Partisan Perspectives in the Medical Literature: A Study of High Frequency Editorialists Favoring Hormone Replacement Therapy

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BACKGROUND: Unfavorable results of major studies have led to a large shrinkage of the market for hormone replacement therapy (HRT) in the last 6 years. Some scientists continue to strongly support the use of HRT.

OBJECTIVES: We analyzed a sample of partisan editorializing articles on HRT to examine their arguments, the reporting of competing interests, the journal venues and their sponsoring societies.

DATA SOURCES: Through Thomson ISI database, we selected articles without primary data written by the five most prolific editorialists that addressed clinical topics pertaining to HRT and that were published in regular journal issues in 2002–2008.

MAIN MEASURES: We recorded the number of articles with a partisan stance and their arguments, the number of partisan articles that reported conflicting interests, and the journal venues and their sponsoring societies publishing the partisan editorials.

KEY RESULTS: We analyzed 114 eligible articles (58 editorials, 16 guidelines, 37 reviews, 3 letters), of which 110 (96%) had a partisan stance favoring HRT. Typical arguments were benefits for menopausal and related symptoms (64.9%), criticism of unfavorable studies (78.9%), preclinical data that showed favorable effects of HRT (50%), and benefits for major outcomes such as osteoporosis and fractures (49.1%), cardiovascular disease (31.6%), dementia (24.6%) or colorectal cancer (20.2%), but also even breast cancer (4.4%). All 5 prolific editorialists had financial relationships with hormone manufacturers, but these were reported in only 6 of the 110 partisan articles. Four journals published 15–37 partisan articles each. The medical societies of these journals reported on their websites that several pharmaceutical companies sponsored them or their conferences.

CONCLUSIONS: There is a considerable body of editorializing articles favoring HRT use and very few of these articles report conflicts of interest. Full disclosure of conflicts of interest is needed, especially for articles without primary data.

KEY WORDS: hormone replacement therapy; menopause; postmenopausal women.

J Gen Intern Med 25(9):914–9

DOI: 10.1007/s11606-010-1360-7

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INTRODUCTION

When evidence suggests that the large proportion of a blockbuster market and of the activities of a medical specialty are unjustified, both the industry and medical specialists may try to challenge this evidence to maintain the status quo. Some debate is entirely healthy and may include the conduct of more studies or scrutiny of existing studies. However, other efforts may be spurious, such as industry-sponsored ghostwriting of favorable articles with academic authors to advance sales of hormone replacement therapy (HRT) use in menopausal women.¹

HRT has attracted wide attention in the scientific literature and the media. Until 2002, the HRT market had annual sales of many billions of dollars.¹ Handling menopause symptoms nurtured the specialty of menopause medicine and gynecological endocrinology. After 2002, however, the Women's Health Initiative (WHI)² and the Million Women Study (MWS)³ demonstrated considerable harms and more modest benefits from HRT. Currently, perceived harms include increased risks of breast cancer, heart disease, strokes and possibly dementia, and perceived benefits include decreased risks for colorectal cancer, and fractures—besides control of menopausal symptoms. There is still debate on whether specific subgroups/settings exist in which there are more favorable risk-benefit ratios. However, the results of the WHI and MWS studies markedly decreased the use of HRT in the community.^{4,5} Most scientific and public health organizations currently advocate that HRT should have limited, circumscribed, short-term focused applications, not wide use.^{6–9} It is not surprising that this change in clinical practice recommendations would encounter opposition.

Between healthy debate on one hand and drug industry-driven articles on the other, one may identify investigators who genuinely believe in HRT and ardently write supportive editorials, reviews, or other pieces without primary data. The aim of our study was to evaluate how partisan supporters of an intervention continue to defend its wider use despite unfavorable evidence. We identified authors who have published a large number of HRT-favoring editorials and related articles without primary data. We scrutinized their typical arguments and disclosure of potential conflicts of interest, and examined

Electronic supplementary material The online version of this article (doi:10.1007/s11606-010-1360-7) contains supplementary material, which is available to authorized users.

Received September 23, 2009

Revised March 23, 2010

Accepted March 30, 2010

Published online April 28, 2010

whether these articles originate from specific journals and medical societies.

METHODS

Literature Search

We aimed to identify articles without primary data that discussed clinical issues of menopausal hormone therapy and that had been written by authors who had published far more editorializing articles on this subject than other scientists. We first performed a literature search in Thomson ISI with the search strategy estrogen OR hormone replacement OR progestin OR menopause OR postmenopausal OR WHI OR "Women's Health Initiative" limited to the period 2002–2008 (last search performed on January 4, 2009). In this reference corpus, we identified items that are characterized as "Editorial material" by Thomson ISI. We then selected the five authors who had published the largest number of such "Editorial material" items pertaining to HRT in this period.

Many other articles that have no primary data and contain considerable editorializing (e.g., guidelines and reviews) are not included under the "Editorial material" Thomson ISI tag. Therefore, at a second stage, we retrieved all the publications of these selected authors in the reference corpus and evaluated in-depth all their publications that did not report primary data. We then excluded the items that appeared in supplements or proceedings, since they are difficult to locate and usually have less impact in the literature. If anything, this exclusion makes our analysis more conservative, since supplements and proceedings can more easily harbor industry-sponsored articles and hyper-partisan conclusions. For publications in regular journal issues, we retrieved the full text and examined whether there was any discussion of clinical issues on hormones. If so, the article was considered eligible for analysis.

Evaluation of Eligible Articles

For each eligible article, we extracted the following information: title; type of article (editorial; guideline, consensus, or position statement; non-systematic review; systematic review; or letter-to-the-editor); whether clinical issues were the primary focus of the article or not; whether the article had a partisan stance; and, if so, what types of arguments were raised.

The stance of an article was deemed as partisan if there were overall statements in favor of HRT highlighting only benefits or highlighting benefits more than harms, statements making pleas for increased use, or statements criticizing decreased use or criticizing restrictive guidelines. For partisan articles, we noted whether each of the following types of arguments were raised: statements that HRT is effective for menopausal and related symptoms; discussion of preclinical data that showed favorable effects for hormones under at least some circumstances; statements challenging or criticizing studies with unfavorable results for HRT (and if so, whether WHI or MWS were criticized); and statements that HRT may decrease the risk of life-threatening or other serious outcomes (and if so, which). Finally, we recorded whether the article focused on

claiming that some form or setting of hormonal therapy could be particularly beneficial (more effective and/or less harmful) and if so what form or setting was described.

Funding and Conflicts of Interest

In each article of the five most prolific authors, we recorded any disclosed funding source or conflicts of interest. We also examined whether any conflicts of interest were disclosed in any of the analyzed articles. If no conflict was disclosed, we further checked whether they may have co-authored any guidelines, consensus and position statements in their career in any topic where they may have provided such information.

Evaluation of Journals and Societies

For journals that had published over ten eligible articles with a partisan stance, we identified through the web their affiliated scientific society, editorial boards, Thomson Journal Citation Reports 2007 impact factor and proportion of same-journal citations (citations made from other articles published in the same journal). We also examined whether the societies had any corporate sponsors either for their activities overall or for their main scientific meetings, as per their web sites.

Data extraction on all articles including the decision on whether they stated a "partisan" stance for HRT was performed independently by two investigators, and disagreements were resolved by consensus.

RESULTS

Analyzed Articles

The ISI search yielded 63,243 items in the reference corpus; 1,709 were classified as "Editorial material" (Fig. 1), and 2,935 different author names were involved in them. The 1,709 items were published in 426 different journals. The vast majority of authors (2,897/2,935, 98.7%) had authored 1–4 such articles each, and 1.1% (32/2,935) had authored 5–12 such articles each, while 6 authors had published more than 12 "Editorial material" items. Five of these six authors editorialized primarily about clinical issues on HRT, and they stood clearly apart in the number of HRT-related editorials compared with all other authors. These five scientists were all active in the field of gynecological endocrinology and had published 337 articles included in the reference corpus during 2002–2008. After excluding articles with primary data, items published in meeting supplements or proceedings, and articles without discussion of hormone-related clinical issues, 114 articles were evaluated in-depth (Fig. 1; included articles are listed in online Appendix 1).

Partisan Stance

Several titles were already clearly suggestive of a partisan, if not polemical, stance, for example, "WHI, WHI, WHI?" (S65),

Figure 1. Flow chart.

"Risks for healthy women in the WHI greatly overestimated according to new publications" (S73), "Should epidemiology, the media and quangos determine clinical practice?" (S77), "The sound of an International anti-HRT herald!" (S85), "The study with a million women (and hopefully fewer mistakes)" (S86), "A personal initiative for women's health: to challenge the Women's Health Initiative (S107)" (full list appears in online Appendix 2).

Of the 114 articles, 58 were editorials, 16 were guidelines, consensus or position statements, 35 were non-systematic reviews, two were systematic reviews, and three were letters-to-the-editor. Of the 58 editorials, only 7 were written to comment on a specific article with primary data that was published in the same issue of the journal. All the others were impromptu statements favoring HRT or arguments against WHI. For 95 articles, the clinical issues were the primary focus of the article. One hundred ten articles (96%) were deemed to have a partisan stance (98% agreement between data extractors). Of the non-partisan articles, one was a systematic review, and three were non-systematic reviews.

Table 1 shows the various types of partisan arguments, and verbatim examples appear in online Appendix 3. Two-thirds of

Table 1. Types of Partisan Arguments in 114 Analyzed Editorializing Articles Published Between 2002 and 2008

	N (%)
HRT ^a is effective for menopausal and related symptoms	74 (64.9)
Discussion of preclinical data that showed favorable effects for HRT	57 (50.0)
Statements challenging/criticizing unfavorable studies	
Against WHI ^b	89 (78.1)
Against MWS ^c	29 (25.4)
Statements that HRT ^a may decrease life-threatening and other serious outcomes	
Breast cancer	5 (4.4)
Cardiovascular disease	36 (31.6)
Stroke	2 (1.8)
Dementia	28 (24.6)
Ovarian cancer	0
Endometrial cancer	2 (1.8)
Colorectal cancer	23 (20.2)
Osteoporosis/fractures	56 (49.1)
Other	
Hypertension	3 (2.6)
Diabetes mellitus	3 (2.6)
Depression	10 (8.8)
Metabolic syndrome	2 (1.8)
Osteoarthritis	3 (2.6)

^aHRT: hormone replacement therapy; ^bWHI: Women's Health Initiative; ^cMWS: Million Women Study

the articles highlighted the effectiveness of HRT for menopausal and related symptoms, half discussed pre-clinical data showing favorable effects, most articles had statements criticizing WHI and one out of five challenged MWS. Furthermore, several articles included statements that HRT may decrease life-threatening or other serious outcomes. Osteoporosis/fractures were mentioned by about half the articles, a third discussed benefits for cardiovascular disease, and a quarter discussed benefits for dementia. Numerous other benefits were discussed (Table 1), including even claims for reduction of breast cancer risk.

Some arguments were phrased in a repetitive fashion across different articles, even to the point of having, in some cases, whole sentences or paragraphs repeated almost verbatim. Moreover, sometimes the same article was apparently published by the same or overlapping authors two or three times in the same or in different journals—in English, or in English and in German—during the same period of time without referencing each other (examples in online Appendix 4).

Twenty-two articles made suggestions or clearly stated that some form or setting of hormonal therapy could be particularly beneficial. Specifically, eight articles focused on a specific type of hormone, seven on time of therapy initiation and one on patient age, six on route of administration, two on dose, two on use in non-smokers, one on hypertensive patients, and one on co-administration with another drug.

Funding and Conflicts of Interest

Four articles clearly stated there was no funding, and eight reported funding sources (five reported support from a pharmaceutical company and three from a private foundation for art and culture). Five articles clearly stated there were no conflicts of interest and five reported potential conflicts (four of

which consisted of relationships with pharmaceutical companies involving consultative agreements, honoraria for lecturing at scientific meetings or research support). Six of the eight articles that reported funding sources and all five articles stating potential conflicts had a partisan stance. Of the 16 guidelines, consensus and position statements, only 2 reported on funding sources, and only 1 reported conflicts of interest.

All five prolific authors disclosed in at least one of their articles that they had been funded by industry or that they had been related to some potential conflict of interest. However, these relationships with hormone manufacturers were revealed in only 6 of their 110 partisan articles; in the other 104 articles, no such disclosure was stated.

Journals and Societies

The 110 articles with a partisan stance were published in 19 different journals, but most (91/110) appeared in just 4 journals that published 15 to 37 articles each (Table 2). These journals are the official scientific journals of societies related to menopause and gynecological endocrinology. Their impact factor varies from 0.502 to 2.275. The journal with the lowest impact factor has an extremely high same-journal citation rate (88%, 95% CI 82%–94%). The other three have same-journal citation rates of 13–19%. These three journals also had relationships with the five authors we evaluated: one to three of these five authors sit on the editorial boards of each of these three journals. Evaluation of websites of the societies that publish these journals showed that almost all of these societies have disclosed some relationships with manufacturers of HRT medications. The International Menopause Society organizes workshops sponsored by several pharmaceutical companies. The European Menopause and Andropause Society is sponsored by Wyeth, which is mentioned as a corporate member at the society's website. The International Society of Gynecological Endocrinology organizes the World Congress of Gynecologic Endocrinology, which is supported by several companies. Finally,

the Deutsche Gesellschaft für Gynäkologie und Geburtshilfe has pharmaceutical company prizes awarded at its congresses.

INTERPRETATION

We have identified a substantial body of editorializing literature that has a partisan stance in favor of HRT. These articles include mostly editorials, non-systematic reviews, guidelines and consensus statements. They use a standard armamentarium of arguments to support HRT and to criticize the large studies that demonstrated problems with HRT. Similar arguments are repeated across different articles. Four journals have contributed most of the editorializing literature that we analyzed. Both the prolific editorializing authors and the professional societies publishing these journals had relationships to the pharmaceutical industry. However, only 6 of the 110 partisan articles specifically mentioned any such funding or conflicts of interest.

Experience from other fields suggests that even when large trials contradict previous beliefs about the benefits of various interventions, a section of the medical literature continues to support previous practices and raises counterarguments as to why the large studies were wrong. This "die hard" pattern has been demonstrated in vitamin E for cardiovascular prevention, beta-carotene for cancer prevention, estrogen for dementia prevention¹⁰ and percutaneous coronary intervention for stable chronic coronary artery disease¹¹ (in the latter case, the source of resistance came primarily from interventional cardiologists).¹² Moreover, the key vehicle of expressing doubts about large trials has been through editorials and expert statements. Similarly, our study documents a large literature of editorializing articles that emanate from authors and societies involved in the promotion of HRT.

Defending one's practices is not unethical, and many of the arguments raised have some validity or may even be correct. The authors of these articles may be excellent scientists. However, it is concerning that almost none of these partisan articles reported the conflicts of interest of their authors. Obviously, the average reader would not have time to investigate the whole publication corpus of an author to determine whether he or she ever reported any conflicts of interest. Omission of conflicts of interest was prominent not only for short editorials, but also for guideline and consensus articles that were typically sponsored by these professional societies. As of January 2010, three of the four journals that hosted most of the editorializing articles clearly reported (in their instructions to authors) that authors should disclose any conflicts of interest in their manuscripts, and the fourth journal (Geburtshilfe und Frauenheilkunde) mentioned that authors should provide notes for financial or other support in a footnote at the end of the text. Given that these instructions to the authors are online, it is unclear when these policies were implemented. Reporting of conflicts is a responsibility both of the editorialists and of the journals that should ensure that transparent reporting of conflicts is actually enforced.

Most professional societies have industry ties: industry sponsors their meetings, provides awards/grants, and maintains a team of speakers from society members. Societies sponsor and publish scientific journals, and propagate practice guidelines

Table 2. Journals Publishing the Largest Number of Partisan Editorials and Related Articles Without Primary Data Between 2002 and 2008

Journal ^a	Articles	Scientific society	Impact factor	Self-cites
Climacteric	37	IMS ^b	2.275	39/207
Maturitas	20	EMAS ^c	2.023	100/615
Gynecological endocrinology	19	ISGE ^d	1.169	34/277
Geburtshilfe und Frauenheilkunde	15	DGGG ^e / OEGGG ^f	0.502	103/117

^aNineteen journals published the 110 partisan articles that we analyzed, but the 15 journals not shown here had each published only 1–3 such articles

^bIMS: International Menopause Society

^cEMAS: European Menopause and Andropause Society

^dISGE: International Society of Gynecological Endocrinology

^eDGGG: Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (German Society for Gynecology and Obstetrics)

^fOEGGG: Österreichischen Gesellschaft für Gynäkologie und Geburtshilfe (Austrian Society for Gynecology and Obstetrics)—no web site was identified for OEGGG

that influence their members. This creates intricate relationships with industry,^{12–21} especially for societies whose core practice is related to specific products, as is the case for menopause specialists and HRT.

Pharmaceutical involvement in research may affect study design, focus and results,^{22–25} and authors' published positions correlate with financial relationships with manufacturers in review articles and letters to the editor.²⁶ There are also strong interactions between industry and authors of practice guidelines.²⁷ Otherwise excellent scientists may be tempted to produce editorials with non-evidence-based claims. Almost all major field experts have potential financial conflicts; while it is hard to find experts without any conflicts,²⁸ disclosure is essential.²⁹

We built our search for eligible articles around the most prolific partisan editorialists, and this is just a selected fraction of all the editorials written on HRT. However, these authors clearly stood apart in the volume of their editorializing articles when compared with the other 3,000 authors who have written mostly sporadic editorials. Similarly, four specialty journals clearly stood apart in the volume of partisan editorializing items compared with all other journals that may have some interest in the field. The cumulative impact on clinical practice is shaped by diverse opinion leaders, both those who write numerous partisan articles and those who may write a few non-partisan ones. For HRT, most high-impact authorities have made conservative statements about its use. This includes the American Heart Association⁷, the North American Menopause Society⁸, the Canadian Task Force on Preventive Health Care⁹ and the American College of Obstetricians and Gynecologists⁶ (the first three of these also report conflicts of interest in their publications). The cumulative influence of these major authorities is apparently higher than that of concentrated partisan publications in journals with modest impact. Moreover, hundreds of journals published editorials on HRT, and most of them published only a few such items. Even single editorials may have a considerable impact, especially if published in high-impact journals. However, most high-impact general medical journals have very strict policies for conflicts of interest and stringent review filters. Extremely partisan positions may be more difficult to publish in editorials in such journals. Specialty journals sponsored by professional societies may thus be a more convenient publication venue for partisan editorialists.

Finally, we do not wish to make claims about the underlying motives for each article in the partisan literature. Previous studies^{30–33} have pointed even to guest authorship and ghost-writing practices in developing a pro-industry literature. For HRT in particular, several months ago an investigation was announced by Senator Grassley¹ claiming that Wyeth and leading HRT experts were involved in ghost- and guest-authorship favoring Prempro (a combination of estrogen and progesterone). Recently, the Institute of Medicine suggested that medical schools should abandon long-accepted relationships with the industry and practices that create conflicts of interest, threaten the integrity of their missions and their reputations, and jeopardize public trust.³⁴ Nonetheless, we do not intend to blame the authors of the specific articles we examined. The mere wish to defend one's practice, procedures and scientific beliefs may be sufficient explanation, and all the authors involved in these articles may have been fully responsible for and sincere in their writings. However, this complex background where large drug markets are at stake further highlights the need for full

disclosure of conflicts of interest to promote discernment among readers and prevent mistrust.

Author Contributions: Dr. Ioannidis had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Funding/Support: None

Conflict of Interest: None disclosed.

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