readers know that the reporters and editors responsible for assembling such stories fully understand the underpinnings of the scientific process so that readers are provided with the right type of information to make informed conclusions about the validity of the scientific outcomes being reported?

The results of this study suggest that the answer to both questions is the same: readers cannot be sure in either case.

7.2 Summary of results

The results strongly suggest that readers of mainstream Canadian newspapers have not been provided with adequate disclosure in news stories to make informed decisions about the ethical underpinnings that should support biomedical research. More than 80 per cent of the articles identified for this study failed to inform Canadian newspaper readers that researchers had a financial conflict of interest that may have explicitly or implicitly had an impact on the findings of their research. About half of the articles included in this study also failed to inform readers that the research in question was funded by a commercial source that had a financial interest in the success of the research product.

Only four of 87 articles (5 per cent) included the amount of funding being provided by the commercial source. This can be an important piece of information pointing to the financial stakes involved for the private-sector partner, which can be substantial. For example, in one of the four articles that did identify the amount, the funding provided for the clinical trials was $50 million.

This study's finding that 18 per cent of articles identified a researcher's financial conflict of interest with a funding source is slightly higher than results from other similar studies in Canada and the U.S. A 2007 U.S. newspaper content analysis of more than 1,100 articles by Cook, Boyd, Grossmann and Bero found that 11 per cent of the articles identified the financial ties of the researchers. A 2003 study by Cassels and his colleagues analyzed newspaper articles in major Canadian newspapers related to coverage of five key drugs approved for use in Canada. The Cassels *et al.* study found that only 3 per cent of newspaper articles about the five drugs in question reported potential financial conflicts of interest (Cassels *et al.*, 2003), compared to this study's finding that 18 per cent of newspaper articles reported such a conflict of interest.

This study's finding that 51 per cent of the articles (44 of 87) did not report any side effects or dangers is lower than the results of the Cassels *et al.* 2003 study that found 68 per cent of newspaper articles in major Canadian daily newspapers did not report any side effects or harms in coverage of five major drugs approved for use in Canada. This study's findings, however, are roughly comparable with a U.S. study by Moynihan *et al.* (2000) which showed that 53 per cent of sampled U.S. news reports did not report potential harm to patients. The Cassels *et al.* 2003 Canadian study also found that 26 per cent of newspaper articles included information about the source of research funding, compared to this study's finding that 51 per cent of newspaper articles reported funding sources (44 of 87 articles). About 94 per cent of the articles in this study (82 of 87 articles) were positive in tone in their reporting of the biomedical research. Only three of 87 articles were negative in tone, and two were neutral in tone.

7.3 Conclusions

To understand the impact of these results on the reader of a mainstream Canadian newspaper, it is necessary to examine the chain of events, unseen by the reader, that takes place prior to the reader's consumption of the news. The first step in this chain that requires scrutiny occurs at the level of the researcher and the connection that exists between the researcher and the funding source. Numerous studies have shown that research that is funded by a commercial source is more likely to lead to positive findings than research from non-commercial funding sources. Bhandari *et al.* (2004) showed that biomedical research from investigators with a financial conflict of interest was twice as likely to come to a pro-industry finding. Other studies have also shown that research from financially-conflicted researchers is also more likely to lead to the suppression of negative results. Commercially-sponsored research also leads to an increased bias in study design (Bekelman, Li and Gross, 2003).

The convergence between public institution researchers and private-sector funders can also have other, more explicit effects behind the scenes. In

2009, Tereskerz and her colleagues published the results of a large survey of researchers at 33 U.S. universities, which showed that nearly one in 10 respondents who had industry-funded colleagues "had first-hand knowledge of compromises to the well-being of (human) research subjects at their institution because researchers in their department/research unit received industry sponsorship."

As Tereskerz *et al.* noted: "the concern is not that compromising the well-being of human research participants happens frequently but that it happens at all. There should be zero tolerance for compromising the well-being of human research participants in any study, regardless of the source of the study's support." The survey also showed that 35 per cent of respondents in university research department units with industry support noted compromises to research initiatives, 28 per cent noted compromises to publication and 25 per cent noted compromises with interpretation of data (Tereskerz *et al.*, 2009).

As readers of mainstream media consume news about biomedical research, they are largely unaware of these unseen factors that may have already influenced the scientific results being reported. In the overwhelming majority of cases, as this study shows, Canadian readers have not been informed of financial conflicts of interest between researchers and their commercial funders.

This, in turn, suggests the readers are also unaware that:

1. The research findings are much more likely to be positive in favour of the commercial funder;
2. The research is more likely to have had negative results suppressed than research funded by non-commercial sources;
3. The design of the research trial is more likely to have been biased in favour of the commercial funder, and;

4. There were more likely to be publication and data interpretation compromises in favour of the commercial funder.

It is possible that even more articles could have been included in this study (Tereskerz *et al.*, 2009) but were overlooked because of factors related to the researchers' own potential lack of disclosure of financial interests.

In a 2008 study, Weinfurt and his colleagues looked at more than 700 journal publications involving nearly 3,000 authors related to coronary artery stents and found that there was a high rate of non-reporting of financial disclosures by study authors. Weinfurt *et al.* also observed that even when financial disclosures were made, there was great inconsistency in the financial disclosures from publication to publication. A 2009 study by Okike *et al.* in the *New England Journal of Medicine* also showed that 30 per cent of orthaepedic surgeons failed to make disclosure of payments received from medical device manufacturers in their financial conflict of interest statements.

The results of the study dealt with in this dissertation show that a significant majority of news articles about biomedical research advances omit key pieces of information that would help provide the reader with better scientific context. These omissions, created at the level of the reporter, may help frame the news article in an artificially positive manner.

To summarize the findings of this study:

1. More than 80 per cent of Canadian news articles reporting on biomedical research developments over an eight-year period failed to alert readers to a potential financial conflict of interest between the researchers and the private-sector company that funded the research.
2. In half of the news articles reporting on biomedical developments, readers were not even made aware that the research was being funded by the private sector – an important omission, given that the

private-sector sponsor has a financial stake in the success or failure of the research being funded.

3. Nearly 95 per cent of the articles were positive in tone about the research developments being reported.

Drill down into these three findings and the context surrounding their importance becomes easier to understand.

Table 7.1 shows the potential conflicts that can exist between commercial funding entities (such as pharmaceutical companies), biomedical researchers based at public agencies (such as universities and hospitals), journalists who report on biomedical research, and the public, which is the end consumer of both the news and the products being discovered. As the table illustrates, the interests of each party in the conflict are often at odds.

Table 7.1 Possible conflict of interest relationships

CONFLICT 1	INTEREST SERVED
Commercial funders vs. Medical journal article writers (i.e. researchers)	Recoup costs, earn profits or serve own vested interests
	Improve academic status - publish or perish
CONFLICT 2	INTEREST SERVED
Medical journal article writers vs. Medical news article writers (i.e. journalists)	Demonstrate value and rigour of research
	Obtain newsworthy data
CONFLICT 3	INTEREST SERVED
Medical news article writers vs. The public	Disseminate news which will sell newspapers
	Be better informed to improve decision-making on health/wellness issues

However, this is not to suggest that it is necessarily vested financial interests which are to blame for incomplete or inaccurate news reporting of medical discoveries. The lack of understanding by reporters of both the complexities and subtleties of scientific research may have caused the reporters to

improperly frame the news article. Reporters frequently frame articles about biomedical research advances as a triumph of good over evil, often using positive, forward-looking quotes from the researcher that bolster both the reporter's conclusions and the researcher's reputation.

A case study of one biomedical discovery in 2003 allowed for an analysis of two distinct genres – the genre of medical journal research articles, based on Skelton's (1994) move structure, compared to Suhardja's (2008) move structure for medical research news articles published in mainstream newspapers. As the case study illustrates clearly, the genres of medical research journal articles and medical research news articles are highly dissimilar. It is likely these two genres have been constructed to appeal to very different target audiences, and serve different communicative purposes.

Scientists, the intended audience of scientific journal content, are conditioned to consume texts that follow a familiar science template of an Introduction followed by Methods, Results and Discussion. Scientific jargon, statistical assessments and the absence of direct quotes or hyperbole are expected.

In the case of medical research news articles published in mainstream newspapers, the target audience – the general public – has been conditioned to receive news texts in a familiar format that follows the inverted pyramid model. In this model, the most important and salient information is placed at the top of the text and background information is placed closer to the bottom of the text. For news articles related to medical research, mainstream newspaper readers expect journalists to interpret and translate complicated scientific jargon into plainer language, even though journalists often do not possess detailed scientific knowledge.

At the very least, this study shows that an overwhelming majority of news articles about commercially-funded biomedical research advances failed to provide readers with basic information about potential financial conflicts that existed for the researchers, which may have had an impact on the research findings.

7.4 Limitations to the study

It should be pointed out that there are several limitations to this study. It is possible that not all potential articles were captured for this study because of deficiencies with the keyword searches used to identify candidates. As noted above, it is also possible that additional articles should have been included but were overlooked because the researchers themselves did not properly identify a potential financial conflict of interest.

Another limitation was the low response rate from article authors. A large majority of article authors did not respond to requests to participate in the survey. For those authors who did participate, another limitation was the amount of time that had elapsed since the article was first written. This limited the specific recall of details related to the articles in question.

7.5 Recommendations

The first two recommendations suggest further avenues for research into medical reporting, and the third suggests a checklist to assist journalist with medical reporting.

7.5.1 Use of third-party comment in medical news articles

One additional avenue raised by this study for future exploration is the use of third-party comment in articles related to biomedical research. In 46 of 87 articles (53 per cent), comment was included from what has been described here as a neutral third-party source.

But as studies have pointed out, even those neutral third parties may not, in fact, be neutral. As Hotz (2002) wrote: “It is getting harder than ever to find a knowledgeable source who does not have a financial stake in a biomedical controversy.” Those experts who may have direct knowledge of new drug therapies may also be researchers funded by the same drug companies for other work. “The scientists who might be expected to provide the clearest

guidance in such debates are increasingly hobbled by commercial secrecy, financial conflicts, or professional self-interest," Hotz noted.

As Journalist B noted in responses to the questionnaire:

"I try to ask people from whom I am getting outside comment – expert commentary – about their potential conflicts of interests, because that can be as relevant as the disclosures of the authors themselves. With drug studies, often experts who know enough to comment about a study also have financial ties to the drug maker – or the maker of a rival drug."

7.5.2 Further research into actual product delivery

Future research could focus on the positive claims of benefits trumpeted in the study's newspaper articles about the biomedical advances to examine whether or not the products ever reached the commercial market, and if so, did the expected benefits materialize. Anecdotal evidence from a cursory look at some of the products suggests that in some cases, at least, not only did the benefits not materialize – contrary to the optimistic reporting of the articles – but in fact, some of the products were actually found to be harmful when introduced outside of a clinical trial population.

7.5.3 Suggested checklist to assist journalists with medical reporting

In an ideal world, journalists at mainstream newspapers would have formal training not just in the practices of journalism, but they would also have formal training in the specific subject areas they cover. This, however, is neither a reasonable, nor a practical, expectation. It is more reasonable to expect that journalists will have a broad range of experience and interests. It is also reasonable to expect that they will have the necessary training to conduct preliminary research, ask appropriate questions, synthesize the obtained material accurately, and produce reports that are fair and balanced.

In the specific realm of articles related to biomedical research, journalists may not be aware of, or understand, the complexities of the research, the

importance of ethical conduct in science, and the potential that exists for researchers to have a financial conflict of interest.

A checklist of questions that need to be addressed is one tool that could help journalists faced with producing such articles. If one was to construct such a draft checklist for reporters covering news related to pharmaceutical or medical device advances, it could look something like this:

1. Does the article identify the source of the research funding?
2. Is the funding source a public institution (such as a government agency or a charitable foundation), a commercial source (such as a pharmaceutical company) or a combination of the two?
3. Does the article identify any possible financial connection between the researcher(s) and a commercial funding source of the research?
4. Does the article identify the amount of the funding?
5. Does the article include information about possible side effects or dangers of the drug or medical device?
6. Does the article include neutral comment from a third party?
7. Does the article include an opposing view from a third party to balance the article?

It is interesting to note that not one of the 87 articles included in this study satisfied all seven of the checklist questions. It is also interesting to note that 16 of the 87 articles did not satisfy a single one of the seven questions.

7.6 Conclusion

Reputable scientific journals have introduced greater transparency that requires authors to state any potential financial conflicts of interest. That same transparency, however, appears to be frequently missing when it comes to mainstream newspapers. Published studies clearly show research

funded by the private sector is much more likely to come to positive conclusions than research funded by other sources.

In addition, the concept of publication bias is already well-established. Publication bias suggests that positive scientific outcomes will be reported in academic journals more frequently than negative scientific outcomes. Why is that important? When mainstream newspaper reporters look for guidance to help establish the validity of the research they intend to report, one criteria is whether or not the research has been deemed acceptable by the scientific community. What those reporters may not recognize is that the scientific publications themselves may self-select positive outcomes more frequently, and, on top of that, research funded by the private sector is already more likely to come to positive conclusions.

Reporters may also not have adequate scientific training to fully understand important concepts, such as the ethical framework of scientific research and the potential influence of financial conflicts of interest on research findings.
While two-thirds of the journalists who responded to a questionnaire for this study self-reported their level of understanding of science and biomedical concepts as above average to average, half of the questionnaire respondents also indicated they were unaware that most major scientific journals now require researchers to declare potential financial conflicts of interest as a prerequisite for publication.

Journalists rely on researchers to supply them with information about biomedical research advances. Just as readers trust journalists to provide them with accurate, unbiased information, journalists trust scientific researchers to provide them with accurate, unbiased information about their work. This chain of trust must not be broken when it comes to informing the public of possible conflicts of interest which might sway crucial decisions on health care.

Bibliography

Anaissie EJ *et al.* (2006) Clinical research in the lay press: Irresponsible journalism raises a huge dose of doubt. *Clinical Infectious Diseases* 2006: 43:1031–9.

Arneja S (2007) An approach to critical thinking for health care professionals. *B.C. Medical Journal*. 49:547-549.

Associated Press report (2010). Merck moves to settle shareholder Vioxx suits. February 10, 2010.

Bekelman YL, Yan L, Gross CP. Scope and impact of financial conflicts of interes in biomedical research. *JAMA*. 289:454–465.

Bhandari M, Busse JW, Jackowski D, Montori VM, Schünemann H, Sprague S, Mears D, Schemitsch EH, Heels-Ansdell D and Devereaux PJ (2004) Association between industry funding and statistically significant pro-industry findings in medical and surgical randomized trials. *Canadian. Medical Association Journal.* 170: 477-480.

Bhatia VK (2002) Applied genre analysis: a multi-perspective model. *Iberica*. 3-19.

Billgen N (2006) Bayer's Baycol/Lipobay crisis in the news: Themes, frames and sources in German and American newspaper coverage. Dissertation submitted for Master of Science, University of Kansas.

Boyd EA Cho MK and Bero LA (2003) Financial conflict-of-interest policies in clinical research: issues for clinical investigators. *Acad Med*. 2003 Aug:78(8):769-74.

British Medical Journal (2009) Editorial: Disclosure of competing interests. *British Medical Journal*. doi:10.1136/bmj.b4144

Brookes H (1995) Suit, tie and a touch of juju: the ideological construction of Africa in the British press. *Discourse & Society*. Vol. 6, No. 4. 461-494.

Buist S, Walters J and Muhtadie L (2005) Blind Faith newspaper investigative series. *Hamilton Spectator*.

Buist S (1999) The scientific method and how it works. *Hamilton Spectator*. May 8, 1999.

Buist S (2000) Irrationality in the midst of a techno world. *Hamilton Spectator*. August 23, 2000.

Canadian Newspaper Association fact sheet, 2010.

Cassels A, Hughes MA, Cole C, Mintzes B, Lexchin J and McCormack JP (2003) Drugs in the news: An analysis of Canadian newspaper coverage of new prescription drugs. *Canadian Medical Association Journal*. 168(9).

Chaudhry, S, Schroter, S, Smith, R, and Morris, J (2002) Does declaration of competing interests affect readers' perceptions? A randomised trial. *British Medical Journal.* 325:1391-1392.

Cheng R (2009) Newspaper coverage of environmental problems in China: An analysis of three Chinese newspapers. Thesis submitted for Master of Science, Oklahoma State University.

Cook DM, Boyd EA, Grossmann C and Bero LA (2007) Reporting science and conflicts of interest in the lay press. *PLoS ONE*. 2007: 2(12): e1266. Published online 2007 December 5. doi: 10.1371/journal.pone .0001266.

Cooper RJ, Gupta M, Wilkes MS and Hoffman JR (2006) Conflict of interest disclosure policies and practices in peer-reviewed biomedical journals. *J Gen Intern Med* 21: 1248–1252.

Corrigan D (1990) Value coding consensus in front page news leads. *Journalism Quarterly*, 67(4), 653-662.

Drazen JM, Van Der Weyden MB, Sahni P, Rosenberg J, Marusic A, Laine C, Kotzin S, Horton R, Hébert PC, Haug C, Godlee F, Frizelle FA, de Leeuw PW and DeAngelis CD (2009) Disclosure of competing interests. *British Medical Journal.* 2009:339:4144.

Entman RM (1991) Framing U.S. coverage of international news: Contrasts in narratives of the KAL and Iran Air incidents. *Journal of Communication*, 41(4): 6-27.

Entman RM (1993) Framing: Toward clarification of a fractured paradigm. *Journal of Communication*. 1993 43(4), Autumn: 0021-9916.

Fairclough N (1989) *Language and power.* Essex: Longman.

Fairclough N (2003) *Analysing discourse: textual analysis for social research*. London: Routledge.

Fairclough N (2002) Discourse, social theory, and social research: the discourse of welfare reform. *Journal of Sociolinguistics*. 163-195

Fanelli D (2009) How many scientists fabricate and falsify research? A systematic review and meta-analysis of survey data. *PLoS ONE* 4(5): e5738. doi:10.1371/journal.pone.0005738

Ferree MM, Gamson WA, Gerhards J, Rucht D (2002) Shaping Abortion Discourse: Democracy and the Public Sphere in Germany and the United States. *Cambridge University Press.* Chapter 6. 105-120.

Friedman PJ (2002) The impact of conflict of interest on trust in science. *Science and Engineering Ethics*. 2002 8:413-420.

Gasher M, Hayes M, Hackett R, Gutstein D, Ross I and Dunn J (2007) Spreading the news: Social determinants of health reportage in Canadian daily newspapers. *Canadian Journal of Communication*. 32:557-574.

Gitlin T (1980) The whole world is watching: Mass media in the making and unmaking of the New Left. *University of California Press.*

Hall HT (2008) Brand Jane-Finch: A Critical Discourse Analysis of print media discourse on a Toronto low income community. *York University*. Master's thesis submission.

Harris G (2005) Drug regulators are trying to quash study, senator says. *New York Times newspaper.* Feb. 12, 2005.

Haskell DM (2009) Through a lens darkly: How the news media perceive and portray evangelicals. Chapter 4: News and news framing. *Clements Academic Publishing*, Toronto.

Hester J and Gibson R (2007) The agenda-setting function of national versus local media: A time-series analysis for the issue of same-sex marriage. *Mass Communication and Society*, 10(3), 299-317.

Hotz RL (2002) The difficulty of finding impartial sources in science. *Nieman Reports*. 56(3):6-7.

Knoll E (1992) What is scientific misconduct? *Science Communication*, Vol. 14 No. 2. December 1992 174-180.

Konig T (2009) Frame Analysis: A Primer. *Economic and Social Research Council.*

Kosicki G (1993) Problems and opportunities in agenda-setting research: A 20-year assessment. *Journal of Communication*. 43:113.

Krimsky S and Rothenberg LS (2001) Conflict of interest policies in science and medical journals: editorial practices and author disclosures. *Sci Eng Ethics* 7: 205–218.
Kuypers, J (2002) Press bias and politics: How the media frame controversial issues. *Praeger*.

Lexchin JR (2005) Implications of pharmaceutical industry funding on clinical research. *Ann Pharmacother*. 2005 Jan:39(1):194-7.

Lexchin JR, Bero LA, Djulbegovic B and Clark O (2003) Pharmaceutical industry sponsorship and research outcome and quality: systematic review. *British Medical Journal*. 2003 May 31:326(7400):1167-70.

McComas KA and Simone LM (2003) Media coverage of conflicts of interest in science. *Science Communication*, Vol. 24 No. 4, June 2003: 395-419.

McGregor S (2004) Critical Discourse Analysis: A Primer. *Kappa Omicron Nu Forum*. 15:1

Mirowski P and Van Horn R (2005) The contract research organization and the commercialization of scientific research. *Social Studies of Science*. 35:503.

Moriarty C, Jensen J and Stryker J (2008) A Content Analysis of Frequently Cited Sources in Cancer News Coverage: Examining the Relationship Between Cancer News Content and Source Citation. *Paper presented at the annual meeting of the International Communication Association, Montreal, Quebec, Canada*. May 21, 2008.

Moynihan R, Bero L, Ross-Degnan D, Henry D, Lee K, Watkins J and Soumerai SB (2000) Coverage by the news media of the benefits and risks of medications. *New England Journal of Medicine*. 2000 Jun 1:342(22):1645-50.

Murray T (2002) Conflict of Interest in the Professions – Book Review. *New England Journal of Medicine*. Vol 346, No. 23: 1835-36

Novartis International AG (2010) Drug Discovery and Development Process. *Company information sheet.*

Okike K, Kocher MS, Wei EX, Mehlman CT and Bhandari M (2009) Accuracy of conflict of interest disclosures reported by physicians. *New England Journal of Medicine*. 2009 Oct 8;361(15):1466-1474.

Palmer J (2000) Spinning into control: news values and source strategies. *Continuum Publishing Group*. Chapter 1: The News Encounter.

Reed R (2001) (Un-)Professional discourse? Journalists' and scientists' stories about science in the media. *Journalism*, 2 (3):279-298.

Reuters News Wire (2009) Stanford Medical School web site lists consulting activities for faculty members. Sept. 15, 2009.

Richardson J (2007) Analysing Newspapers: An Approach from Critical Discourse Analysis. *Palgrave Macmillan.*

Riffe D (2002) Framing: An editorial comment. *Journalism and Mass Communication Quarterly*. 79 (1): 2-6.

Sahu DR and Abraham P (2000) Authorship: rules, rights, responsibilities and recommendations. *J Postgrad Med* 2000 46:205-210.

Scheufele DA and Tewksbury D (2007) Framing, agenda setting, and priming: The evolution of three media effects models. *Journal of Communication.* 57:9-20.

Seo SK (1988) Source-press relationship: Major characteristics of sources which influence selection of sources in news coverage. *Paper presented to*

the newspaper division, Association for Education in Journalism and Mass Communication, Portland, Oregon.

Shuchman M and Wilkes MS (1997) Medical scientists and health news reporting: A case of miscommunication. *Annals of Internal Medicine*, June 15, 1997 vol. 126 no. 12:976-982.

Shuchman M (2005) The Drug Trial: Nancy Olivieri and the scandal that rocked the Hospital for Sick Children. *Random House Canada*.

Sismondo S (2008) How pharmaceutical industry funding affects trial outcomes: Causal structures and responses. *Social Science and Medicine.* 66(9):1909-1914.

Skelton J (1994) Analysis of the structure of original research papers: An aid to writing original papers for publication. *British Journal of General Practice, 44*, 455-459.

Stonbely, S (2011) Content Analysis. *International Collaborative Dictionary of Communications*.

Swales, J (1990) *Genre analysis: English in academic and research settings*. Cambridge: Cambridge University

Swales, J. (2000). *Genre Analysis: English in Academic and Research Settings*. Cambridge: University of Aston in Birmingham.

Swales, J. and University of Aston in Birmingham. Language Studies Unit. (1981) *Aspects of Article Introductions*. Birmingham: Language Studies Unit, University of Aston in Birmingham.

Suhardja I (2008) *The Discourse of 'Distortion' and Health and Medical News Reports: A Genre Analysis Perspective.* University of Edinburgh

Tereskerz PM, Hamric AB, Guterbock TM and Moreno JD (2009) Prevalence of industry support and its relationship to research integrity. *National Institutes of Health Public Access*. 16(2): 78–105.

Trimble L and Sampert S (2009) Mediations: Making News about Politics. *Mediating Canadian Politics*.

Tuchman G (1978) Making news: A study in the construction of reality. *The Free Press.*

United States Department of State (2006) Focus On: Intellectual Property Rights. *U.S. Department of State Bureau of International Information Programs.* January 2006.

United States National Cancer Institute (2004) Cancer facts and the war on cancer. Information sheet.

Van Dijk TA (1988) News as Discourse. Erlbaum

Van Dijk TA (1995) Political Communication in Action. *Hampton Press.* Chapter 1: Power and the News Media.

Van Dijk TA (1998) Critical Discourse Analysis. *Handbook of Discourse Analysis*. Chapter 18.

Weinfurt KP, Seils DM, Tzeng JP, Lin L, and Schulman KA (2008) Consistency of financial interest disclosures in the biomedical literature: The case of coronary stents. *PLoS ONE* 3(5): e2128.

White DM (1950) The Gatekeeper: A case study in the selection of news. *Journalism Quarterly* 27 1950:383-390.

World Association of Medical Editors (2010) Publication ethics policies for medical journals. *BMJ Publishing Group*.

APPENDIX A:

QUESTIONNAIRE (FINANCIAL CONNECTION NOT IDENTIFIED):

NAME:

PUBLICATION / NEWS OUTLET:

(NOTE: For multiple-choice questions below, please place an X in front of the response that is most appropriate.)

1. How many years have you been a journalist?
   0-5 years
   6-10 years
   11-15 years
   16-20 years
   More than 20 years

2. What is your primary beat (e.g. health, science, business, general assignment)?

If your beat is primarily health/medical or science:

2a. How many years have you been a health/medical or science reporter?
   0-3 years
   4-6 years
   7-10 years
   11-15 years
   More than 15 years

3. What percentage of the stories you write are focused primarily on health and/or science topics?
   Less than 25 per cent
   26 to 50 per cent
   51 to 75 per cent
   More than 75 per cent

4. What is the highest level of formal science education you have attained?
   Post-graduate degree (Master's/PhD/post-doctoral)
   Bachelor's degree
   Some university courses
   Some college courses
   High school courses

5. How would you rate your understanding of science and biomedical concepts:

Excellent ("I can tell you what the A, T, C and G stand for in DNA base pairs.")
Above average ("I can tell you that DNA stands for deoxyribonucleic acid.")
Average ("I can tell you that genes are made up of strands of DNA.")
Below average ("I can spell DNA.")
Poor ("What is DNA?")

6. Does your publication have any written policies or guidelines that pertain specifically to the writing of health and/or science topics? (For example, specific policies and guidelines about reporting funding sources of clinical trials, affiliations of principal investigators or reporting the generic names of pharmaceutical products.)
Yes
No
Not sure

7. Does your publication have any unwritten or informal policies and guidelines that pertain specifically to the writing of health and/or science topics?
Yes
No
Not sure

8. Does your publication have any written policies or guidelines that specifically govern a potential financial conflict of interest for a reporter when writing about a topic? (For example, specific polices and guidelines that might prevent a reporter from writing about a company if the reporter owns stock in that company, or using information obtained in the process of writing an article to purchase stock in a company.)
Yes
No
Not sure

9. Does your publication have any unwritten or informal policies and guidelines that specifically govern a potential conflict of interest for a reporter when writing about a topic?
Yes
No
Not sure

10. How would you rate your understanding of clinical research ethics in science and/or medicine?
Excellent
Above average
Average
Below average
Poor

11. Are you aware that most scientific journals now require authors of

research papers to declare potential conflicts of interest as a prerequisite for publication?

Yes
No

12. When writing about medical or scientific research, how often do you report all funding sources of the research?

Always
Most of the time
Some of the time
Occasionally
Rarely / never

13. Is it important or is it not important for readers of mainstream newspapers to be made aware of all funding sources in an article about medical and/or scientific research? Please explain briefly.

14. When writing about medical or scientific research, how often do you report, when applicable, that a researcher may have a financial connection to a commercial funding source of the research?

Always
Most of the time
Some of the time
Occasionally
Rarely / never

15. Is it important or is it not important for readers of mainstream newspapers to be made aware that a researcher may have a financial connection to a commercial funding source of the research? Please explain briefly.

16. Your article reported on a noteworthy development in biomedical research. Pick four separate words or terms that would best summarize the overall message that readers would take away from your article.

1)
2)
3)
4)

17. In your opinion, are readers of mainstream newspapers provided with enough information in articles concerning biomedical advances to understand the benefits and limitations of biomedical research? Please explain briefly.

18. As best as you can recall, why did you not indicate in your story that the researcher had a financial connection to the commercial funding source of the research? (Select all applicable choices.)

It did not occur to me to ask.
I wasn't sure if it was important.
I would feel uncomfortable/awkward asking the researcher.
It's not important for the reader to know that.

It's not relevant to the story.
I did include it but it was edited out.
None of the above statements apply.

19. Do you have any other comments you'd like to make about the issue of scientific ethics and potential financial conflicts of interest in biomedical research?

QUESTIONNAIRE (FINANCIAL CONNECTION IDENTIFIED):

NAME:

PUBLICATION / NEWS OUTLET:

(NOTE: For multiple-choice questions below, please place an X in front of the response that is most appropriate.)

1. How many years have you been a journalist?
0-5 years
6-10 years
11-15 years
16-20 years
More than 20 years

2. What is your primary beat (e.g. health, science, business, general assignment)?

If your beat is primarily health/medical or science:

2a. How many years have you been a health/medical or science reporter?
0-3 years
4-6 years
7-10 years
11-15 years
More than 15 years

3. What percentage of the stories you write are focused primarily on health and/or science topics?
Less than 25 per cent
26 to 50 per cent
51 to 75 per cent
More than 75 per cent

4. What is the highest level of formal science education you have attained?
Post-graduate degree (Master's/PhD/post-doctoral)
Bachelor's degree

Some university courses
Some college courses
High school courses

5. How would you rate your understanding of science and biomedical concepts:
Excellent ("I can tell you what the A, T, C and G stand for in DNA base pairs.")
Above average ("I can tell you that DNA stands for deoxyribonucleic acid.")
Average ("I can tell you that genes are made up of strands of DNA.")
Below average ("I can spell DNA.")
Poor ("What is DNA?")

6. Does your publication have any written policies or guidelines that pertain specifically to the writing of health and/or science topics? (For example, specific policies and guidelines about reporting funding sources of clinical trials, affiliations of principal investigators or reporting the generic names of pharmaceutical products.)
Yes
No
Not sure

7. Does your publication have any unwritten or informal policies and guidelines that pertain specifically to the writing of health and/or science topics?
Yes
No
Not sure

8. Does your publication have any written policies or guidelines that specifically govern a potential financial conflict of interest for a reporter when writing about a topic? (For example, specific polices and guidelines that might prevent a reporter from writing about a company if the reporter owns stock in that company, or using information obtained in the process of writing an article to purchase stock in a company.)
Yes
No
Not sure

9. Does your publication have any unwritten or informal policies and guidelines that specifically govern a potential conflict of interest for a reporter when writing about a topic?
Yes
No
Not sure

10. How would you rate your understanding of clinical research ethics in science and/or medicine?
Excellent

Above average
Average
Below average
Poor

11. Are you aware that most scientific journals now require authors of research papers to declare potential conflicts of interest as a prerequisite for publication?
Yes
No

12. When writing about medical or scientific research, how often do you report all funding sources of the research?
Always
Most of the time
Some of the time
Occasionally
Rarely / never

13. Is it important or is it not important for readers of mainstream newspapers to be made aware of all funding sources in an article about medical and/or scientific research? Please explain briefly.

14. When writing about medical or scientific research, how often do you report, when applicable, that a researcher may have a financial connection to a commercial funding source of the research?
Always
Most of the time
Some of the time
Occasionally
Rarely / never

15. Is it important or is it not important for readers of mainstream newspapers to be made aware that a researcher may have a financial connection to a commercial funding source of the research? Please explain briefly.

16. Your article reported on a noteworthy development in biomedical research. Pick four separate words or terms that would best summarize the overall message that readers would take away from your article.
1)
2)
3)
4)

17. In your opinion, are readers of mainstream newspapers provided with enough information in articles concerning biomedical advances to understand the benefits and limitations of biomedical research? Please explain briefly.

18. How did you acquire the information that the researcher had a financial

connection to the commercial funding source of the research?
Asked the researcher directly in an interview
Researcher supplied the information unsolicited
Obtained from the scientific journal publication
Obtained from a press release
Obtained from the commercial funding source
Not sure / cannot recall

19. Do you have any other comments you'd like to make about the issue of scientific ethics and potential financial conflicts of interest in biomedical research?

QUESTIONNAIRE (FOR REPORTERS WITH ARTICLES THAT DID AND DID NOT IDENTIFY FINANCIAL CONNECTIONS):

NAME:

PUBLICATION / NEWS OUTLET:

(NOTE: For multiple-choice questions below, please place an X in front of the response that is most appropriate.)

1. How many years have you been a journalist?
0-5 years
6-10 years
11-15 years
16-20 years
More than 20 years

2. What is your primary beat (e.g. health, science, business, general assignment)?

If your beat is primarily health/medical or science:

2a. How many years have you been a health/medical or science reporter?
0-3 years
4-6 years
7-10 years
11-15 years
More than 15 years

3. What percentage of the stories you write are focused primarily on health and/or science topics?
Less than 25 per cent
26 to 50 per cent
51 to 75 per cent

More than 75 per cent

4. What is the highest level of formal science education you have attained?
Post-graduate degree (Master's/PhD/post-doctoral)
Bachelor's degree
Some university courses
Some college courses
High school courses

5. How would you rate your understanding of science and biomedical concepts:
Excellent ("I can tell you what the A, T, C and G stand for in DNA base pairs.")
Above average ("I can tell you that DNA stands for deoxyribonucleic acid.")
Average ("I can tell you that genes are made up of strands of DNA.")
Below average ("I can spell DNA.")
Poor ("What is DNA?")

6. Does your publication have any written policies or guidelines that pertain specifically to the writing of health and/or science topics? (For example, specific policies and guidelines about reporting funding sources of clinical trials, affiliations of principal investigators or reporting the generic names of pharmaceutical products.)
Yes
No
Not sure

7. Does your publication have any unwritten or informal policies and guidelines that pertain specifically to the writing of health and/or science topics?
Yes
No
Not sure

8. Does your publication have any written policies or guidelines that specifically govern a potential financial conflict of interest for a reporter when writing about a topic? (For example, specific polices and guidelines that might prevent a reporter from writing about a company if the reporter owns stock in that company, or using information obtained in the process of writing an article to purchase stock in a company.)
Yes
No
Not sure

9. Does your publication have any unwritten or informal policies and guidelines that specifically govern a potential conflict of interest for a reporter when writing about a topic?
Yes
No

Not sure

10. How would you rate your understanding of clinical research ethics in science and/or medicine?

Excellent
Above average
Average
Below average
Poor

11. Are you aware that most scientific journals now require authors of research papers to declare potential conflicts of interest as a prerequisite for publication?

Yes
No

12. When writing about medical or scientific research, how often do you report all funding sources of the research?

Always
Most of the time
Some of the time
Occasionally
Rarely / never

13. Is it important or is it not important for readers of mainstream newspapers to be made aware of all funding sources in an article about medical and/or scientific research? Please explain briefly.

14. When writing about medical or scientific research, how often do you report, when applicable, that a researcher may have a financial connection to a commercial funding source of the research?

Always
Most of the time
Some of the time
Occasionally
Rarely / never

15. Is it important or is it not important for readers of mainstream newspapers to be made aware that a researcher may have a financial connection to a commercial funding source of the research? Please explain briefly.

16. Your article reported on a noteworthy development in biomedical research. Pick four separate words or terms that would best summarize the overall message that readers would take away from your article.

1)
2)
3)
4)

17. In your opinion, are readers of mainstream newspapers provided with enough information in articles concerning biomedical advances to understand the benefits and limitations of biomedical research? Please explain briefly.

FOR YOUR STORY (OR STORIES) THAT DID IDENTIFY A RESEARCHER'S FINANCIAL CONNECTION TO THE COMMERCIAL FUNDING SOURCE:

18. How did you acquire the information that the researcher had a financial connection to the commercial funding source of the research?

Asked the researcher directly in an interview
Researcher supplied the information unsolicited
Obtained from the scientific journal publication
Obtained from a press release
Obtained from the commercial funding source
Not sure / cannot recall

FOR YOUR STORY (OR STORIES) THAT DID NOT IDENTIFY A RESEARCHER'S FINANCIAL CONNECTION TO THE COMMERCIAL FUNDING SOURCE:

19. As best as you can recall, why did you not indicate in your story that the researcher had a financial connection to the commercial funding source of the research? (Select all applicable choices.)

It did not occur to me to ask.
I wasn't sure if it was important.
I would feel uncomfortable/awkward asking the researcher.
It's not important for the reader to know that.
It's not relevant to the story.
I did include it but it was edited out.
None of the above statements apply.

20. Do you have any other comments you'd like to make about the issue of scientific ethics and potential financial conflicts of interest in biomedical research?

APPENDIX B:

TEXT ANALYSIS SPREADSHEET

YEAR	DATE	REPORTER	PUBLICATION	KEYWORDS	POSITIVE?	DANGERS/SIDE EFFECTS?	OPPOSING VIEW?	NEUTRAL COMMENT?
2001	2/13/2001	Down, Jeff (AP)	Prince Rupert Daily News	tremendous breakthrough, landmark, importance	YES	YES	NO	YES
2001	3/1/2001	Morrison, Suzanne	Hamilton Spectator	significantly better, start of a new era, best in the world, significant benefits, major advantage, could be beneficial,	YES	NO	NO	NO
2001	3/14/2001	Morrison, Suzanne	Hamilton Spectator	major study, big advance	YES	NO	NO	NO
2001	3/20/2001	Morrison, Suzanne	Hamilton Spectator	biggest breakthrough, enormous impact, change way medicine practised, major step forward, very significant improvement, breakthrough, huge impact, effective, major advance	YES	NO	NO	NO
2001	3/20/2001	CP	Guelph Daily Mercury	highly effective treatment, could potentially prevent 100,000 heart emergencies a year in US, breakthrough, change the practice of medicine, impact will be even greater, monster benefits, very exciting	YES	YES	NO	YES
2001	3/20/2001	Altman, Lawrence	National Post	super Aspirin, could save 500,000 from death, significantly lower, greeted enthusiastically, might benefit many, highly significant, best news since	YES	YES	NO	YES
2001	5/13/2001	Richwine, Lisa	Ottawa Citizen	promise, promising, possible advance, excitement, remarkable, step forward,	YES	NO	NO	NO
2001	8/16/2001	Morrison, Suzanne	Hamilton Spectator	clearly benefit, biggest drug breakthrough	YES	NO	NO	NO
2001	8/16/2001	Harrison, Don	Vancouver Province	could save the lives, landmark study, most significant breakthrough, clear benefits	YES	YES	YES	YES
2001	8/16/2001	Laucius, Joanne	Ottawa Citizen	dramatically reduce the risk, landmark CanadianHed study, groundbreaking new study, vastly beneficial, change the way cardiology practised, tremendously important,	YES	YES	YES	NO
2001	8/16/2001	Evenson, Brad	National Post	important step, right direction,	YES	YES	NO	NO
2001	8/16/2001	Yelaja, Prithi	Toronto Star	offer new hope, additive benefit, change clinical practice,	YES	YES	NO	NO
2001	9/25/2001	Yelaja, Prithi	Toronto Star	my own personal miracle, major breakthrough, such dramatic results, amazing, rapidity of response,	YES	YES	NO	NO
2001	10/2/2001	Haney, Daniel (AP)	Prince George Citizen	substantially delay, discovery, even more dramatic, so excited, major dent, major impact,	YES	NO	NO	YES
2001	10/17/2001	Morrison, Suzanne	Hamilton Spectator	potential life-saving drug, windfall for investors, tremendous potential, hope, great things	YES	NO	NO	NO
2001	10/18/2001	AP	Sarnia Observer	may prevent diabetes, expressed caution, potentially important,	YES	NO	NO	YES
2001	12/11/2001	Kirkey, Sharon	Windsor Star	promising a breakthrough, even more valuable, most significant, complete shift in the treatment, big splash, really excited, revolutionize breast cancer	YES	YES	NO	NO
2001	12/12/2001	Kirkey, Sharon	Victoria Times-Colonist	revolutionize, complete shift in the treatment, substantially more effective, big splash, significant early survival advantage, implications ... huge,	YES	YES	NO	NO
2002	2/28/2002	Yelaja, Prithi	Toronto Star	potential medical breakthrough, major advance, huge step up,	YES	YES	NO	NO
2002	3/22/2002	Bhandari, Aparita	Toronto Star	modest reduction,	YES	NO	NO	NO
2002	5/16/2002	Spears, Tom	Ottawa Citizen	incredible vanishing trick, potential to fight, pushing hard, very excited, very confident, works pretty damn well, hopeful, exciting	YES	NO	NO	NO
2002	6/21/2002	Yelaja, Prithi	Toronto Star	critical role, better treatments,	YES	NO	NO	NO
2002	8/8/2002	AP	Toronto Star	startling side effect, surprising	NEUTRAL	YES	NO	NO
2002	10/1/2002	Bowman, Lee (Scripps Howard)	Windsor Star	promising discovery, very effective, most promising, positive results	YES	NO	NO	NO

2002	10/31/2002	Morrison, Suzanne	Hamilton Spectator	reap the same benefits, clear benefit, benefit,	YES	NO	NO	NO
2002	10/31/2002	Kirkey, Sharon	Ottawa Citizen	significantly cut the risk, groundbreaking, effective therapies	YES	NO	NO	YES
2002	11/19/2002	AP	Peterborough Examiner	significantly reduce, huge benefit, results significant,	YES	NO	NO	NO
2002	12/9/2002		National Post	significantly better, optimism,	YES	YES	NO	NO
2002	12/18/2002	Evenson, Brad	National Post	powerful evidence, huge impact,	NO	YES	YES	YES
2003	1/4/2003	Morrison, Suzanne	Hamilton Spectator	blockbuster, life-saving, internationally-acclaimed, major positive impact, better and safer, major discovery, windafal for investors, promising cures for life-threatening diseases,	YES	NO	NO	NO
2003	8/30/2003	McConnaughey, Janet (AP)	Peterborough Examiner	potential breakthrough, discovery as big as . . ., significant long-term advancement, akin to a breakthrough	YES	NO	NO	YES
2003	9/3/2003	Ross, Emma	Prince George Citizen	milestone, drastically increase	YES	NO	NO	NO
2003	10/10/2003	Branswell, Helen (CP)	Hamilton Spectator	important new weapon, sea change in treatment,	YES	NO	NO	YES
2003	10/10/2003	Laucius, Joanne	Ottawa Citizen	groundbreaking, new hope, very exciting	YES	YES	YES	YES
2003	10/10/2003	Woods, Allan	National Post	so successful, offers hope, dramatic results, hope,	YES	YES	YES	YES
2003	10/10/2003	Lukits, Ann	Kingston Whig-Standard	extraordinary early results, potentially exciting new treatment, new hope, astonishing preliminary findings, so dramatic, extraordinary, exciting,	YES	YES	NO	NO
2003	10/10/2003	Torstar	Guelph Mercury	[illegible] findings were so dramatic, sea change in treatment, new era of hope, results are so important, like watching Tiger Woods hit a golf ball, substantially	YES	YES	NO	YES
2003	10/10/2003	Picard, Andre	Globe and Mail	bolstered, data were so impressive, live cancer-free, big step, sea change, results were so promising, cloud has now been lifted,	YES	NO	NO	YES
2003	11/5/2003	Tanner, Lindsey	Toronto Star	startlingly big implications, promising, unusually effective, clearly on the level of a breakthrough, far-reaching implications, surprisingly quick results,	YES	NO	NO	YES
2003	11/6/2003	Tanner, Lindsey (AP)	Peterborough Examiner	startlingly big implications, promising, clearly on the level of a breakthrough, surprisingly quick results, especially efficient	YES	NO	NO	YES
2003	11/13/2003	Haney, Daniel (AP)	Hamilton Spectator	clearly superior, considerably better job,	YES	NO	YES	NO
2003	11/26/2003	Kirkey, Sharon	Ottawa Citizen	no difference, fairly flabbergasted,	NO	NO	YES	NO
2004	3/11/2004	Branswell, Helen (CP)	Peterborough Examiner	change the practice of breast cancer, astounding	YES	NO	YES	YES
2004	5/1/2004	Neergaard, Lauran (AP)	Prince George Citizen	discovery, could benefit thousands, incredibly	YES	NO	NO	YES
2004	6/17/2004	Donn, Jeff (AP)	Guelph Mercury	pivotal study, new era, long-lasting effect, promising	YES	YES	NO	YES
2004	6/17/2004	Donn, Jeff (AP)	Sault Star	promising, highly effective, pivotal study, greatly	YES	YES	NO	YES
2004	7/21/2004	CP	Timmins Daily Press	breakthrough, great ray of hope,	YES	YES	NO	NO
2004	8/30/2004	Hirschler, Ben	National Post	pivotal, blockbuster, excited	YES	YES	NO	NO
2004	12/9/2004	Kirkey, Sharon	National Post	breakthrough, stronger argument, significant	YES	YES	NO	NO
2005	1/18/2005	De Almeida, Jacquie	Hamilton Spectator	may also be effective	NEUTRAL	NO	NO	NO
2005	3/11/2005	Ubelacker, Sheryl (CP)	Prince George Citizen	significant advance, new standard of care, improve	YES	NO	NO	NO
2005	3/12/2005	AP	Cornwall Standard-	can help save lives, first big advance, big impact, great	YES	YES	YES	NO
2005	4/22/2005	CP	Prince George Citizen	significantly reduce, definitive evidence, welcome	YES	NO	NO	NO
2005	5/4/2005	Fidelman, Charlie	Saskatoon Star-Phoenix	greatest breakthrough, tremendous news, looks	YES	NO	YES	YES
2005	5/5/2005	Branswell, Helen (CP)	Globe and Mail	cervical cancer a thing of the past, major breakthroughs, very exciting times, heady times, virtually eliminate cervical cancer, very promising	YES	NO	NO	YES

2005	5/15/2005	Carey, Elaine	Toronto Star	breakthrough, revolution in cancer treatment, seeing improvement, real hope, new standard of treatment	YES	NO	NO	NO
2005	10/20/2005	Priest, Lisa	Globe and Mail	potential breast cancer cure, simply stunning, potential cure, dramatic, maybe even a cure, revolutionary, most dramatic results,	YES	YES	NO	YES
2005	10/21/2005	Donn, Jeff (AP)	Prince George Citizen	astonishingly effective, long-sought breakthrough,	YES	NO	YES	YES
2005	12/9/2005	Ruttan, Susan	Edmonton Journal	confirms the importance, virtually everybody ... should	YES	YES	NO	NO
2005	12/10/2005	AP	Prince George Citizen	looks promising, promising, another boost, convincing case	YES	YES	NO	YES
2006	3/14/2006	Hall, Celia	National Post	discovery, could prevent ... thousands of people, Holy	YES	NO	NO	NO
2006	6/13/2006	Kirkey, Sharon	Calgary Herald	significant breakthrough, desperate for a treatment,	YES	YES	NO	NO
2006	6/13/2006	Gandhi, Unnati	Globe and Mail	significant breakthrough, home run, very excited,	YES	NO	NO	YES
2006	6/13/2006	Carey, Elaine	Toronto Star	step closer to a cure, effectively demonstrated	YES	YES	NO	YES
2006	7/19/2006	Lampert, Allison	Montreal Gazette	hailed as ... greatest breakthrough, extremely	YES	NO	NO	YES
2006	7/25/2006	Abraham, Carolyn	Globe and Mail	raising hopes, breakthrough class of drugs, cusp of	YES	YES	NO	YES
2006	9/15/2006	Frketich, Joanna	Hamilton Spectator	prevent ... growing epidemic, star researchers, major	YES	NO	NO	NO
2006	9/16/2006	Frketich, Joanna	Hamilton Spectator	raised hope around the world, major public health	YES	YES	NO	YES
2006	9/16/2006	Branswell, Helen (CP)	St. John Telegraph-Journal	medical breakthrough, one more weapon, growing	YES	YES	YES	YES
2006	9/16/2006	Kirkey, Sharon	Regina Leader-Post	this is huge,	YES	YES	YES	YES
2006	9/16/2006	Talaga, Tanya	Toronto Star		YES	YES	NO	YES
2007	3/29/2007	Frketich, Joanna	Hamilton Spectator	breathe easier, novel, great discovery, huge	YES	YES	YES	YES
2007	4/28/2007	CP	Prince George Citizen	hailed as a landmark, costly drug, no obvious benefit	NO	YES	YES	YES
2007	5/17/2007	Highfield, Roger	Edmonton Journal	raised hopes, cure, in the hope, potentially find cures,	YES	NO	NO	YES
2007	5/17/2007	Lauerman, John (Bloomberg)	Globe and Mail	cure for baldness,	YES	NO	NO	YES
2007	5/17/2007	Lauerman, John (Bloomberg)	Toronto Star	cure for baldness	YES	NO	NO	YES
2007	6/4/2007	AP	Guelph Mercury	patients get hope, improves survival, impressive,	YES	NO	NO	YES
2007	11/7/2007	AP	Prince George Citizen	great promise, dramatically cuts, hugely important	YES	YES	YES	YES
2007	11/15/2007	Spears, Tom	Ottawa Citizen	another weapon, cancer fight, one more tool, may also	YES	NO	NO	NO
2008	4/1/2008	Brown, Dana	Hamilton Spectator	effective, optimize their health	YES	YES	NO	NO
2008	5/1/2008	Carey, Elaine	Toronto Star	ideal, would be a breakthrough, huge relief	YES	NO	NO	NO
2008	7/22/2008	Smith, Rebecca (Daily	Saskatoon Star-Phoenix	offered new hope, major breakthrough, exciting	YES	YES	NO	YES
2008	9/12/2008	Chang, Alicia (AP)	Moncton Times-Transcript	legacy effect, stresses the importance	YES	YES	NO	YES
2008	10/15/2008	Kirkey, Sharon	Saskatoon Star-Phoenix	baldness breakthrough,	YES	NO	NO	YES
2008	11/10/2008	Stein, Rob (Wash. Post)	Vancouver Sun	powerful evidence, potent protection, potential ...	YES	YES	YES	YES
2008	11/12/2008	Marchione, Marilynn	Fredericton Daily Gleaner	hailed as a watershed event, whole new level,	YES	YES	YES	YES
2008	12/15/2008	Marchione, Marilynn	Moncton Times-Transcript	fresh hope, surprising, significant benefits	YES	YES	YES	YES

APPENDIX C:

CONTENT ANALYSIS SPREADSHEET

YEAR	DATE	REPORTER	PUBLICATION	STUDY AUTHOR(S)	JOURNAL	FUNDING SOURCE	FUNDING AMOUNT	FUNDING IDENTIFIED?	CONNECTION IDENTIFIED?
2001	2/13/2001	Donn, Jeff (AP)	Prince Rupert Daily News	Bernard et al	New England Journal of Medicine	Eli Lilly	Unknown	YES	YES
2001	3/1/2001	Morrison, Suzanne	Hamilton Spectator	Turpie, Alex	New England Journal of Medicine	Sanofi-Synthelabo	Unknown	NO	NO
2001	3/14/2001	Morrison, Suzanne	Hamilton Spectator	Yusuf et al	New England Journal of Medicine	Boehringer-Ingelheim	Unknown	NO	NO
2001	3/20/2001	Morrison, Suzanne	Hamilton Spectator	Yusuf et al	New England Journal of Medicine	Sanofi-Synthelabo/Bristol Myers Squibb	Unknown	YES	NO
2001	3/20/2001	CP	Guelph Daily Mercury	Yusuf et al	New England Journal of Medicine	Sanofi-Synthelabo/BMS	Unknown	YES	NO
2001	3/20/2001	Altman, Lawrence	National Post	Yusuf et al	New England Journal of Medicine	Sanofi-Synthelabo/BMS	YES - $50 million	YES	NO
2001	5/13/2001	Richwine, Lisa	Ottawa Citizen	Saltz et al	ASCO conference findings	ImClone	Unknown	NO	NO
2001	8/16/2001	Morrison, Suzanne	Hamilton Spectator	Mehta et al	The Lancet/NEJM	Sanofi-Synthelabo/Bristol Myers Squibb	Unknown	NO	NO
2001	8/16/2001	Harrison, Don	Vancouver Province	Mehta et al	The Lancet/NEJM	Sanofi-Synthelabo/Bristol Myers Squibb	Unknown	NO	NO
2001	8/16/2001	Laucius, Joanne	Ottawa Citizen	Mehta, Yusuf et al	The Lancet/NEJM	Sanofi-Synthelabo, Bristol-Myers Squibb	Unknown	YES	NO
2001	8/16/2001	Evenson, Brad	National Post	Mehta, Yusuf et al	The Lancet/NEJM	Sanofi-Synthelabo, Bristol-Myers Squibb	Unknown	YES	YES
2001	8/16/2001	Yelaja, Prithi	Toronto Star	Mehta, Yusuf et al	The Lancet/NEJM	Sanofi-Synthelabo, Bristol-Myers Squibb	Unknown	YES	NO
2001	9/25/2001	Yelaja, Prithi	Toronto Star	Shepherd et al	New England Journal of Medicine	Novartis	Unknown	YES	NO
2001	10/2/2001	Haney, Daniel (AP)	Prince George Citizen	Brenner et al	New England Journal of Medicine	Merck	Unknown	NO	NO
2001	10/17/2001	Morrison, Suzanne	Hamilton Spectator	Hirsh	GH9001 study	GlycoDesign	Unknown	YES	YES
2001	10/18/2001	AP	Sarnia Observer	Yusuf et al	JAMA	Hoechst, AstraZeneca, King	Unknown	YES	NO
2001	12/11/2001	Kirkey, Sharon	Windsor Star	Goss, Paul	Journal of Clinical Oncology	Novartis	Unknown	NO	NO
2001	12/12/2001	Kirkey, Sharon	Victoria Times-Colonist	Ellis et al	San Antonio conference	Novartis	Unknown	YES	YES
2002	2/28/2002	Yelaja, Prithi	Toronto Star	Reid, Ian et al	New England Journal of Medicine	Novartis Pharmaceuticals	Unknown	YES	NO
2002	3/22/2002	Bhandari, Aparita	Toronto Star	Bosch, Yusuf et al	British Medical Journal	Hoechst, AstraZeneca, King	Unknown	NO	NO
2002	5/16/2002	Spears, Tom	Ottawa Citizen	Pepys, Mark et al	Nature	Hoffmann LaRoche	Unknown	NO	NO
2002	6/21/2002	Yelaja, Prithi	Toronto Star	Penninger, Josef et al	Nature	Amgen	Unknown	NO	NO
2002	8/8/2002	AP	Toronto Star	Mahon et al	New England Journal of Medicine	Novartis	Unknown	NO	NO
2002	10/1/2002	Bowman, Lee	Windsor Star	DeLuca, Hector	Proceedings of the National Academy of Sciences	Deltanoid Pharmaceuticals	Unknown	NO	NO

2002	10/31/2002	Morrison, Suzanne	Hamilton Spectator	Lonn, Yusuf et al	Journal of American College of Cardiology	Hoecsht/King/AstraZeneca	Unknown	NO	NO
2002	10/31/2002	Kirkey, Sharon	Ottawa Citizen	Lonn, Yusuf et al	Journal of American College of Cardiology	Hoecsht/King/AstraZeneca	Unknown	YES	NO
2002	11/19/2002	AP	Peterborough Examiner	Topol et al	JAMA	Bristol-Myers Squibb, Sanofi-Synthelabo	Unknown	YES	YES
2002	12/9/2002		National Post	Druker et al	American Society of Hematology proceedings	Novartis	Unknown	NO	NO
2002	12/18/2002	Evenson, Brad	National Post	Leenen et al	JAMA	Pfizer	Unknown	YES	NO
2003	1/4/2003	Morrison, Suzanne	Hamilton Spectator	Weitz, Gerstein et al		Multiple		NO	NO
2003	8/30/2003	McConnaughey, Janet (AP)	Peterborough Examiner	Eisen, Howard	New England Journal of Medicine	Novartis Pharmaceuticals	Unknown	YES	NO
2003	9/3/2003	Ross, Emma	Prince George Citizen	Fox et al	The Lancet	Servier	Unknown	YES	NO
2003	10/10/2003	Branswell, Helen (CP)	Hamilton Spectator	Goss, Paul et al	New England Journal of Medicine	Novartis Pharmaceuticals	Unknown	NO	NO
2003	10/10/2003	Laucius, Joanne	Ottawa Citizen	Goss, Paul et al	New England Journal of Medicine	Novartis Pharmaceuticals	Unknown	NO	NO
2003	10/10/2003	Woods, Allan	National Post	Goss, Paul et al	New England Journal of Medicine	Novartis Pharmaceuticals	Unknown	NO	NO
2003	10/10/2003	Lukits, Ann	Kingston Whig-Standard	Goss, Paul et al (and Pater)	New England Journal of Medicine	Novartis Pharmaceuticals	Unknown	YES	NO
2003	10/10/2003	Torstar	Guelph Mercury	Goss, Paul et al	New England Journal of Medicine	Novartis Pharmaceuticals	Unknown	NO	NO
2003	10/10/2003	Picard, Andre	Globe and Mail	Goss, Paul et al	New England Journal of Medicine	Novartis	YES - $20 million, $12 million from Novartis	YES	NO
2003	11/5/2003	Tanner, Lindsey	Toronto Star	Nissen, Steven	Journal of the American Medical Association	Esperion Therapeutics	Unknown	YES	NO
2003	11/6/2003	Tanner, Lindsey (AP)	Peterborough Examiner	Nissen, Steven	Journal of the American Medical Association	Esperion Therapeutics	Unknown	YES	NO
2003	11/13/2003	Haney, Daniel (AP)	Hamilton Spectator	Nissen, Steven	Journal of the American Medical Association	Pfizer	Unknown	YES	NO
2003	11/26/2003	Kirkey, Sharon	Ottawa Citizen	Rosenheck	JAMA	Eli Lilly	Unknown	YES	NO
2004	3/11/2004	Branswell, Helen (CP)	Peterborough Examiner	Coombes et al	New England Journal of Medicine	Pfizer	Unknown	YES	NO
2004	5/1/2004	Neergaard, Lauran (AP)	Prince George Citizen	Meyerson et al	Science / NEJM	Novartis/ AstraZeneca	Unknown	NO	NO
2004	6/17/2004	Donn, Jeff (AP)	Guelph Mercury	Edwards et al	New England Journal of Medicine	Roche	Unknown	NO	NO
2004	6/17/2004	Donn, Jeff (AP)	Sault Star	Edwards et al	New England Journal of Medicine	Roche	Unknown	YES	NO
2004	7/21/2004	CP	Timmins Daily Press	Mackey, John et al		AstraZeneca	Unknown	NO	NO
2004	8/30/2004	Hirschler, Ben	National Post	Van Gaal et al	The Lancet	Sanofi-Aventis	Unknown	NO	NO
2004	12/9/2004	Kirkey, Sharon	National Post	Mackey, John et al	The Lancet	AstraZeneca	Unknown	YES	YES
2005	1/18/2005	De Almeida, Jacquie	Hamilton Spectator	Sharma et al		Boehringer-Ingelheim	Unknown	NO	NO
2005	3/11/2005	Ubelacker, Sheryl (CP)	Prince George Citizen	Mason et al	New England Journal of Medicine	Schering-Plough	Unknown	NO	NO
2005	3/12/2005	AP	Cornwall Standard-Freeholder	Canon et al	New England Journal of Medicine	Sanofi-Aventis, Bristol-Myers Squibb	Unknown	YES	YES
2005	4/22/2005	CP	Prince George Citizen	Wasan et al	Annals of Oncology	Novartis	Unknown	NO	NO
2005	5/4/2005	Fidelman, Charlie	Saskatoon Star-Phoenix	Ferenczy et al	Lancet Oncology	Merck Frosst	Unknown	NO	NO
2005	5/5/2005	Branswell, Helen (CP)	Globe and Mail	Ferenczy et al	Lancet Oncology	Merck Frosst	Unknown	NO	NO

2005	5/15/2005	Carey, Elaine	Toronto Star	Moore, Malcolm	Journal of Clinical Oncology	Genentech/OSI Pharmaceuticals	Unknown	NO	NO
2005	10/20/2005	Priest, Lisa	Globe and Mail	Leyland-Jones et al	New England Journal of Medicine	Roche	Unknown	NO	NO
2005	10/21/2005	Donn, Jeff (AP)	Prince George Citizen	Romond et al	New England Journal of Medicine	Genentech	Unknown	YES	NO
2005	12/9/2005	Ruttan, Susan	Edmonton Journal	Mackey et al	San Antonio Breast Cancer Symposium	Aventis	Unknown	NO	NO
2005	12/10/2005	AP	Prince George Citizen	Slamon et al	Trial results	Sanofi-Aventis / Genentech	Unknown	YES	YES
2006	3/14/2006	Hall, Celia	National Post	Tardif et al	JAMA	AstraZeneca	Unknown	NO	NO
2006	6/13/2006	Kirkey, Sharon	Calgary Herald	McLaurin, Joanne	Nature Medicine	private company/patent	Unknown	NO	NO
2006	6/13/2006	Gandhi, Unnati	Globe and Mail	McLaurin, George-Hyslop et al	Nature Medicine	private company/patent	Unknown	NO	NO
2006	6/13/2006	Carey, Elaine	Toronto Star	McLaurin. George-Hyslop et al	Nature Medicine	private company/patent	Unknown	YES, partially	NO
2006	7/19/2006	Lampert, Allison	Montreal Gazette	Steben, Marc	Clinical and Vaccine Immunology	Merck Frosst	Unknown	YES	NO
2006	7/25/2006	Abraham, Carolyn	Globe and Mail	Walmsley	Medscape General Medicine	Pfizer	Unknown	YES, partially	NO
2006	9/15/2006	Frketich, Joanna	Hamilton Spectator	Yusuf/Gerstein et al	The Lancet/New England Journal of Medicine	Sanofi/Aventis, Glaxo, King Pharmaceuticals	YES - $25 million	YES, partially (companies not named)	NO
2006	9/16/2006	Frketich, Joanna	Hamilton Spectator	Yusuf/Gerstein et al	The Lancet/New England Journal of Medicine	Sanofi/Aventis, Glaxo, King Pharmaceuticals	YES - $25 million	YES, partially (companies not named)	YES, partially (companies not named)
2006	9/16/2006	Branswell, Helen (CP)	St. John Telegraph-Journal	Yusuf et al	The Lancet/New England Journal of Medicine	Sanofi/Aventis, Glaxo, King Pharmaceuticals	Unknown	YES	YES
2006	9/16/2006	Kirkey, Sharon	Regina Leader-Post	Yusuf et al	The Lancet/New England Journal of Medicine	Sanofi/Aventis, Glaxo, King Pharmaceuticals	Unknown	YES	YES
2006	9/16/2006	Talaga, Tanya	Toronto Star	Yusuf et al	The Lancet/New England Journal of Medicine	Sanofi/Aventis, Glaxo, King Pharmaceuticals	Unknown	YES	NO
2007	3/29/2007	Frketich, Joanna	Hamilton Spectator	Cox et al	New England Journal of Medicine	Asthmatx	Unknown	NO	NO
2007	4/28/2007	CP	Prince George Citizen	Montori et al vs. Yusuf, Gertein et al	BMJ vs. The Lancet	Sanofi/Aventis, Glaxo, King Pharmaceuticals	Not applicable	Not applicable	NO
2007	5/17/2007	Highfield, Roger	Edmonton Journal	Cotsarelis et al	Nature	Follica	Unknown	YES, partially	YES
2007	5/17/2007	Lauerman, John (Bloomberg)	Globe and Mail	Cotsarelis et al	Nature	Follica	Unknown	YES, partially	YES, partially
2007	5/17/2007	Lauerman, John (Bloomberg)	Toronto Star	Cotsarelis et al	Nature	Follica	Unknown	YES, partially	NO
2007	6/4/2007	AP	Guelph Mercury	Llovet et al	American Society of Clinical Oncology meetings	Bayer/Onyx Pharmaceuticals	Unknown	YES	YES
2007	11/7/2007	AP	Prince George Citizen	Antman et al	New England Journal of Medicine	Eli Lilly/Daiichi Sankyo	Unknown	NO	NO
2007	11/15/2007	Spears, Tom	Ottawa Citizen	Jonker et al	New England Journal of Medicine	Bristol-Myers Squibb	Unknown	NO	NO
2008	4/1/2008	Brown, Dana	Hamilton Spectator	Yusuf et al	New England Journal of Medicine	Boehringer-Ingelheim	Unknown	NO	NO
2008	5/1/2008	Carey, Elaine	Toronto Star	Vadas et al	New England Journal of Medicine	National Peanut Board/Peanut Foundation	Unknown	NO	NO
2008	7/22/2008	Smith, Rebecca	Saskatoon Star-Phoenix	de Bono et al	Journal of Clinical Oncology	Cougar Biotechnology	Unknown	NO	NO
2008	9/12/2008	Chang, Alicia (AP)	Moncton Times-Transcript	Holman et al	New England Journal of Medicine	Glaxo, Merck et al	Unknown	NO	NO
2008	10/15/2008	Kirkey, Sharon	Saskatoon Star-Phoenix	Richards et al	Nature Genetics	GlaxoSmithKline	Unknown	NO	NO
2008	11/10/2008	Stein, Rob (Wash. Post)	Vancouver Sun	Ridker et al	New England Journal of Medicine	AstraZeneca	Unknown	YES	NO
2008	11/12/2008	Marchione, Marilynn (AP)	Fredericton Daily Gleaner	Ridker	American Heart Association conference	AstraZeneca	Unknown	YES	YES
2008	12/15/2008	Marchione, Marilynn	Moncton Times-Transcript	Coleman et al	Cancer conference findings	Novartis	Unknown	YES	YES