Drugs in the News

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by Alan Cassels, Merrilee Atina Hughes, Carol Cole, Barbara Mintzes, Joel Lexchin and James McCormack

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Canadian Centre for Policy Alternatives

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The content, opinions, and any errors contained in this report are solely the responsibility of the authors.

About the Authors

Alan Cassels is a researcher in the School of Health Information Science at the University of Victoria. **Merrilee Atina Hughes** is a researcher in the School of Journalism and Department of Health Care and Epidemiology at University of British Columbia. **Carol Cole** is a researcher with the Centre for Health Services and Policy Research and The Institute of Health Promotion Research at UBC. **Barbara Mintzes** is a graduate student in Health Care and Epidemiology at UBC. **Joel Lexchin** is an emergency department physician in Toronto and an associate professor in the School of Health Policy and Management at York University. **James McCormack** is a professor at the Faculty of Pharmaceutical Sciences at UBC. Cassels, Lexchin and Mintzes are research associates with the Canadian Centre for Policy Alternatives, specializing in drug policy issues.

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To correspond directly with the authors of this study, please contact
Alan Cassels at alan@alancassels.com or James McCormack at jmccorma@interchange.ubc.ca

CCPA National Office
410 – 75 Albert Street
Ottawa, Ontario K1P 5E7
tel: 613-563-1341
fax: 613-233-1458
email: ccpa@policyalternatives.ca

CCPA BC Office
1400 – 207 West Hastings Street
Vancouver, BC V6B 1H7
tel: 604-801-5121
fax: 604-801-5122
email: info@bcpolicyalternatives.org

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Summary

PRESCRIPTION DRUGS ARE AN INCREASINGLY IMPORTANT PART OF HEALTH CARE in Canada. Collectively, Canadians spend $15 billion per year on pharmaceuticals – more each year than we do on doctors – and we are bombarded daily by media stories about new medicines. While the public wants and needs information about new drugs, there is growing concern that the quality of information provided through news reports is often poor and may promote unrealistic expectations regarding the benefits of drugs. In short, this study set out to assess whether Canadians can rely on a major source of information – daily newspapers – to provide us with the good, the bad and the ugly about new drugs.

Methods

We selected five prescription drugs launched in Canada during the last five years that had received a high degree of media attention. They were: Celebrex® (celecoxib) for symptoms of arthritis; Lipitor® (atovastatin), a cholesterol-lowering drug; Evista® (raloxifene), for post-menopausal osteoporosis; Tamiflu® (oseltamivir), for influenza; and Aricept® (donepezil), to treat Alzheimer's disease. In the year 2000, in a search of 24 of Canada's largest daily newspapers, we found 193 articles describing the health effects of these drugs, and then examined the way in which these particular drugs were reported.

Findings

To make an informed decision about whether to take a particular drug, consumers – and their doctors – need to know the likelihood that the drug will actually help them, the risk of experiencing side effects, and the likely magnitude of both the potential benefits and harms.

Our results raise concerns about the quality of information Canadian consumers receive about new medications through the media. In particular, we found:

- Newspaper articles more often emphasized the benefits of new drugs, paying less attention to possible harms, regardless of the length of the article. All of the articles mentioned a drug benefit, but 68 per cent made no mention whatsoever of possible side effects.
- Newspaper articles often failed to distinguish between real clinical benefits of a drug – effects that have an actual impact on patient health, such as reducing heart attacks and fractures – and what health professionals refer to as "surrogate" benefits – merely changes in some measurement that is only a risk factor for disease, such as lowering cholesterol and increasing bone density. For two of the drugs studied, clinical benefits of those drugs were mentioned about half the time.

- Basic information that *quantified* the benefits or harms of these drugs was reported in only one out of every four articles – and when it was provided, 26 per cent of the time it was presented in misleading terms. Only 14 per cent of the time was the timeframe mentioned.
- Benefits were most often identified in the first quarter of the article, while harms were usually identified in the third quarter of the article. Fifty-three per cent of the benefits were mentioned in the first half against 39 per cent of the harms.
- Eighteen per cent of health effects were described with adjectives or explanatory phrases. When harms were mentioned, they were more often described with language that *downplayed* the risk to patients, while benefits were more often described using language that *emphasized* the potential benefit.
- Contraindications – those conditions under which it is *not safe* to take the drugs – were mentioned in only four per cent of the articles.
- Only about one in six articles mentioned non-drug treatment options, such as exercise or diet.
- Lastly, financial interests at work behind the scenes were rarely discussed. In some cases, spokespeople for patient groups or academic researchers were cited without any discussion of the financial links these individuals may have had to the manufacturers of the drug they were discussing. Making these financial links transparent, as is done in medical journals, is vital for consumers to adequately judge the quality of drug information.

Conclusions and recommendations

- Media reports are an important source of information on new drugs for Canadians, yet that information needs to be balanced, accurate, and provide proper context for readers if it is to contribute to informed health decisions.
- Journalists who report on a new drug should strive to disseminate complete information regarding real benefits and harms associated with that drug, its costs, and where the new drug fits within a spectrum of alternative drug and non-drug treatment options.
- For those entrusted with informing Canadians about new drugs – public policy makers, schools of journalism, media outlets and health professionals – this research should bolster demands that quality, balanced drug information be disseminated to the Canadian public.
- Canadians generally place trust in the media – yet need to know whether that trust is warranted when they use it to inform themselves of something as important as health treatments. Journalists and media outlets, therefore, must ensure that when a new drug arrives on the scene, the Canadian public gets the full story – the good, the bad and even the ugly – of new pharmaceuticals.
- For consumers wanting to know what to look for in a news story about new drugs, and for journalists wishing to properly report on new drugs, we have prepared a **Journalist's Guide to Covering Prescription Drugs** (Appendix C), based on this research.

Introduction

Why did this study need to be done, and why now?

While highly influential, the media is not always a reliable source of information about new drugs. Reporting on pharmaceuticals demands an ability to interpret complex scientific information while remaining resistant to the aggressive marketing techniques of the pharmaceutical industry.

IT'S HARD TO MISS THE EXPLOSION IN NEWS STORIES REGARDING NEW pharmaceuticals. They're everywhere. But how reliable is the information Canadians – including patients and health care professionals – are receiving from our country's mainstream newspapers? Are we hearing about the limitations and potential harms of new drugs, as well as the benefits? Are we getting the whole story about the cost of new drugs? What about non-drug alternatives? And who are those spokespeople – the various specialists, patient representatives and celebrities – who endorse a new drug? Do the journalists who write these stories know the backgrounds – including potential conflicts of interest – of the "experts" who speak about drugs?

In short, when we as consumers, doctors or interested readers pick up the morning paper to get the lowdown on the latest breakthrough drug, are we getting all the goods? This study is an attempt to answer these questions.

As a nation, we now spend more on prescription drugs each year than we do on doctors.[1] And the evidence suggests that what we read in our newspapers is influencing how that money is spent. As individuals we are turning increasingly to the media, after our family doctors, for information about new drugs.[2] Furthermore, we are taking what we learn from the media into our consultations with doctors: of 250 Canadian doctors surveyed in 1999, 84 per cent said they believed that media reports influenced the kind of treatments their patients asked for.[3] Similarly, 58 per cent of people surveyed by the U.S. National Health Council in 1997 said they had been prompted to modify some aspect of their behaviour by a health-related story reported in the media.[4]

It's not only consumers who are influenced by media. Doctors, nurses and other health care professionals also read these stories. While the extent to which a cautious and well-informed physician will be influenced by mainstream news reporting is arguable, recent research has shown that the cumulative effect of media reports, combined with other educational materials provided to physicians, can have an impact on prescribing practices.[5]

While highly influential, however, the media is not always a reliable source of information about new drugs. Reporting on pharmaceuticals demands an ability to interpret complex scientific information while remaining resilient to the aggressive marketing techniques of the pharmaceutical industry. At the same time, there are few independent experts to assist journalists in interpreting the medical research. In a 1998 report prepared for Health Canada, Canadian journalists themselves raised several concerns related to the accuracy of pharmaceutical reporting, including:

- the lack of formal policy guiding news coverage of science "breakthrough" stories;
- the staging of elaborate press conferences by commercial public relations firms hired by the pharmaceutical industry;
- the difficulty in obtaining independent information on pharmaceuticals and a perceived "abdication" by government of a role in providing that information; and
- the decline of consumer advocacy groups that might have provided an alternative, non-commercial viewpoint, largely because of lack of resources.

The result is that press coverage of new drugs may be unbalanced, with an impact for drug manufacturers that one journalist described as "even better than free advertising."[6]

There is little doubt that the drug industry makes it very easy for journalists to cover new drug stories. Major pharmaceutical companies routinely employ public relations agencies to build investor, physician and consumer interest before, during and after a drug's launch.[7] Reporting of clinical trial recruitment, clinical study results, regulatory approval and provincial plan coverage (or lack of coverage, as the case may be) can all be used to stimulate media interest. When a new drug is launched, sophisticated press kits containing user-friendly press releases, profiles of the new drug, and quotations from experts and scientific papers provide ready content for print or broadcast. Media-savvy physicians and coached patient-spokespeople are front and centre at press conferences, helping journalists create stories with multiple sources.[8] A Dutch study found that the pharmaceutical industry was the third most frequently cited source of information in newspaper articles about drugs, although journalists in the study denied using industry as a source of ideas and information.[9]

The obvious danger is that when a "breakthrough" drug is first reported in the media, the gung-ho nature of that initial coverage may encourage the immediate use of the drug on a much wider basis than is warranted by the scientific evidence. When celecoxib – more commonly known by its brand name Celebrex® – was launched onto the Canadian market in April 1999 it broke all records for new drug sales. Although clinical studies had been done, no full trial reports had been published by the time the drug was launched, so doctors were prescribing the drug without being able to review evidence as to the drug's benefits, or of the possible risks it could pose to their patients. Even if data from clinical trials are available when a new drug is launched, it is usually much too early for there to be complete evidence about the drug's safety, particularly over the long term. This is an obvious reason for caution in prescribing any new drug,[10] but to what degree do you hear about such cautions in news reports of new drugs?

To date, only one systematic analysis of media coverage of the benefits and risks of medications has been published, a study out of Harvard University that examined U.S. print and television news reports on alendronate (an osteoporosis drug), pravastatin (used to lower cholesterol) and aspirin.[11] The researchers found that the media reports consistently emphasized the benefits of the drugs, while the incidence of harmful side effects was downplayed. Perhaps most disturbingly, 83 per cent of the stories that cited benefits in quantitative terms used relative rather than absolute numbers. The distinction is critical. Say

The obvious danger is that when a "breakthrough" drug is first reported in the media, the gung-ho nature of that initial coverage may encourage the immediate use of the drug on a much wider basis than is warranted by the scientific evidence.

The aim of this study was to assess the information Canadians are receiving about prescription drugs from their daily newspapers. Good and complete drug information is vital if consumers are to make rational, safe and economical use of these technologies.

you are told that a drug will decrease your risk of developing a certain cancer from 2 in 100 to 1 in 100. Is that an important difference? Is it important enough for you to take the drug? What if taking the drug would increase your risk of contracting other illnesses or conditions? What if there was a chance it could leave you impotent five years from now? Chances are, you'd think twice about taking the drug off the pharmacist's shelf.

Yet that difference, from 2 in 100 to 1 in 100 – a mere *1 per cent* difference in absolute terms – is often reported as a *50 per cent* decrease in cancer risk when reported in relative terms. It's not hard to guess which interpretation of the numbers usually ends up on the front page. (See *Why absolute numbers tell us more than relative ones* on page 11).

Until now, there have been no published systematic studies to shed light on the quality of pharmaceutical reporting by Canadian media. If Canadians rely on information from newspapers when making medication-related decisions, what are the characteristics of the information they receive? And does what they receive provide the type of information needed for shared, informed health care decisions?

THIS RESEARCH PROJECT STUDIED THE coverage of five new drugs in 24 Canadian newspapers in 2000. We examined whether journalists were including enough information about the drugs for readers to reach informed conclusions.

Information considered pertinent included:

- The benefits and harms;
- Whether the benefits and harms mentioned are meaningful to patients (such as reductions in symptoms, heart attacks, strokes, cancers, fractures, etc.) or whether they were measurements that may or may not be meaningful (cholesterol levels, bone densities, viral replication, etc.);
- The magnitude of the benefits and harms and how those magnitudes were reported;
- The frequency, type and quality of studies or trials reported;
- Drug costs, drug and non-drug alternatives, contraindications; and,
- The financial affiliations of quoted spokespeople.

The aim of this study was to assess the information Canadians are receiving about prescription drugs from their daily newspapers. It is hoped that this analysis will help inform journalists about the critical issues that need to be covered in any story on new health technologies. **(A Journalist's Guide to Covering Prescription Drugs** is provided in Appendix C.) Good and complete drug information is vital if consumers are to make rational, safe and economical use of these technologies.

Furthermore, this study could inform physicians, pharmacists, academic researchers and policy makers of the limitations of one of the major sources of health information for the public, and highlight for them important elements that constitute quality, balanced and useful drug information.

IN FOCUS

The five drugs examined in this study

Trade name (generic name)	Launch date	Condition treated
Aricept® (donepezil)	August 1997	Alzheimer's disease
Celebrex® (celecoxib)	April 1999	Arthritis
Evista® (raloxifene)	January 1999	Osteoporosis
Lipitor® (atorvastatin)	March 1997	High cholesterol
Tamiflu® (oseltamivir)	January 2000	Influenza

Methodology

How was the information collected and analyzed? According to what criteria?

Drug selection

We conducted a content analysis of Canadian newspapers to investigate the quality of pharmaceutical drug information being communicated to the public. From a list of never-before-released drugs with Canadian launch dates in the past five years (1996 to 2001), we selected five drugs representing diverse drug classes that had received sufficient coverage in preliminary searches to permit quantification of benefits/harms. These drugs covered the basic categories of acute, chronic and preventative treatments. A key word search was performed using both the brand and generic names of the five drugs for the entire year 2000.

Inclusion/exclusion

We selected both English and French Canadian daily newspapers with a weekday circulation greater than 50,000; this yielded 24 newspapers from seven provinces. The two French tabloid newspapers *(Le Journal de Montreal* and *Le Journal de Quebec)* were excluded due to their absence from any databases indexing daily newspapers.

Two national papers *(The Globe and Mail* and *The National Post)* are produced in Toronto, but distributed nationally. Of the 22 city papers in the sample, one third (eight papers) were from Ontario. No papers came from Newfoundland, Prince Edward Island, New Brunswick or any of Canada's territories. (For a complete list of newspapers and their circulation see Appendix A.)

Given the complex licensing agreements between Canadian newspapers and database providers, it was necessary to search four separate databases to access all full-text articles appearing in each of our selected newspapers. Fifteen newspapers were available through Infomart's Special Edition; four newspapers were obtained through Virtual News Library; three through Eureka; and two through *The Globe & Mail* CD-ROM.

Table A: Retrieved and included articles

Drug	Total articles retrieved from 24 newspapers in the year 2000	Number of articles included in the study (% of total articles included)
celecoxib	82	31 (16%)
atorvastatin	75	17 (9%)
raloxifene	59	41 (21%)
oseltamivir	74	59 (31%)
donepezil	66	45 (23%)
total	**356**	**193 (100%)**

Each article was stripped of its title, source, date and byline and then assigned a study code. Two members of the research team manually, and independently of each other, reviewed all stripped articles separately to determine their inclusion in the study. A third member arbitrated any inclusion differences. Articles lacking any mention of benefit or harm were excluded. Articles with any reference to benefits or harms of our study drugs were included even if the article predominantly dealt with another topic. All types of newspaper stories were accepted, including news briefs, business stories and "Dear Doctor" style articles.

Retrieved articles meeting the inclusion criteria

In 2000, 356 articles mentioning at least one of our five study drugs appeared in Canada's 24 largest newspapers. Of those articles, 193 (54 per cent) discussed a harm or benefit of one of the study's five drugs. None of the excluded articles mentioned any drug benefits or harms (i.e. no health claims were made). Many of the excluded articles mentioned the study drugs by name, but discussed them only peripherally, such as in the context of a business story relating to the share prices of a particular pharmaceutical company.

The number of articles per drug ranged from a low of 17 for atorvastatin to a high of 59 for oseltamivir. In this one-year study period, a greater volume of media activity was concentrated on drugs that were newer to the Canadian market. Atorvastatin (trade name Lipitor®), for example, had been on the Canadian market since March 1997, and made up the smallest part of our sample (9 per cent of articles analyzed). The newest drug in our sample, oseltamivir (trade name Tamiflu®), an antiviral flu drug new to the Canadian market in January 2000, had 59 included articles, accounting for 31 per cent of the overall sample. In fact, this drug and a competitor – zanamivir (trade name Relenza®) – were launched almost simultaneously at the height of flu season, which may have contributed to the high volume of media stories associated with it.

Article coding

A coding sheet was developed to extract and categorize the information contained in each article for entry into a database. The coding sheet was pilot tested and refined. Two members of the research team independently coded all the stripped articles that met the inclusion criteria for our study. Any discrepancies were resolved by a third member prior to entering the data into our database.

A CLOSER LOOK

The difference between clinical and surrogate benefits

It is important to know the different types of benefits and how they are reported. Atorvastatin has been shown to lower cholesterol, raloxifene increases bone density, and celecoxib reduces intestinal polyps; however, all of these benefits are surrogate markers.

A surrogate marker is "a laboratory measurement or physical sign used as a substitute for a clinically meaningful endpoint that measures directly how a patient feels, functions or survives."[34] What one really wants to know is whether atorvastatin has been shown to reduce heart attacks, raloxifene decreases clinical fractures, or celecoxib decreases the chance of colon cancer. These are the true clinical endpoints that clinicians and patients need to know. Often all we know about a drug is the benefit it has on surrogate markers. Readers need to know that a drug with a surrogate benefit will not necessarily produce any clinically important health benefits.

Benefits and harms were categorized as being surrogate or clinical in nature (see Tables B and C on page 14). Surrogates are not diseases in and of themselves, but are measurements that may be associated with an increased risk for future disease. For example, cholesterol and blood pressure readings are associated with cardiovascular disease; bone density readings may be linked to fractures. Elevated blood pressure or cholesterol levels or low bone density are typically symptomless (i.e. the patient doesn't feel any different) and are of much less importance to a patient than clinical outcomes, such as heart attacks, strokes or fractures.

We thought it was important to look at whether surrogate or clinical outcomes were mentioned in news reports because the most important measure is whether a drug has a beneficial *clinical* effect. Does it prevent death, disease or disability, or lead to fewer uncomfortable or distressing symptoms? While modification of some surrogate markers can lead to improved health outcomes, people need to be aware that there are numerous examples in the literature where drugs produce what appear to be positive changes to surrogate markers, but produce no clinical benefit. There are incidences where the drug improved the surrogate measurement, but left the patient in worse health than if he or she had been taking a placebo.[12]

In addition to the type of outcome discussed, to make a truly informed decision about the potential benefit of drug therapy, clinicians and patients must have an idea of the actual magnitude of the benefit. Our rationale was that it is not enough for a person to be told "here, take this drug, it might help" – a person needs to hear *how much* a drug will help before considering taking it. We therefore recorded all magnitudes of benefits and harms that were expressed.

The magnitude of benefits and harms were further categorized as either absolute or relative. Relative values are frequently used to describe the benefits of drug therapies, but they can be misleading.[13] One will often hear reports such as "cholesterol lowering drug reduces chances of heart attacks by 30 per cent" or "lowering blood pressure cuts the risk of stroke in half." While these reductions are technically correct, they are also misleading. For

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A CLOSER LOOK

Why absolute numbers tell us more than relative ones

Research has shown that patients and physicians preferentially choose medications depending on whether the benefits are presented in relative terms or absolute terms.[14] If, for example, disease A occurs in 2 in 100 people, the absolute occurence of disease A is 2 per cent. Taking drug X reduces the incidence to 1 in 100, or an *absolute risk reduction* of 1 per cent. This drug, therefore, could also be said to reduce risk by 50 per cent because 1 per cent is half of 2 per cent. This is called a *relative risk reduction*.

Absolute risk reduction provides the reader with a less misleading account of the magnitude of the benefit of the drug. If the disease occurs in 4 per cent of people who don't take the drug, but can be reduced to 2 per cent for those who do take the drug, the reduction in absolute risk is 2 per cent. Reducing your risk by 50 per cent sounds a lot more impressive than 2 per cent, but you shouldn't be fooled: they are the SAME thing. If they make the effect sound more substantial, drug companies and the media are more likely to highlight relative figures than absolute ones.

instance, typically in studies of cholesterol or blood pressure lowering drugs, the patients' chance of heart attacks or strokes are reduced from 6 per cent in the placebo group to 4 per cent in the drug group. This is usually reported as a 33 per cent reduction because 4 is 33 per cent lower than 6. The 33 per cent is a relative risk reduction. However, the absolute difference between the groups is 6 minus 4, or 2 per cent, an absolute risk reduction. Two per cent means 2 out of 100 or 1 in 50. In other words, 50 people would have to be treated for one person to receive the benefit. Treating 50 people to give one person a benefit is not what most people would automatically assume a "33 per cent reduction" to mean.

In addition to the magnitude of the benefit or harm, the articles were examined to see what kind of descriptive language was used to discuss that magnitude (see Tables E1 and E2 in the next section). All adjectives used to describe the magnitude of a benefit or harm, or otherwise characterize the general properties of the drug, were coded. These descriptions were categorized as lending either an *emphasizing* or a *minimizing* quality to the magnitude of the benefit or harm. Terms such as "substantially" or "highly" are examples of language that *emphasizes* the magnitude of the benefit or harm; descriptions such as "marginal," "limited," or "mild" were considered *minimizing* magnitude of the benefit or harm.

Next, the quoted spokespeople and trials cited in the articles were recorded, along with any disclosed financial affiliations to the drug industry. This information was deemed important, as research suggests that spokespeople or researchers who have financial ties to the drug being studied tend to make more favourable interpretations of drug data compared to those who have no such financial ties.[15] It is therefore important to know whether readers are informed of such financial ties when they exist.

Finally, any mention of drug indications (the reasons for using a drug), contraindications (who should not take the drug), costs, drug alternatives and non-drug alternatives were also noted. Non-drug alternatives might include herbal remedies, lifestyle or diet modifications or simple "watchful waiting."

Any study cited in the article was recorded, as well as the journal in which the study appeared or meeting at which its findings were presented. The study's design (e.g. a randomized controlled trial or another type of study), the number of people in the study, the characteristics of those people (age, sex, etc.) and funding sources were also recorded.

The influence of the length of each article on the number of benefits/harms mentioned was also analyzed. The physical size of each article was measured and its length, in centimetres, was recorded. We calculated length by printing each article on 8.5 x 11 inch paper, measuring the length in centimetres, and adjusting for those articles with an 8 or 10 point font so that they would match the 12 font calculations. We defined a "news brief" as any article measuring 6 cm long or less. This distinction was made in order to look at any differences in reporting of drug benefits or harms in news briefs versus longer articles.

Findings

What did the results show?

Overall benefit/harm

How many drug benefits versus harmful effects were mentioned?

In total, in the 193 articles examined in this study, 421 potentially beneficial effects and 90 potentially harmful effects were mentioned. In other words, if a health effect was mentioned it was 4.7 times more likely to be a benefit than a harm. Sixty-eight per cent (132) of the articles made *no* mention of any possible harmful effects.

On average, 2.2 drug benefits were mentioned per article. The number of benefits per drug ranged from 30 in 17 articles dealing with atorvastatin (1.8 benefits per article) to 158 in the 59 articles on oseltamivir (2.7 benefits per article). The number of articles mentioning harmful effects also varied by drug, ranging from 5 of 31 articles on celecoxib (16 per cent) to 26 of 41 raloxifene articles (63 per cent) (see Chart 1 and Tables B and C). On average, 82 per cent of all health effects mentioned were benefits and 18 per cent were harms. For a breakdown by drug, see Chart 1.

Benefits

How many articles reported the magnitude of the benefits?
Using relative or absolute numbers?
Using clinical or surrogate benefits?

For all the drugs combined, 308 of 421 (73 per cent) of the benefits mentioned were clinical benefits. The percentage of clinical benefits var-

Chart 1: Percentage of health claims that were benefits versus harms

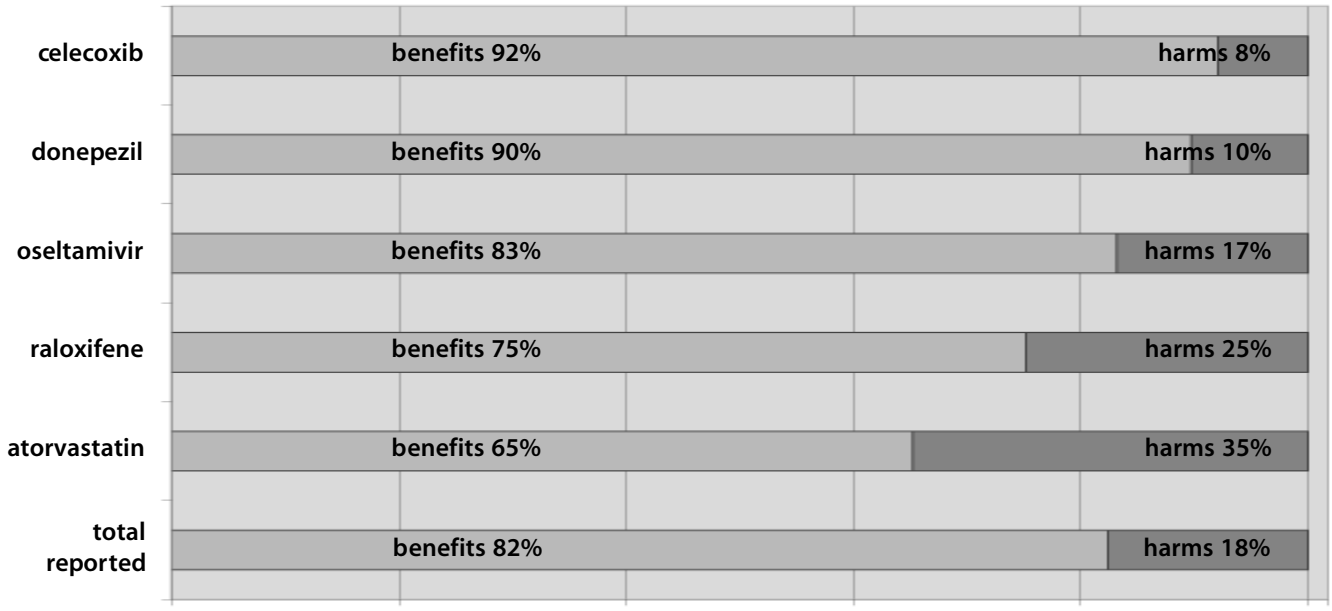


Table B: Benefits reported

		Types and numbers of benefits mentioned (%)					
Drug	Benefits reported	Clinical markers		Cost issues	Surrogate markers		Articles with only surrogate benefits mentioned
celecoxib	58	• Reduced pain/inflammation 14 (24%) • Fewer gastrointestinal problems 15 (26%) • Fewer side effects 7 (12%)	• Fewer deaths 2 (3%) • Really helped, felt good, breakthrough drug 11 (19%)	Fewer doctor visits 2 (3%)	Blocks enzyme 4 (7%)	Reduces polyps 3 (5%)	7/31 (23%)
atorvastatin	30	• Fewer cardiac events 5 (17%) • Fewer fractures 3 (10%)	• Fewer strokes 1 (3%) • Fewer deaths 5 (17%)		Reduces lipids 15 (50%)	Increases bone density 1 (3%)	8/17 (47%)
raloxifene	79	• Fewer breast cancers 24 (30%) • Fewer fractures 3 (4%)	• Fewer cardiac events 1 (1%) • Miracle drug, huge benefits, effective, estrogen like 11 (14%)	Frees up beds 1 (1%)	Increases bone density 34 (43%)	Reduces lipids 5 (6%)	16/41 (39%)
oseltamivir	158	• Reduced duration of symptoms 44 (28%) • Reduced severity of symptoms 26 (16%) • Prevents flu 9 (6%) • Fewer complications 15 (9%)	• Fewer deaths 5 (3%) • Decreases antibiotic use 7 (4%) • Superior drug, miracle drug, fewer side effects, no side effects 18 (11%)	Reduced hospital admissions, doctor visits, absenteeism 5 (3%)	Reduces replication of virus 29 (18%)		4/59 (7%)
donepezil	96	• Stabilizes or slows down progression 17 (18%) • Slows down or reduces memory loss or symptoms 17 (18%)	• Improves day to day tasks 8 (8%) • Fewer institutionalizations 7 (7%) • Enhances life, improves condition 33 (34%)	Government drug plans savings 6 (6%)	Improves mental/cognition scores 3 (3%)	Increases enzyme activity 5 (5%)	2/45 (4%)
Total	421						37/193 (19.2%)

Table C: Harms reported

		Types and numbers of harms mentioned (%)		
Drug	Harms reported	Clinical markers		Surrogate markers
celecoxib	5	• Increases cardiac events 1 (20%) • Upsets stomach 1 (20%)	• Nonspecific, unknown 3 (60%)	
atorvastatin	16	• Causes muscle or joint pain 3 (19%) • Problems related to urinary tract, skin, endocrine, central nervous system or liver 11 (69%)	• Risk of death 1 (6%) • Death due to violent causes 1 (6%)	
raloxifene	26	• Increases blood clots 13 (50%) • Increases hot flashes 5 (19%) • Causes leg cramps 3 (12%)	• Risk of endometrial cancer 3 (12%) • Unknown long term side effects 2 (8%)	
oseltamivir	32	• Gastrointestinal 21 (66%) • Mild allergic reactions 6 (19%)	• Risk of serious, kidney, liver effects 2 (6 %) • Risk of death 1 (3%)	• Resistant strains 2 (6%)
donepezil	11	• Gastrointestinal problems 3 (27%) • Muscle pain 1(9%)	• Risk of central nervous system effects 5 (46%) • General side effect or comment on risk 2 (18%)	
Total	90			

ied between drugs and was lowest for atorvastatin and raloxifene, accounting for 47 per cent and 49 per cent respectively of all benefits mentioned. To put this in perspective, this means approximately half the time the benefits of these two drugs were described using surrogate outcomes that may not lead to meaningful health impacts. One in five or 37 of 193 articles (19 per cent) reported *only* surrogate benefits. The proportion of articles reporting only surrogate marker benefits was highest for atorvastatin, 8/17 (47 per cent) and raloxifene, 16/41 (39 per cent).

The drug described with the highest proportion of clinical outcomes was the Alzheimer's drug donepezil 82/96 (85 per cent). However, this number may be misleading as some donepezil benefits, such as the drug's ability to "stabilize" or "slow down progression" of Alzheimer's disease, were classified as "clinical" benefits when such classification is open to question.[16]

Twenty-four per cent of the study's articles (100/421) included a measurement of the magnitude of the benefit expected (see Table D). In 14 per cent of the cases, benefits were described with a time frame along with the magnitude of benefit. In other words, only 15 of the 421 (4 per cent) benefits contained suf-

Chart 2: Proportion of listed benefits and harms that included no quantitative measures

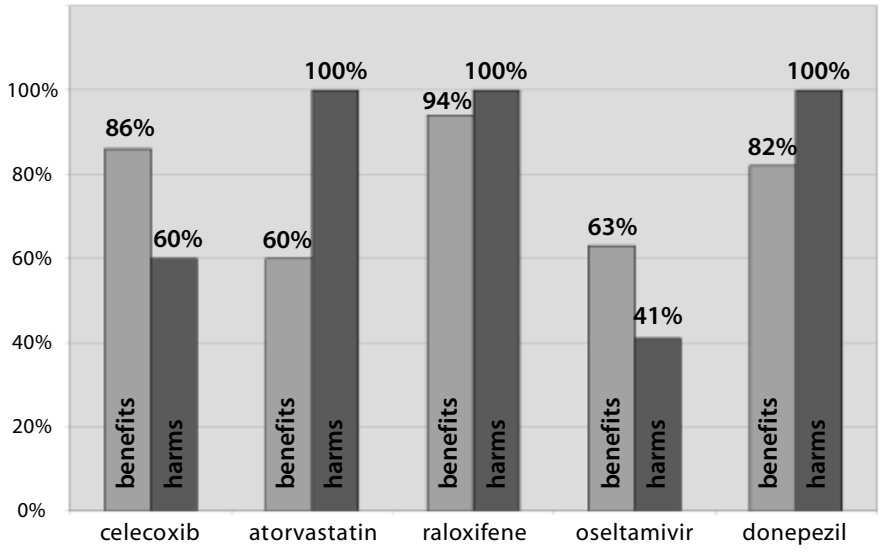


Table D: Benefits and harms expressed quantitatively

Drug	Total number of benefits/ harms	Mention of quantitative benefits and harms						No mention of quantitative benefits and harms	
		Only absolute numbers		Only relative numbers		Both absolute and relative numbers			
		Benefits	Harms	Benefits	Harms	Benefits	Harms	Benefits	Harms
celecoxib	58/5	4 (7%)	1 (20%)	3 (5%)	0	1 (2%)	1 (20%)	50 (86%)	3 (60%)
atorvastatin	30/16	1 (3%)	0	10 (33%)	0	1 (3%)	0	18 (60%)	16 (100%)
raloxifene	79/26	2 (3%)	0	3 (4%)	0	0	0	74 (94%)	26 (100%)
oseltamivir	158/32	42 (27%)	17 (53%)	14 (9%)	1 (3%)	2 (1%)	1 (3%)	100 (63)%	13 (41%)
donepezil	96/11	17 (18%)	0	0	0	0	0	79 (82%)	11 (100%)
total	**421/90**	**66 (16%)**	**18 (20%)**	**30 (7%)**	**1 (1%)**	**4 (1%)**	**2 (2%)**	**321 (76%)**	**66 (73%)**

ficient numeric values to provide the reader with an idea of the actual degree of benefit and the time frame over which that benefit would be expected to occur. For example, an article on donepezil stated that the drug "improved the condition of 40 per cent of the patients with Alzheimer's disease who took it" based on "the six-month clinical test."[17]

Overall, 24 per cent (100 out of 421) of reports of benefits included a measure of the magnitude of the benefits. When the magnitude of benefits was described, absolute numbers were provided in 70 per cent (70 out of 100) of cases.

Harms reported

How many articles reported the magnitude of the harms? Using relative or absolute numbers? Clinical or surrogate harms?

Only 21 of the 90 harmful effects (23 per cent) included a measure of the magnitude of the drugs' potential problems or side effects, but 20 of these (95 per cent) used absolute numbers.

All but two of the 90 mentions of harm (98 per cent) were classified as clinical effects. (For a comprehensive list of the common and rare side effects associated with the five study drugs see Appendix B.)

Language used to describe benefit and harm

What descriptions were used and did those descriptions emphasize or minimize the magnitude of the harm or benefit being described?

Altogether there were 511 health effects mentioned. Of these, 94 (18 per cent) were described either with adjectives or explanatory phrases. Harmful effects were more than twice as likely to include descriptions than beneficial effects. 61/421 (14 per cent) of the benefits had descriptions attached to them versus 33/90 (37 per cent) of the harms. Most descriptions emphasized benefits or minimized harm (see Chart 3 and Tables E1 and E2). Of the 61 descriptions of benefits, 17 (28 per cent) minimized the benefits and 72 per cent emphasized them; of the 33 descriptions of harm, 28 (85 per cent) minimized harm and only 5 (15 per cent) emphasized harmful effects.

Chart 3: Descriptions of benefits and harms that emphasize or minimize the effect

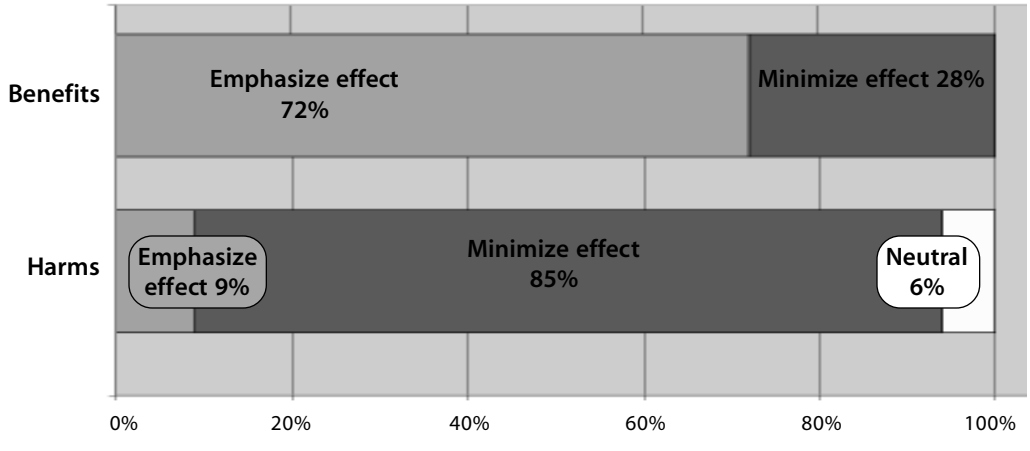


Table E1: Descriptions of benefit

Benefit descriptions used (actual quoted language)	Number of times description used (n=61)	Does it emphasize the benefit?
promised; appealing; proven remedies	9 (15%)	yes
dramatically; highly; major; tremendous; a very, very big difference	8 (13%)	yes
modest; limited; mild to moderate; marginal	8 (13%)	no
substantially	7 (12%)	yes
breakthrough; pioneering; designer treatment	6 (10%)	yes
doesn't eliminate risk entirely; uncertain; not proven; no more effective; not significant	6 (10%)	no
cancer scare doesn't exist	3 (5%)	yes
far fewer	3 (5%)	yes
not substantially; far from being a wonder drug	3 (5%)	no
significant; more effective	3 (5%)	yes
alleviates all; most important	2 (3%)	yes
only clinically proven	1 (2%)	yes
shorter length, faster	1 (2%)	yes
some	1 (2%)	yes
total descriptions	**61 (100%)**	
total benefit descriptions emphasizing benefit	**44/61 (72%)**	

Table E2: Descriptions of harm

Descriptions of harm (actual quoted language)	Times mentioned (n=33)	Does it minimize the harm?
minor, reversible; most people went on to finish the treatment anyway; usually mild and improve over time	10 (30%)	yes
rarely; rare;	6 (18%)	yes
deemed small; small but significant; so small hardly worth mentioning	5 (15%)	yes
very few; relatively few; fewer than [other drug]	4 (12%)	yes
terrible; really bad	3 (9%)	no
minority [of people who use the drug]	2 (6%)	yes
I don't know what to make of that finding	1 (3%)	no
no cases after four years	1 (3%)	yes
some people	1 (3%)	no
total descriptions	**33 (100%)**	
total harm descriptions minimizing harm	**28/33 (85%)**	

Placement

Where were harms and benefits mentioned?

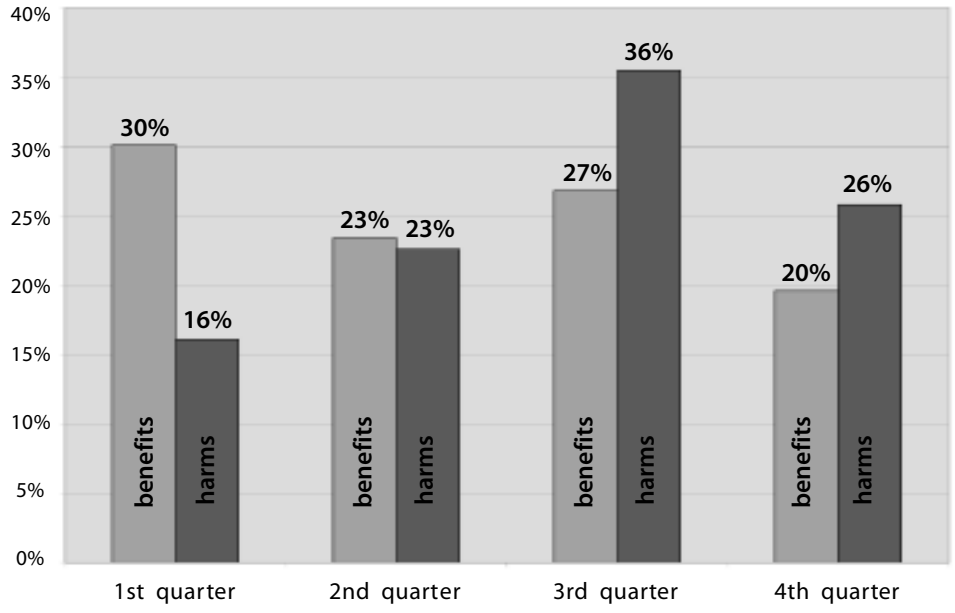
Benefits were most often identified in the first quarter of the article, while harms were usually identified in the third quarter of the article (see Chart 4). Fifty-three per cent of the benefits were mentioned in the first half against 39 per cent of the harms.

Length of article

Were longer articles more likely to discuss the benefits and harms of a new drug?

The articles varied in length from 3 cm (about one-eighth of a page) to 111 cm (5.1 pages). The average article length was 24.3 cm (1.1 pages). The trend toward a more frequent mentioning of benefits over harms occurred in all study articles, regardless of their length. A larger proportion of the news briefs did not mention a single harmful effect (9/11 or 82 per cent) compared to the longer articles (122/182 or 67 per cent). Otherwise, the ratio of benefits/ harms did not increase incrementally with the longer articles.

Chart 4: Placement of benefits and harms in the article



Indications

How many articles reported indications for the drug?

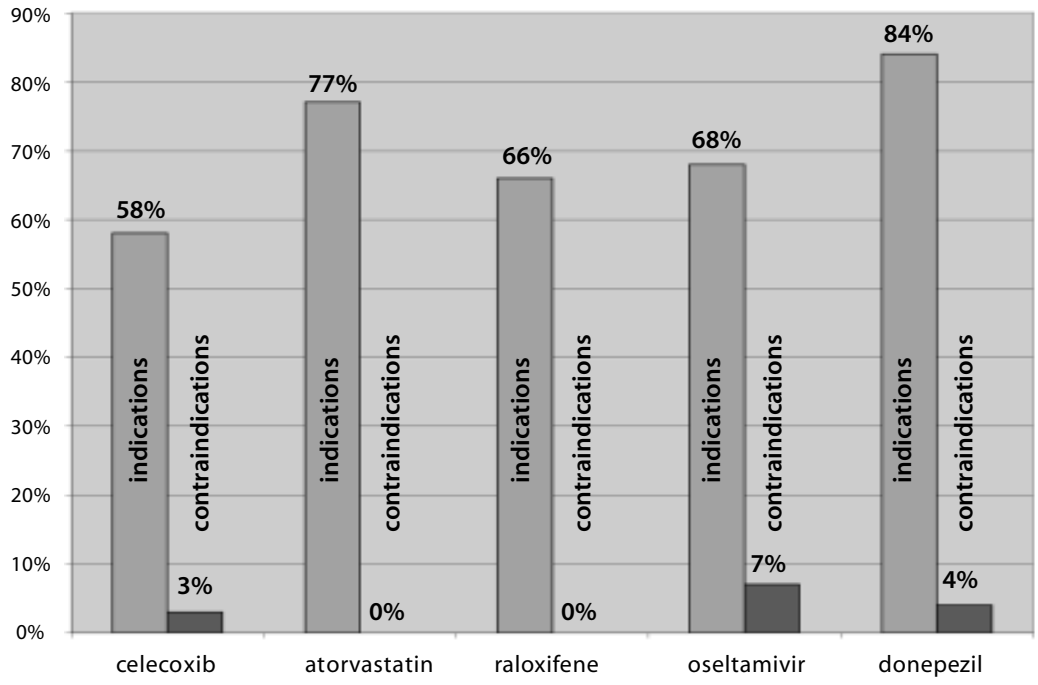
A drug's "indication" is the officially approved reason for its use; for example, to treat symptoms of the flu, pain or inflammation. As one would expect, most articles mentioned the indication for the drug. On average one or more indications were stated in seven out of 10 articles. Mention of indication varied for individual drugs, ranging from 18/31 (58 per cent) for celecoxib to 38/45 (84 per cent) for donepezil.

Contraindications

How many articles reported contraindications for the drug?

In contrast, only seven of the study articles (4 per cent) mentioned contraindications – specifying who should not take a drug. These were primarily articles on oseltamivir, which reminded readers that the drug was only for adults, only for the flu, and should only be taken within 48 hours of the onset of symptoms.

Chart 5: Percentage of articles mentioning indications and contraindications



Drug alternatives

How many articles reported drug alternatives?

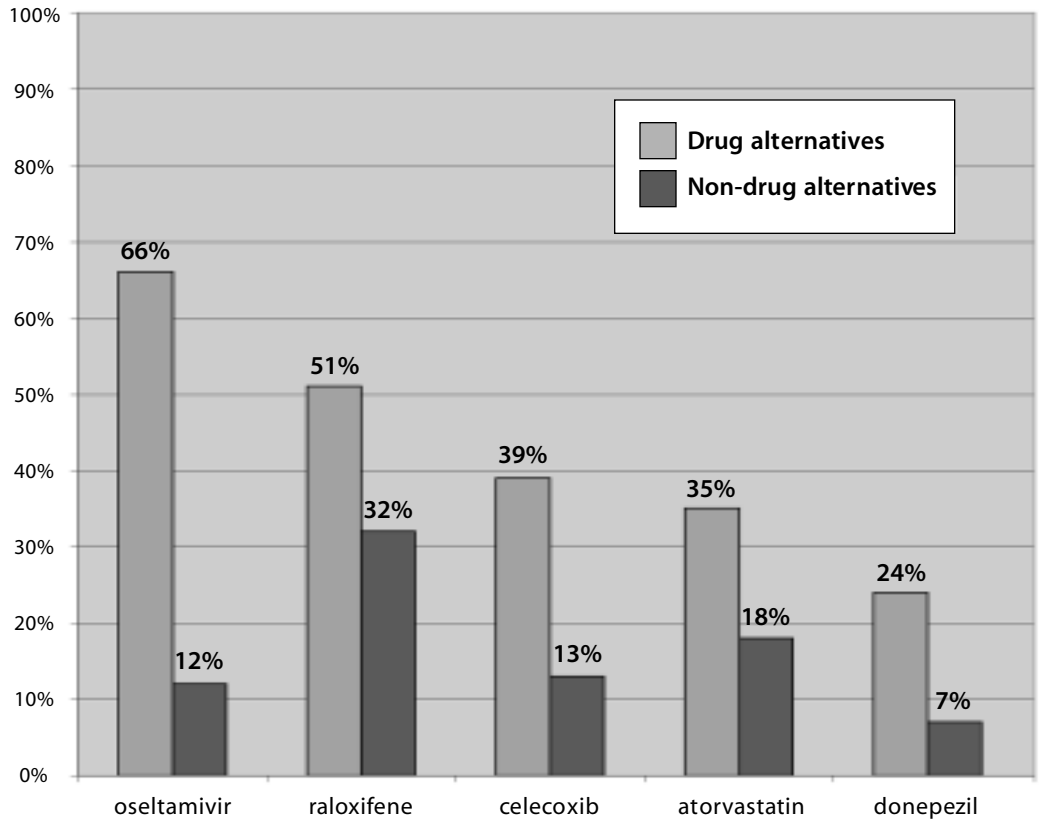
Nearly half the articles (89/193 or 46 per cent), mentioned a drug alternative (another drug that can be used to treat the same illness). Articles on oseltamivir were most likely to mention drug alternatives. Alternatives mentioned were mainly flu vaccines and oseltamivir's competitor, the antiviral zanamivir (brand name, Relenza®). Both flu drugs were launched onto the Canadian market at around the same time and there were many flu epidemic stories in which both new drugs were mentioned. More than half (51 per cent) of the raloxifene stories mentioned estrogen replacement therapy or other osteoporosis drugs, such as the bisphosphonates (drugs such as Fosamax® or Didrocal®).

Non-drug alternatives

How many articles reported non-drug alternatives?

We classified any mention of lifestyle, diet or other alternative treatments as "non-drug alternatives" that may be effective treatments for the condition or useful complements to drug therapy. Only 30 of the 193 articles (16 per cent) mentioned non-drug alternatives. Stories on raloxifene typically included information on lifestyle activities (exercise, soy intake) that post-menopausal women should consider.

Chart 6: Percentage of articles mentioning drug or non-drug alternatives

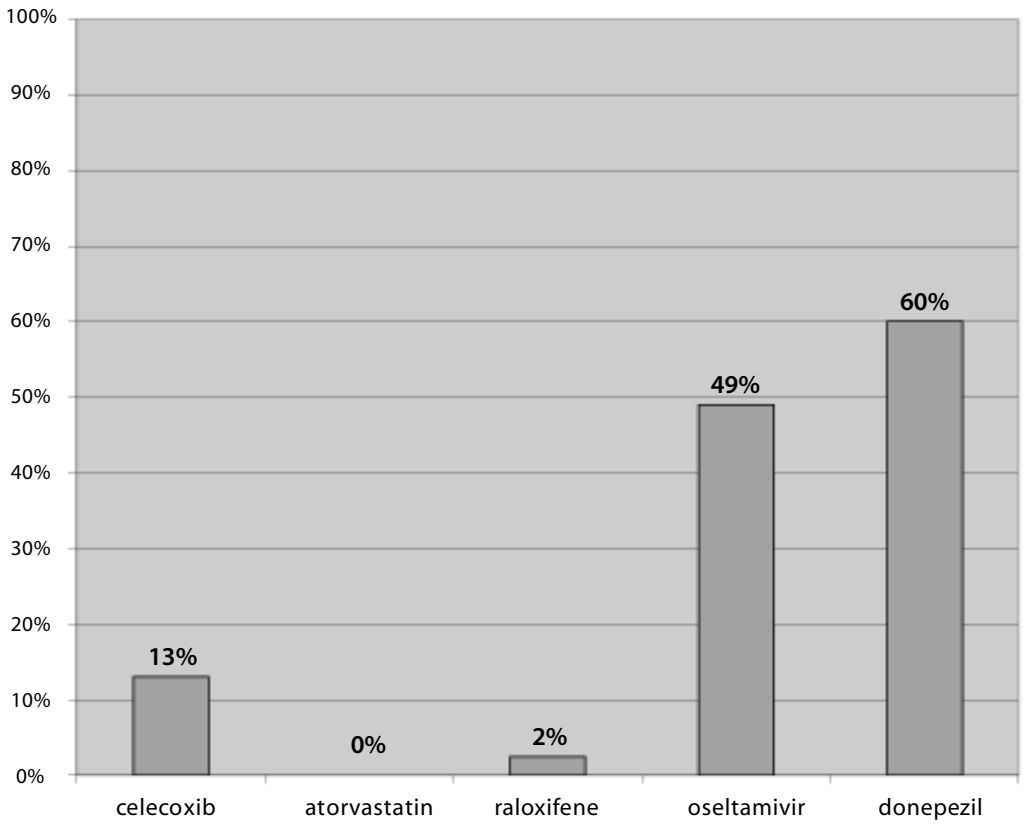


Costs

How many articles reported the cost of the drug?

The cost of the drug was mentioned in 61 articles (32 per cent). Costs were most likely to be mentioned in articles on donepezil (27 articles or 60 per cent) and oseltamivir (29 articles or 49 per cent). The most common theme in the donepezil stories concerned getting provincial governments (mostly from Saskatchewan and Quebec) to cover the cost of the drug.

Chart 7: Percentage of articles mentioning the cost of the drug



Trial or study

How many articles refer to a trial or a study when describing the properties of the drug?

Fifty-seven of the 193 study articles (30 per cent) referred to a trial or study of the drug. Thus, most mainstream media reports of these drugs failed to directly refer to any research results to support the reported health claims.

Trial design

Was the trial's design reported?

Reporters provided some information on study design in 36 of the 57 articles (63 per cent) that mentioned a study.

Trial population

Was the population size reported?

Twenty of 57 articles discussing a study (35 per cent) stated how many patients had been involved.

Trial funding

Were funding sources of the study mentioned?

Fifteen of the 57 articles (26 per cent) discussing a study included information on who funded it. Most studies of new drugs are funded by manufacturers, yet this funding link was not revealed nearly three quarters of the time.[18]

Table F: Information on reported trials and studies

Drug	Total number of articles	How many articles reported a trial or a study?[1]	Was the study design discussed?[2]	Was the study population stated?[3]	Was the funding of the study revealed?[4]
celecoxib	31	14 (45%)	8/14 (57%)	5/14 (36%)	4/14 (29%)
atorvastatin	17	12 (71%)	11/12 (92%)	8/12 (67%)	8/12 (67%)
raloxifene	41	10 (24%)	7/10 (70%)	4/10 (40%)	2/10 (20%)
oseltamivir	59	14 (24%)	4/14 (29%)	2/14 (14%)	1/14 (7%)
donepezil	45	7 (16%)	6/7 (86%)	1/7 (14%)	0/7 (0%)
	193 (100%)	**57 (30%)**	**36/57 (63%)**	**20/57 (35%)**	**15/57 (26%)**

[1] Bracketed figure represents percentage of drug-specific articles reporting a study or trial.
[2] Bracketed figure represents percentage of articles discussing a trial or study that also discussed the trial design.
[3] Bracketed figure represents percentage of articles discussing a trial or study that also discussed the study population.
[4] Bracketed figure represents percentage of articles discussing a trial or study that also discussed the funding of the study.

Quoted spokespeople

How many articles quoted spokespeople, and what is the breakdown by drug and by type of quoted spokesperson?

In total, 120 of 193 articles (62 per cent) quoted one or more person discussing the drug, and on average two people were quoted in each of these articles (see Table G1). Those most often quoted were government representatives, physicians or academic researchers. Twenty-eight of 193 articles (15 per cent) quoted an industry source, 12 per cent quoted patient groups and 11 per cent quoted individual patients. Only 10 articles (5 per cent of all articles) quoted pharmacists, despite their expertise in drug treatment. All of these pharmacists were quoted discussing a single drug, oseltamivir. One sports celebrity, a golfer, was quoted in four articles on celecoxib.

The type of quoted spokespeople varied considerably by drug (see Table G2); for example, almost all of the government sources discussed either oseltamivir or donepezil. In the case of oseltamivir, many were public health authorities discussing flu epidemics; those quoted in articles on donepezil were mainly commenting on the controversy surrounding provincial reimbursement of this new Alzheimer's drug.

Only one quarter of the articles on raloxifene included any quoted spokespeople, as compared to 80 per cent of articles on oseltamivir and 82 per cent on donepezil. Just over half of the articles on celecoxib and atorvastatin quoted spokespeople of some sort. Half of the spokespeople quoted on raloxifene were individual patients, although in total, for all five drugs, individual patients made up just over 11 per cent of quoted people.

Chart 8: Percentage of articles quoting at least one spokesperson

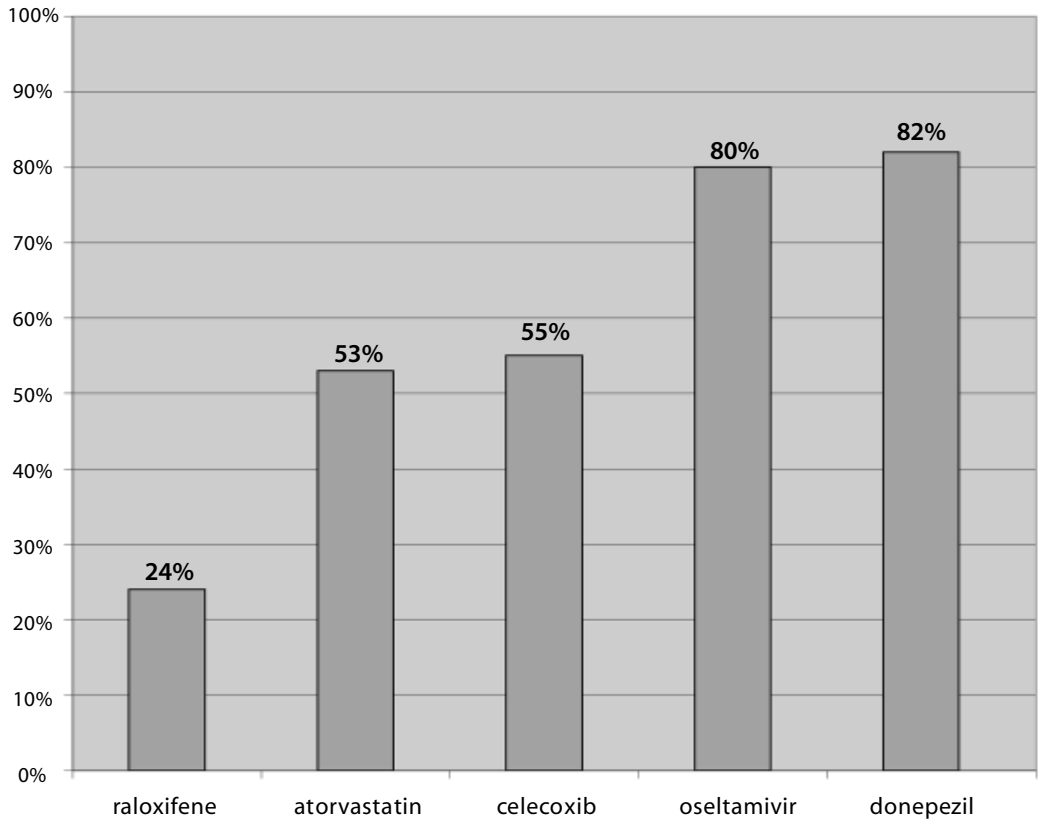


Table G1: Overall numbers of quoted spokespeople, by type of source mentioned

Type of spokesperson	Overall number of times spokespeople were quoted, n=244[2]	Number of times spokespeople were repeated	# of spokespeople where financial links are mentioned[3]
government	49 (20%)	21 (43%)	na
doctors	50 (21%)	18 (36%)	1 (2%)
academic researchers	43 (18%)	7 (16%)	3 (7%)
industry	31 (13%)	6 (19%)	na
patient groups	26 (11%)	12 (46%)	1 (4%)
patients	26 (11%)	12 (46%)	0
pharmacists	13 (5%)	4 (31%)	0
sports celebrities	4 (2%)	3 (75%)	0
miscellaneous[1]	2 (1%)	0	0
total	**244 (100%)**	**83 (34%)**	**5/164 (3%)**

[1] One consumer group, one affiliation not stated
[2] Some spokespeople were quoted in multiple articles, this represents the entire body of quotes
[3] Those with government (49) or industry (31), where the funding is obvious, are not included for a total of 164.

Table G2: Quoted spokespeople by drug and by type of quoted spokesperson

	celecoxib n=29	atorvastatin n=15	raloxifene n=12	oseltamivir n=108	donepezil n=80	total n=244
government	1 (3%)	0%	0%	26 (24%)	22 (28%)	49 (20%)
doctors	10 (34%)	3 (20%)	1 (8%)	29 (27%)	7 (9%)	50 (20%)
academic/researchers	10 (34%)	7 (47%)	3 (25%)	10 (9%)	13 (16%)	43 (18%)
industry	0	4 (27%)	0	22 (10%)	5 (6.3%)	31 (13%)
patient groups	2 (7%)	0%	2 (17%)	0%	22 (28%)	26 (11%)
patients	2 (7%)	0	6 (50%)	7 (7%)	11 (14%)	26 (11%)
pharmacists	0	0	0	13 (12%)	0	13 (5%)
sports celebrities	4 (14%)	0	0	0	0	4 (2%)
other	0	1 (7%)	0	1 (1%)	0	2 (1%)

Financial links

Were funding sources of quoted spokespeople revealed?

Very few quoted spokespeople were identified as having financial links to manufacturers (see Table G1). Excluding industry and government spokespeople (the latter because financial links to manufacturers are unlikely), five articles in 164 (3 per cent) mentioned a financial link.

In only one case was a financial link mentioned between a patient group and a pharmaceutical company. No links were mentioned between individual patients and manufacturers. Only one of the four articles citing a sports celebrity hinted at a financial link. Golf pro Bruce Summerhays said he "liked it [Celebrex®] so much that he agreed to be the spokesperson for the company." Financial links were mentioned for 3/40 (8 per cent) of the academic researchers. It was beyond the scope of this study to investigate all quoted sources to determine whether they had unrevealed ties to industry.

Overall, just over one third of all quoted spokespeople were mentioned in more than one article. This increased to nearly half of individual patients or patient group representatives who were quoted multiple times. Nearly half of individual patients or patient group representatives were quoted several times. This suggests that these people spoke at press conferences, were cited in press releases, or journalists were referred to them.

Distinct bylines (author identification)

How many articles had bylines?

Slightly over one quarter (26 per cent) of the articles were written by journalists who wrote only one article on any of the five study drugs during the year 2000. One in five (22 per cent) were without a byline. Of the study's 193 articles, 32 (17 per cent) were written by a single syndicated health columnist. Journalists who wrote between two and six articles on these five drugs during the year wrote the remaining 35 per cent of the articles.

Table H: Bylines

Byline	Number of articles per writer	Total	Percentage of total articles
articles without byline	44	44	22.8%
Dr. Paul Donohue	32	32	16.6%
Anne Kyle; Sharon Kirkey	6	12	6.2%
Murray Mandryk; Sue Bailey; W. Gifford-Jones	5	15	7.8%
Brad Evenson; Marilyn Linton; Pamela Fayerman	4	12	6.2%
Alexandra Paul; Clare Mellor; Dr. Peter Gott	3	9	4.7%
Gerrie Grevatt; Hattie Klotz; Jenny Lee; Jocelyn Bell; Krista Foss; L. Lemieux; D. Perreault; Tanya Talaga; The Arthritis Society	2	18	9.3%
all other writers	1	51	26.4%
total	**72 individual writers**	**193**	**100%**

Discussion

What do the findings mean?

How balanced was the information on drug benefits and risks in these news reports? In general, it was unbalanced.

ON AVERAGE, EVERY DAY IN 2000, AT LEAST ONE ARTICLE MENTIONING THE NAME of one of these five new drugs was published in Canada's 24 largest daily newspapers, and just over half of these articles included information on health effects. This collection of articles represents a considerable source of health and drug information for Canadian consumers.

How balanced was the information on drug benefits and risks in these news reports? In general, it was unbalanced: the articles were nearly five times as likely to mention beneficial as harmful effects and 68 per cent made no mention at all of side effects or harms. When benefits were mentioned, they were more often in the first part of the article; when harms were mentioned, they were usually further down. Readers browsing a newspaper are most likely to read the first part of an article.

These systematic differences occurred both for shorter articles ("news briefs") and full-length reports, though they were more pronounced for the briefs.

Not only did more articles describe benefits than risks, but most risks were also described in ways that minimized their impacts. If benefits were described with adjectives or an explanatory phrase, they were usually emphasized. Typically a side effect would be described as "minor" or "rare," yet such adjectives were used to describe drug benefits only about a third of the time, even if the benefits and side effects occurred at similar frequency or intensity.

Language that emphasized benefits was also often in stark contrast to the actual quantitative significance of those benefits or harms. Articles on oseltamivir, for example, often reported that the flu drug was "highly effective" at preventing flu even when the drug was only shown to reduce the duration of flu symptoms by 0.8 to 0.9 of a day.[19]

Verbal descriptions of the magnitude of a drug's effect can be misleading; there is very little agreement on what terms such as "substantially," "very low," or "highly important" actually mean.[20] There is a growing movement in medicine against the use of inexact language such as "rare" or "frequent"; international organizations such as the Council for International Organizations of Medical Sciences (CIOMS) are beginning to standardize exactly what those terms mean in quantitative terms.[21] Some commentators have even pointed out that using such terms to describe the frequency of drug benefits is virtually meaningless.[22]

A CLOSER LOOK

Balancing drug benefits against the harms

A drug that relieved symptoms of the common cold but caused deaths in 1 in 100,000 cases might not have an acceptable benefit-to-harm ratio. But if you had a condition in which you had a 50-50 chance of dying, a drug that caused death in 1 in 4 (e.g. killed 25 per cent of people, but helped the other 75 per cent) might have an acceptable ratio to you. This balance must be considered when taking drugs for disease prevention. It would be important to know that the drug you are taking to reduce the risk of some outcomes doesn't cause other health problems down the road.[23]

Additionally, one in five articles (19 per cent) reported *only* surrogate benefits. None of these articles explained to readers that the beneficial effect was on a risk factor for disease, rather than on a disease state.

The public is often unaware that a new drug may not be safer or more effective in comparison to older alternatives, or what information to look for when deciding whether a drug is worth trying. It is therefore important, when considering a drug therapy, to know how safe and effective new drugs are relative to older drugs and to non-drug therapies, and the costs, benefits and harms associated with each.

All pharmacologically active substances are capable of causing harm as well as benefit, and any decision to use a medicine involves weighing the likelihood of potential benefit against potential harm. The probability that a person benefits or is harmed by a medicine varies depending not only on the product characteristics, but other factors such as the patient's age, sex, health status, and other medicines they are taking that may interact with the new drug. Additionally, patients' acceptance of benefits versus harms varies with the disease; one would have a different standard when facing a life-threatening illness such as AIDS versus an illness that generally resolves on its own such as the flu or common cold.

Other potentially important information concerning available treatments was often lacking, such as lifestyle changes, self-help activities, acupuncture, naturopathy or other forms of already available drug therapy. Without knowing that there are alternatives and that new drugs typically compete with a whole range of existing medications, consumers cannot make informed health care choices.

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A CLOSER LOOK

Raloxifene: A "proven remedy" that displays "very few side effects"?

Articles on raloxifene often referred to the drug's ability to fight osteoporosis and called it a "proven remedy" to strengthen bones, while causing blood clots "in very few."

The information in articles describing the benefits of raloxifene likely came from trials of the drug against a placebo.[24] Raloxifene did indeed reduce the incidence of spinal fractures (what is often called vertebral collapse, because it is a loss of vertebral height as measured on an x-ray, not an actual broken bone). These kinds of fractures are usually asymptomatic (i.e. people don't usually feel them) though they can cause height loss and the development of a "widow's hump." In this study, only 12.3 per cent of the vertebral fractures caused back pain. The frequency of painful vertebral collapses was lower in the group of women taking raloxifene (0.6 per cent vs 1.4 per cent on placebo, with an absolute risk reduction of 0.8 per cent). A reduction of this magnitude means that to prevent one painful vertebral collapse, 125 women would need to be treated for three years. This benefit would have to be measured against the potential for harm in those women who took the drug.

Raloxifene is associated with an increased risk of thromboembolic events (blood clots, which can be life-threatening). In the same trial, 1.0 per cent of raloxifene users versus 0.3 per cent on placebo experienced a venous thromboembolic event, an absolute risk increase of 0.7 per cent over three years. Of 143 women receiving raloxifene for three years one will develop a blood clot in the legs or lungs.

So, in essence, the measured beneficial effect over three years is a 0.8 per cent difference in painful vertebral fractures. This is quite similar in frequency to the measured harmful effect, a 0.7 per cent difference in blood clots in the legs or lungs. Moreover, we don't know what happens after three years as the drug's benefits and harms were only observed over the three years that the study lasted. It is unknown what would happen if women stay on this drug longer than three years.

It is thus misleading to characterize the drug as a "proven remedy" on the one hand, and say that the blood clots occurred only in "very few."

The failure to report drug costs (mentioned only in about a third of articles) has consequences for both consumers and policy makers. Given the importance of a sustainable health care system to the Canadian public and the increasing share of public health dollars that drugs consume, information about the benefits and harms of new therapies in relation to their costs is vital.

To maintain high rates of return for shareholders, pharmaceutical manufacturers must continually bring new products to the market – and those new products are almost always accompanied by higher prices. If, however, there is little to no evidence of an advantage, in terms of improved efficacy and/or safety, for new products, governments (and consumers as well) may be unwilling to pay the higher prices. Hence, information about a drug's benefits and harms and the cost of the treatment are all essential parts of decision-making on new drugs. One of the "side effects" of biased reporting on drugs is that it can lead consumers to pressure policy makers into covering those new drugs even if they are not cost-effective (or are not even very effective). In this sense, the sustainability of publicly-funded health plans could be adversely affected by biased or misleading media coverage of drugs.

Only a third of the articles referred to a trial or study and fewer discussed any details of those studies. There are three important points that a report needs to cover concerning drug studies: who was studied (are they people like you?), the quality of the study (and does it measure outcomes of importance to you?), and how was it designed and carried out (was it a survey or a controlled experiment and how long did it last?).

The articles mentioned a variety of types of drug studies spanning a spectrum from opinion surveys to randomized, double-blind placebo-controlled trials, which are the gold standard in drug research. Conclusions that should be drawn from an opinion survey on donepezil funded by its maker, Pfizer, however, are very different from those to be drawn from randomized, placebo-controlled studies. In the latter case, it is also important for readers to know whether the manufacturer or an independent agency funded a study, as systematic reviews have shown that studies funded by manufacturers are more likely to report favourable results.[26]

Journalists who report on drugs infrequently may have limited expertise with which to judge this information. Only 12 of the 73 journalists in this sample, or 16 per cent, wrote more than one article. Science or medical reporters are more likely to be able to judge the information provided to them. One writer, a syndicated health columnist, frequently answers questions from his readers about new drugs. He was able to demonstrate that it is possible, even with limited space, to present information about both harms and benefits.[27]

Another notable finding was the small number of articles, only five (3 per cent) in total, that mentioned any financial link between manufacturers and quoted spokes-

A CLOSER LOOK

Why do we need cost information?

Individual consumers need to know the price tag that comes with new drugs, as they often enter the market at premium prices. Most importantly, consumers want to know if the new drug is going to be covered by their provincial health plan or private insurance. If it is not covered, there is likely to be a good reason; for example, it may be, like Viagra®, that the drug is considered a lifestyle drug. More likely, it may be that the new drug has little if any benefit over other established therapies to justify the expensive price tag.

The debate over a new drug being too marginal in benefit to qualify for provincial coverage was at the heart of many of the study's articles on the Alzheimer's drug Aricept® (generic name donepezil). While clinical trials of donepezil did report changes in some cognitive function scores as compared to a placebo, the magnitude of the benefit was only 3 to 4 points on average on a 70-point scale. It is an open question what this actually means to a patient's life or whether there will be a sufficiently noticeable change to outweigh negative effects such as diarrhea and nausea, which occur in 10 per cent or more of patients.[25]

people. Many of the researchers quoted were involved in pre-marketing studies of the drugs, which are almost always funded by the manufacturer. However, financial links between the academic researchers and the company were mentioned in only three cases. Moynihan's *New England Journal* study of the media reporting of drugs, which sought out the actual funding ties of quoted spokespeople, found that 85 of 170 (50 per cent) of articles in the study cited at least one expert with a tie to industry, yet this tie was only mentioned in 33 of 85 (39 per cent) of those articles.[28]

Only one article documented a financial link between a patient group representative and the manufacturer, although given that many patient groups receive funding from pharmaceutical companies we suspect that the actual number is much larger.[29] None of the journalists mentioned a financial link between individual patients and the product's manufacturer. Yet, nearly half of quoted individual patients or representatives of patient groups were quoted in more than one article. Repeat citations of the same person suggest that journalists may have been led in some way to the patient or patient group representative; for example, the patient spoke at a press conference, was quoted in press releases or listed as an available contact. *Toronto Star* journalist Don Sellar reported that drug company press conferences often include a patient, a clinician and company representative, all with financial links to the manufacturer.[30]

A *Wall Street Journal* article on the launch of a drug for obsessive-compulsive disease did not mince words when describing the somewhat shady use of third-party spokespeople: "The drug companies typically leave few fingerprints, running their disease campaigns through PR [public relations] firms, patient groups, "institutes" and other third parties."[31]

It was not possible, within the scope of this project, to assess the degree to which quoted sources had financial links to product manufacturers, but the absence of such disclosure is consistent with other research in this area.[32]

One notable finding was the small number of articles, only five in total, that mentioned any financial link between manufacturers and quoted spokespeople.

Limitations of this study

We recognize that there are several shortcomings to this study:

- We examined only daily newspapers and hence have no data to show if differences would be found between newspapers and other print media. Neither is it possible to make inferences as to the quality of the reporting of new drugs in the broadcast media, such as radio, television and the Internet.[33] Such research would give a broader understanding of where limitations in those media are found.
- We looked only at whether specific types of information were present or absent. We did not examine, confirm or dispute the accuracy of the claims, some of which we know to be false (the claim that celecoxib is safer than other non-steroidal anti-inflammatory drugs is clearly not supported by the evidence).[35] Further analysis of the factual nature of claims of benefit or harm would provide even more insight into the quality of newspaper reporting about drugs.
- We were unable, within the timeframe of the study, to examine the financial links of quoted spokespeople. We therefore could not determine how many of the quoted spokespeople or published sources actually had links to the manufacturers and the degree to which those links were not reported in the articles.
- Although all five of the drugs examined in this study had been on the Canadian market less than five years, the launch dates differed and this affected the numbers of articles associated with each drug in the sample.
- This study was a sample of reporting on five specific drugs over a single time period. It may or may not be representative of broader trends in newspaper reporting of all new drugs entering the Canadian market in the past five years; however, it does provide some evidence of where improvements in the quality of that reporting could be made.

Conclusion and recommendations

WE FOUND A CONSIDERABLE IMBALANCE IN THE WAY DRUGS' BENEFITS VERSUS harmful effects were reported. We also found that important context for information in the articles was often missing, particularly in terms of whether the benefits were meaningful to people who might use the product. When the magnitudes of the benefits were reported, they were often done so in a manner that exaggerated the drugs' beneficial effects and downplayed their harmful effects. Important information on financial links between researchers involved in studies of new drugs, spokespeople quoted about those drugs, and the drugs' manufacturers was very infrequently reported. Additionally, many articles provided little information on costs and drug or non-drug alternatives, making it difficult for the public to accurately assess how the drug under discussion might contribute to treatment in comparison to other alternatives.

We identified a number of limitations in the reporting of new drugs in Canada's daily newspapers.

1. Imbalance in reporting of harmful effects.

Overall, 68 per cent of the articles we examined mentioned a drug's benefit but made *no* mention of possible harm or side effects. By contrast, no articles failed to mention a drug's benefit. The number of articles reporting harms ranged from 5/31 (16 per cent) for celecoxib, to 26/41 (63 per cent) for raloxifene. Overall, the articles identified 4.7 times more benefits than harms (421 versus 90 respectively).

2. Surrogate vs. clinical benefits not appropriately reported.

Meaningful versus maybe-meaningful benefits were not consistently reported. While three quarters (73 per cent) of benefits mentioned were clinical benefits, one in five study articles (19 per cent) reported only surrogate benefits. This type of reporting can lead to a misleading impression of a drug's effectiveness, particularly as none of these articles explained the difference between a surrogate endpoint and a clinical benefit. The drugs with the most frequent reporting of surrogate benefits were atorvastatin (47 per cent) and raloxifene (39 per cent), both drugs for which evidence of clinical benefits is minimal.

3. Poor quantification of drug benefits or harms.

Only one quarter of study articles quantified the degree of benefit or harm associated with the drug. To be able to make an informed decision to use drug therapy, clinicians and patients need to have a clear and unambiguous idea of the magnitude of the benefit and harm.

4. Underutilization of absolute vs. relative numbers when discussing benefits associated with prescription drugs.

Distinguishing between absolute and relative numbers is vital to making informed health decisions. Even though 70 out of 100 articles that reported a magnitude of a benefit used absolute numbers, this represents only 17 per cent (70 out of 421) of all benefits mentioned. Presenting benefits of drugs with only relative numbers (such as stressing a 33 per cent reduction

in heart attacks when the risk was reduced from 6 per cent to 4 per cent) has been shown to be misleading. Presenting benefit or harm information in a misleading way may affect clinicians' willingness to prescribe and patients' acceptance of therapy.

5. Infrequent reporting of financial links of spokespeople and of funding sources for drug studies.

Financial links to pharmaceutical companies were mentioned for only 3 per cent of all non-government, non-industry spokespeople. Funding was usually not mentioned when a study was cited. It is important for readers to know if a quoted patient or patient group representative has received money or other resources from the company. Similarly, if a clinician or academic researcher with financial links to manufacturers praises a study, readers are likely to judge the information differently than they would for information from an independent assessment. Some quoted spokespeople are likely to be industry-sponsored, yet those financial links are almost never reported. The number of actual spokespeople who received industry funding would surely be much higher than 3 per cent.

6. Articles frequently lack other crucial information needed to make informed drug decisions.

While it is good that, on average, 70 in 100 articles contained information on drug indications (approved reasons for using a drug), only four in 100 articles specified any contraindications (who should not take a drug). One third of the articles mentioned the cost of the drug, nearly half mentioned a drug alternative, but only about one in six articles mentioned non-drug alternatives such as exercise or diet. Newspaper articles that give the impression a drug is simply "good for you" are not helpful to readers unless they also report on what the drug is indicated for, the magnitude of benefits and harms, the drug's costs, and treatment alternatives.

Public policy implications

What are the implications of the findings for various audiences?

Consumers

Consumers have the most to lose when they use drugs unnecessarily or without understanding the full harms and benefits associated with them. This research should encourage healthy skepticism and assist consumers to assess the content of news stories. It will, hopefully, re-energize consumer groups to build alliances with independent drug information sources. Additionally, this research should also help improve the quality of communication on drugs, especially helping people to ask the right questions when they are presented with the option of drug therapy. Consumers should feel encouraged to read beyond the headlines, to seek out independent sources of drug information, and to demand quality drug information from health practitioners, patient groups and governments.

Newspaper articles that give the impression a drug is simply "good for you" are not helpful to readers unless they also report on what the drug is indicated for, the magnitude of benefits and harms, the drug's costs, and treatment alternatives.

Policy makers

Some of the most obvious policy implications of this research will relate to the nature and extent to which public institutions should be involved in the production, dissemination and evaluation of quality drug information for prescribers and consumers. Public policy makers, particularly those involved in drug benefit plan management, may find value in using some of the issues raised by this research to improve sources of drug information. Health promotion and disease prevention programs could also benefit from this research when planning to launch public information campaigns concerning drugs and other medical technologies.

Reporters are known for their jaundiced eye; as this study has shown, even a bit more healthy skepticism would go a long way towards improving news reports on medicines.

Schools of journalism and health care

Schools of journalism may be encouraged by this research to invest more resources into basic statistical literacy training for students and otherwise prepare students to cover drugs or new medical technologies by asking the right questions.

Since journalists may find independent drug information hard to locate and may tend to forget important issues that need to be covered when reporting a drug story, we have created a "Journalists Guide to Covering Prescription Drugs" (see Appendix C).

University programs that train health care professionals need to inform students that their future patients may demand treatments based on information they received from the media rather than treatment supported by research evidence. Students need to be taught not only how to interpret this information, but how to disseminate it accurately to their patients.

Media outlets

This research may encourage media outlets to invest more resources in having scientifically-trained journalists cover medical issues, or otherwise allow journalists the time and space to do a thorough investigation and report. Cutting corners in medical reporting does no one any favours, especially when it concerns human health. Having a dedicated reporter for medical/science issues, rather than using general reporters who may only have time to cover information provided by a news release, may also improve the quality of reporting.

Doctors/academics

A key message from this research has to be directed towards academic physicians who conduct drug research. If a physician is funded by a pharmaceutical company to carry out a study on the company's drug, he or she should be as open in declaring this conflict of interest in a press conference as in an academic journal. Researchers should participate in industry-funded studies only if there is an adequate "firewall" between the sponsor and the design, analysis and reporting of the study results. Information should be presented in both relative and absolute terms; information on new drugs should be situated within the context of existing treatment alternatives, including older medications and non-drug therapies.

Where is further research needed?

Research that assesses and attempts to improve the quality of medical reporting is vital to ensure health care dollars are spent rationally. Given that the intensity of manufacturers' promotional efforts change over time, and the availability of information on drug safety and longer term efficacy may also increase over time, it would be interesting to examine how media coverage of drugs evolves before, during and after a new drug launch. Following a drug through its product cycle may be a better way to assess the quality of the news coverage it receives.

We were able to look at only one side of the story: how journalists report on a sample of new drugs. We did not look directly at the techniques companies use to promote products to the media, or at the relationship between media concentration and medical reporting.

Research into how information is presented in other forms of media – TV especially – is clearly called for. It would also be useful to research news reporters, their background, training, the length of time they spend on a story, and how often they seek-out independent sources of information. In general, research into what would lead to better and more balanced news reporting on medicines needs to be encouraged. Reporters are known for their jaundiced eye; as this study has shown, even a bit more healthy skepticism would go a long way towards improving news reports on medicines.

APPENDIX A

Newspapers included in the study

Newspapers	Number of articles in the study	Circulation of the paper	Average readership of weekday issue (% of local adults 18+)	Province
Edmonton Journal	20	138,699	44.2%	AB
Victoria Times Colonist	18	71,638	58.5%	BC
Regina Leader-Post	13	52,211	59.6%	SK
Ottawa Citizen	13	138,302	40.0%	ON
Globe and Mail	10	372,704	8.1%	NAT
Saskatoon Star Phoenix	10	55,556	62.2%	SK
Hamilton Spectator	9	106,573	52.7%	ON
La Presse (Montreal)	9	183,771	18.5%	PQ
National Post	9	311,343	7.0%	NAT
Toronto Star	9	460,473	34.0%	ON
Halifax Chronicle-Herald	8	110,440	27.7%	NS
Kitchener-Waterloo Record	8	63,346	43.1%	ON
Vancouver Sun	8	187,991	32.2%	BC
Montreal Gazette	7	136,447	13.4%	PQ
Windsor Star	7	75,408	65.1%	ON
Calgary Herald	6	112,128	41.3%	AB
Toronto Sun	6	216,701	18.8%	ON
Le Soleil (Quebec City)	5	81,205	23.9%	PQ
Edmonton Sun	4	75,775	27.1%	AB
London Free Press	4	94,949	54.9%	ON
Vancouver Province	4	160,334	31.9%	BC
Winnipeg Free Press	4	118,670	51.9%	MB
Calgary Sun	1	69,019	32.4%	AB
Ottawa Sun	1	51,689	18.8%	ON
total: 24 newspapers	**193**			

Sources: Audit Bureau of Circulations FAS-FAX Report – September 30, 2001
2000 NADbank Study
2001 Population Counts for Census Metropolitan Areas – Statistics Canada

APPENDIX B

Common and rare side effects of the study drugs

Drug	Common Incidence of 1% or more	Rare Incidence less than 0.1%
celecoxib	nausea, dyspepsia, GI ulceration or bleeding, diarrhea, headache, dizziness, salt and fluid retention	esophageal ulceration, heart failure, hyperkalemia, renal impairment, confusion, bronchospasm
atorvastatin	myalgia, transient GI symptoms, headache, insomnia, dizziness	rhabdomyolysis, renal failure, hepatitis, liver failure, peripheral neuropathy, anaphylaxis, angioedema, toxic epidermal necrolysis
raloxifene	hot flushes, sweating, leg cramps, peripheral edema, sleep disorders, hyperglycemia	deep vein thrombosis, pulmonary embolism, retinal vein thrombosis
oseltamivir	nausea, vomiting	unknown
donepezil	nausea, vomiting, diarrhea, abdominal pain, dyspepsia, anorexia, headache, insomnia, fatigue, dizziness, tremor, weight loss, muscle cramps, urinary incontinence, increased sweating	syncope, bradycardia, heart block, seizure, hallucination, agitation, confusion, GI hemorrhage, hypertension

Notes

1. This information is taken from the 2002 edition of the Australian Medicines Handbook.
2. There are more rare side effects for celecoxib and atorvastatin but these are the most serious.
3. For raloxifene and donepezil, all the rare side effects are listed.
4. No rare side effects were listed for Oseltamivir.

APPENDIX C

A journalist's guide to covering prescription drugs

☑ *An essential checklist for reporters and editors*

❑ **Drug indications**	What medical conditions has this drug been officially approved to treat? Regulatory approval of a drug for treating specific conditions ensures there is evidence that the drug has some beneficial effect for that condition. If it hasn't been approved for a condition, there is no guarantee the drug can provide any benefit and patients may be needlessly put at risk for side effects. If an unapproved use is discussed in an article, it is worth mentioning that this use has not been approved and there may be little to no evidence of benefits. (For example, oseltamivir is indicated only for people with the flu whose symptoms began less than 40 hours ago – past this point it is unlikely to be of any benefit.)
❑ **Drug contra-indications**	Who should avoid this drug? Contraindications identify who could be more harmed than helped by a drug. (For example, atorvastatin should not be given to pregnant women or patients with liver disease.)
❑ **Clinical benefits**	Do the claimed benefits of the drug have a tangible, meaningful impact on the health of patients? (Atorvastatin may lower cholestorol, but is there evidence that it lowers the chance of heart attack? Donepezil may produce changes on cognitive tests, but does it help patients with daily living activities?) Non-clinical benefits, often called surrogate or intermediate endpoints, can lead to an exaggerated impression of drug effectiveness.
❑ **Clinical harms**	All drugs have risks as well as benefits. Are the harmful effects of the drug mentioned? Is this information presented in as much detail as the benefits, to provide the potential user with a balanced understanding of all of the drug's effects? (For example, the severity of clinical harm can range from the nausea and vomiting sometimes associated with oseltamivir to bleeding ulcers sometimes associated with celecoxib.)
❑ **Magnitude**	Have numbers been included to unambiguously explain the degree of benefit or harm? (For example, without numbers to provide the magnitude of benefits and harms, how is a patient to know if the benefits are proportionally greater than the risks?)
❑ **Absolute numbers**	Have magnitudes of benefits and harms been provided as absolute differences? For example, a medication may reduce the proportion of patients having a heart attack from 10 in 100 to 7 in 100. In relative terms, there is a 30% reduction in risk, while in absolute terms the risk has been reduced by 3%. Relative values can be very misleading and any numbers greater than 10 per cent are usually relative numbers. Journalists should always cite the "absolute" magnitude of benefit or harm.

Time

How long do patients need to take the drug to achieve a benefit? Drug therapies for acute conditions are usually taken over a very specific period of time. Chronic and preventative therapies can be taken over an indeterminate or extended period of time. Audiences should be informed if there is a minimum length of therapy necessary to achieve any benefit and whether benefit and harm profiles can shift during long-term therapy.

Drug and non-drug alternatives

Have drug and non-drug alternatives to the drug of interest been included in the story? There are often several treatments available for a specific problem, including both drugs and other options. Different drug treatments can have radically different benefits and harms or surprisingly similar characteristics depending on their mechanism of action. However, drug alternatives create options for patients when deciding upon a treatment with their physician. Non-drug alternatives such as exercise and diet changes should also be included in any discussion of drugs in the news.

Costs

Has the price of the drug therapy been included in the article? In an ideal world costs would be relevant only when comparing identical drugs, but, as the public ultimately shoulders the burden of high drug expenditures, journalists need to inform their audience of costs. (For example, do consumers feel that taking oseltamivir to possibly shorten flu symptoms from 5-7 days to 4-6 days is worth $45 or more?) The cost of diagnostic tests needed to initiate or monitor a drug prescription should also be considered.

Study design

What kind of research method was used in the study? Research data on drugs is only as good as the study's design, and an opinion survey of 100 people is considerably less reliable than a clinical trial of 1,000 people. A randomized-controlled trial (RCT) is the study design that yields the most reliable drug data. In RCTs, researchers randomly assign patients to drug or placebo treatments with neither the patient nor the researcher knowing who received which. Studies involving more patients for greater periods of time also improve the strength of the data. Publication in peer-reviewed medical journals does not guarantee that the results provide meaningful information for evaluating the safety and effectiveness of new drugs. However, the quality of data presented only at meetings and conferences or published in non-peer reviewed journals is even less certain.

Follow the money

Has pharmaceutical industry funding of any studies and spokespeople been disclosed to the audience? Following the money trail in pharmaceutical reporting can be just as important as in political reporting. While regulatory safeguards are in place to minimize the presence of ineffective and dangerous drugs on the market, financial allegiances can strongly influence the interpretation of drug data. Likewise, pharmaceutical companies provide educational material and guest speakers for public information nights under the guise of patient groups or organizations. Independent sources of drug information are ideal for journalists requiring expert opinion on the quality of drug claims. Below is a list of some drug information resources that are independent of the pharmaceutical industry.

Missing elements

If any of the information mentioned above is unavailable, has the audience been alerted to its absence and the impact this may have on the interpretation of the remaining information? Frequently, study articles and research summaries selectively report information about benefits, harms and study funding. Providing incomplete drug information to the public can be as misleading as inaccurate information.

Independent sources of drug information

Source	Web site	Phone	Fax
Australian Prescriber	www.australianprescriber.com/	61 (2) 6289-7038	61 (2) 6289-8641
CMA Infobase (guidelines)	www.cma.ca/cpgs/	1 (800) 663-7336	1 (613) 565-2382
British National Formulary	www.bnf.vhn.net/home/	Not available	Not available
Cochrane Library	www.cochranelibrary.com/	1 (888) 855-2555	1 (613) 236-8864
Drug and Therapeutics Bulletin	www.which.net/health/dtb/main.html	44 (20) 7770-7571	44 (20) 7770-7665
Drugs of Choice	www.cma.ca/catalog/252.htm	1 (888) 855-2555	1 (613) 236-8864
Food and Drug Administration (USA)	www.fda.gov/cder/	Not available	Not available
Medical Letter	www.medletter.com/	1 (800) 211-2769	1 (914) 632-1733
Prescrire International	www.esculape.com/prescrire/	33 (1) 492-372-65	33 (1) 480-787-32
Therapeutics Letter	www.ti.ubc.ca/pages/letter.html	1 (604) 822-0700	1 (604) 822-0701
Therapeutic Choices	www.cdnpharm.ca/	1 (800) 917-9489	1 (613) 523-0445
Worst Pills, Best Pills	www.citizen.org/hrg/	1 (202) 588-1000	1 (202) 588-7798

Source: Therapeutics Initiative (based at the University of British Columba). "Sources of Drug Therapy Information." *Therapeutics Letter*, Issue 35, May / June 2000. www.ti.ubc.ca/pages/letter35.htm

Endnotes

[1] Canadian Institute for Health Information, 2001. This report estimates total expenditure on prescribed and non-prescribed drugs to be $12.4 billion in 1998. Total drug expenditures will have likely reached $14.7 billion by 2000. In 1985 drugs made up 9.5 per cent of total health expenditures. This has risen each year to approximately 15.5 per cent in 2000. Among major categories of health expenditures, drugs accounted for the second largest share in 1998, after hospitals; physician services ranked third.

[2] Recent consumer research has found that the mainstream media are a close second to health professionals as a source of drug information for Canadians. The work of the Canada Drug Guide Study (Nair, K. et al., 2002) confirmed that consumers place a high amount of trust in the media as an unbiased source of drug information.

[3] Gregg et al., 2001. This survey was funded by Bayer, Inc. and sponsored by the Canadian Science Writers' Association. It also reported that 44 per cent of doctors are asked by patients about medical news stories at least once a week, 26 per cent at least once a day. The reported margin of error was +/-6.4 per cent, 19 times out of 20.

[4] National Health Council, 1997.

[5] Maclure, M. et al., 1998. This is a study of the impact of adverse news about a class of high blood pressure medications called Calcium Channel Blockers. It noted that an educational intervention for physicians, plus stories in the mainstream media, might have had an impact on prescribing of these agents. (See also Phillips, D. et al., 1990; and Wilkes, M. and Kravitz, R., 1992.)

[6] Mintzes, B. and Walker, T., 1998.

[7] Van Trigt, A. et al., 1995.

[8] For better insight into the way PR is used in the launch and promotion of new drugs one should take a look at professional public relations trade magazines where this phenomenon is well reported. For this particular citation see Metcalfe, K. and Rose, H., 2001.

[9] Van Trigt, A. et al., 1994.

[10] A handbook on drug safety produced by the U.S. Consumer Watchdog group Public Citizen entitled *Worst Pills, Best Pills* (Wolfe, S. et al., 1999) reports that most new drugs should come with a "Do not use until five years after release" warning. The authors state that, with the exception of rare "breakthrough" drugs that "provide a documented therapeutic benefit over older proven drugs" new drugs should be treated with extreme caution because we know the least about their safety.

[11] Some of the initial inspiration for this study came from research done at Harvard University led by Australian journalist Ray Moynihan (see Moynihan, R. et al., 2000). Moynihan's study is a landmark document examining the quality of drug information provided by the U.S. media.

[12] The most egregious example of this in the last two decades is the anti-arrhythmic drug Tambocor® (flecanide), which is estimated to have killed up to 50,000 Americans in the mid-1980s. Doctors believed that treating heart arrhythmia (a surrogate marker) with this drug would reduce the risk of death. It was widely prescribed until a proper randomized controlled study found that taking the drug actually *increased* a patient's risk of death. Thomas J. Moore, a professor at George Washington University in Washington, D.C., thoroughly documented the saga of Tambocor® in his book *Deadly Medicine* (see Moore, T.J., 1995). See also Echt, D.S. et al., 1991; and Behar, S. et al., 2000.

[13] Bucher, H.C. et al., 1994.

[14] Hux, J. and Naylor, C., 1995.

[15] Cho, M. and Bero, L., 1996; Djulbegovic, B. et al., 2000.

[16] We reasoned that if the reader would likely infer a clinical benefit from the way the benefits of donepezil are described in the article, they should be coded as such. Evidence seen in clinical trials of donepezil, however, is based on changes in mental/cognition scores on various tests and these are surrogate markers. We are aware that those scores, which form the basis upon which the drug is approved for sale, do not necessarily mean the patient is better able to function in day to day settings.

[17] Mandryk, M., 2000.

[18] The non-disclosure of funding links is also mirrored in the medical literature. In Dorman, P.J. et al., 1999, the authors analyzed randomized trials in acute stroke that were commercially sponsored and found that only a minority of supported trials made explicit statements about the role of the sponsoring company.

[19] Therapeutics Initiative, 2000.

[20] A recent article in *The Lancet* (Berry, D.C. et al., 2002) showed that terms like "common" or "rare" did not accurately connote the magnitude of harm. When given terms instead of actual numbers the study team found that participants vastly overestimated the risk of side effects. People surveyed in shopping malls, libraries and railway stations in the U.K. believed that the risk associated with the word "common" was 50 per cent, and with "rare" was 21 per cent. These estimates are up to 2,000 times greater than the international standard for these frequencies (see next citation).

[21] CIOMS has set international standards defining frequency terms. According to its standard, "very common" is ≥10 per cent of the time; "common" or "frequent" is ≥1 per cent and <10 per cent; "uncommon" or "infrequent" is ≥0.1 per cent and <1 per cent; "rare" is ≥0.01 per cent and <0.1 per cent and "very rare" is <0.01 per cent.

[22] Nakao, M.A. and Axelrod, S., 1983; Loewen, P. et al., 1999.

[23] See Therapeutics Initiative, 2001. This *Therapeutics Letter* used the example of the cholesterol-lowering drug cerivastatin (Baycol®) – which was removed from the Canadian market on August 8, 2001 – to demonstrate the importance of balancing the rate of serious adverse effects (SAEs) against a drug's benefits. The authors conclude that SAEs are an important measure of the health impact of a drug, yet this information is often left unreported in published trials.

[24] All data is drawn from Ettinger, B. et al., 1999, a three year randomized clinical trial of raloxifene in postmenopausal women, measuring its ability to prevent vertebral fractures. We acknowledge that if a reporter states relative benefits and not absolute numbers in an article, is likely due to the fact the medical journals also expressed the numbers that way. Fortunately for journalists (and hence for the general public), medical journals are increasingly supplying both absolute and relative numbers when reporting trial results.

[25] Therapeutics Initiative, 1998.

[26] Bero, L.A. and Rennie, D., 1996.

[27] Dr. Donahue's articles made up 16 per cent of the study sample.

[28] See Moynihan, R., 2000. This study went further in this area than our own, examining the scientific literature to find if financial links of the quoted spokespeople exist. Medical journals typically require authors to disclose all funding links, a practice we believe could bear duplication in the lay press.

[29] Mintzes, B., 1998. See also Johnson, 2000, which profiled the issue of industry-funded patient advocacy groups in Canada.

[30] Mintzes, B. and Walker, T., 1998.

[31] Miller, M.W., 1994.

[32] Moynihan, R. et al., 2000.

[33] See Gregg et al., 1999. While little is known about the quality of the various media with regard to medical reporting, this survey ranked medical trade publications first. Health letters (such as the Berkeley Wellness Letter) and daily newspapers tied for second. Television was rated at the bottom.

[34] Bucher H.C. et al., 1999.

[35] Therapeutics Initiative, 2001.

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