IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF ARKANSAS
WESTERN DIVISION

In re:	MDL Docket No:4:03CV1507WRW
PREMPRO PRODUCTS LIABILITY LITIGATION	ALL CASES
UNNAMED PLAINTIFFS	**DECLARATION OF VIRGINIA BARBOUR IN SUPPORT OF THE PUBLIC LIBRARY OF SCIENCE'S MOTION TO INTERVENE AND MOTION FOR ACCESS TO DISCOVERY MATERIALS**
v.	
WYETH, and its divisions WYETH PHARMACEUTICALS, INC. and ESI LEDERLE, PFIZER, INC., PHARMACIA and UPJOHN COMPANY, PHARMACIA CORPORATION, GREENSTONE, LTD., BARR PHARMACEUTICALS, INC., BARR LABORATORIES, DURAMED PHARMACEUTICALS, INC., BRISTOL-MYERS SQUIBB COMPANY, NOVARTIS PHARMACEUTICALS CORPORATION, SOLVAY PHARMACEUTICALS, INC., formerly known as REID-ROWELL, INC., SOLVAY AMERICA, INC., SOLVAY S.A., GALEN HOLDINGS, PLC, WARNER CHILCOTT, BERLEX LABORATORIES, INC., SCHERING, AG, WATSON PHARMACEUTICALS, INC., ABBOTT LABORATORIES, MYLAN LABORATORIES, INC., and ORTHO-MCNEIL PHARMACEUTICAL, INC.	
Defendants.	

I, VIRGINIA BARBOUR, hereby declare as follows:

1. I am the Chief Editor at the international open access medical journal *PLoS Medicine* (www.plosmedicine.org), published by the Public Library of Science (PLoS). I trained in Natural Sciences and Medicine at Cambridge University and University College London. I specialized in Hematology and then qualified as a Doctor of Philosophy (DPhil – equivalent to a PhD) in Molecular Hematology at Oxford University. I trained as an editor at *The Lancet* and then joined PLoS to launch *PLoS Medicine* in 2004.

2. PLoS is a a tax-exempt, 501(c)3, nonprofit corporation with headquarters in San Francisco, CA, USA and Cambridge, England. The mission of PLoS is to make the world's biomedical literature a freely available public good. PLoS publishes seven biomedical journals, including *PLoS Medicine*, and all are open access—this means that every article is free to read (there is no charge to access it) and free to reuse for all legal purposes (e.g., it is legal to make copies, translations, and derivative works provided the authors are given proper credit).

3. *PLoS Medicine* is a "top tier" general medical journal—by one metric (known as the journal impact factor) it is ranked as 4th among the world's general medical journals. *PLoS Medicine* is unusual compared with other general medical journals (such as the *New England Journal of Medicine* or *The Lancet*) in two important ways. First, we are the only top tier general medical journal that refuses to publish paid advertisements for drugs or medical devices. Second, unlike other top tier medical journals, we allow anyone to make unlimited numbers of copies of any paper. What this means is that we do not benefit financially from "exclusive reprint sales" to drug companies. Other top tier

medical journals own an exclusive copyright on the papers that they publish, and they sell thousands of copies of these papers (known as "reprints") to drug companies. The drug companies purchase these reprints in order to distribute them to prescribing physicians and thus promote their drugs. These two unique features of *PLoS Medicine* mean that we have a greater degree of independence from the pharmaceutical industry than other medical journals.

4. There are a number of ways that drug companies are believed to attempt to manipulate the medical literature. Such manipulation occurs as part of the highly strategic, coordinated, and well-funded promotional activities of pharmaceutical companies targeted at physicians. Components include:

- sponsoring clinical trials of their products (trials funded by the pharmaceutical industry are more likely to produce results favorable to industry than trials with a non-profit or public sponsor);
- placing advertisements for drugs and devices in academic medical journals to encourage physicians to use these products;
- purchasing reprints of articles in medical journals that are favorable to a drug company (including articles that the company ghost authored) and distributing these articles to prescribing physicians;
- drug detailing, i.e., one-on-one promotion of drugs to doctors by pharmaceutical sales representatives (about $5 billon per year is spent in the US on detailing);
- and medical ghostwriting, which occurs when someone contributes substantially to writing a manuscript in a medical journal and yet this author's role is not mentioned when the manuscript is published.

Writing in *PLoS Medicine*, Dr Sergio Sismondo of Queen's University, Kingston, Ontario, Canada uses the term "ghost management" to describe the broad range of hidden activities that influence the final published paper. Sergio Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, PLOS MED., vol. 4(9) at e286 (2007) (attached as Exhibit 1). Ghost management, he says, is when: "pharmaceutical companies and their agents control or shape multiple steps in the research, analysis, writing, and publication of articles. Such articles are 'ghostly' because signs of their actual production are largely invisible—academic authors whose names appear at the tops of ghost-managed articles give corporate research a veneer of independence and credibility. They are 'managed' because those companies shape the eventual message conveyed by the article or by a suite of articles."

5. Medical ghostwriting is a particularly troubling form of manipulation. When they are appropriately acknowledged for their involvement, medical writers paid by drug companies (usually the drug companies contract with medical writing companies rather than individual writers) may have a legitimate role in helping shape papers for publication. However, when the medical writers' involvement is *hidden* they become ghostwriters, and hence they are unaccountable for their work. The fact that ghostwriters are paid for by drug companies, and that their role is by definition hidden, suggests that it is likely that they will write about a company's products in a biased way (i.e., ghostwriters are likely to write favorably about the products). When ghost writers are used, readers are unaware that the company was ever involved in shaping the article's

contents. Instead, the published article bears only the names of academic physicians or scientists, who are often highly renowned and trusted in their fields. By keeping the company's role in the article hidden, the article has greater credibility in the eyes of the medical community, and thus greater opportunity for influencing the prescribing behavior of physicians.

6. Several different types of articles in medical journals have involved ghostwriters—including research papers, expert commentaries from "key opinion leaders" (those whose views can shape how physicians practice medicine), and articles that review the evidence on whether a treatment works or not (known as "review articles"). Ghostwriting encompasses a number of different activities, in which a drug company's involvement in shaping the article is kept hidden. "Ghost authorship" (a broader term than "ghost writer") may involve, for example, a "ghost statistician" from industry who gives input into the analysis of the data (the role of the company statistician is kept hidden when the final article is published). Ghostwriting appears to be a common phenomenon (i.e., it is unlikely to be restricted to a few isolated cases). However, because of its hidden nature, it is very difficult to estimate the exact prevalence of ghost authorship. Studies using three different types of research method have attempted to estimate its frequency:

- One method is to confidentially survey those authors whose names *do* appear on a published article—and ask them whether there were any individuals who provided writing assistance or made other contributions but who were not named as authors. One study that used this method, by Annette Flanagin and colleagues, found that 11% of articles published in three large-circulation academic general

medical journals had evidence of ghost authors. Annette Flanagin *et al.*, *Prevalence of Articles With Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals*, 280 JAMA 222, 222-224 (1998) (attached as Exhibit 2).

- A different method relies on the fact that before a clinical trial can be conducted, the researchers doing the trial must write a detailed trial protocol explaining what they will do and how the data will be analyzed. These trial protocols name the people who will do the study and those who will analyze the data. Protocols are submitted to institutional review boards (IRBs) ahead of a trial being performed. By requesting a copy of these protocols from the IRBs, one can then compare the names which appeared in the protocol against names appearing on the eventual published paper to look for evidence of ghost authorship. In a study published in *PLoS Medicine*, Peter Gøtzsche and colleagues used this method to study industry-initiated trials approved by the Scientific-Ethical Committees for Copenhagen and Frederiksberg in Denmark in 1994–1995. Peter Gøtzsche *et al.*, *Ghost Authorship in Industry-Initiated Randomised Trials*, PLoS MED., vol. 4(1) at e19 (2007) (attached as Exhibit 3). They found evidence for ghost authorship in 75% of the published trial reports.
- A third method is to study drug company documents that are made public through litigation. Two studies used this method:
    - Joseph Ross and colleagues analyzed documents originally obtained during litigation against Merck & Co, Inc. related to the drug rofecoxib (Vioxx). The documents were Merck internal and external

correspondence, reports, and presentations. Joseph Ross *et al.*,*Gue st Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation*, 299 JAMA 1800, 1800-12 (2008) (attached as Exhibit 4). Several documents described Merck employees contracting with medical publishing companies to ghostwrite review articles about Vioxx and subsequently recruiting academic researchers to be guest authors. These contracts led to the publication of 72 review articles about Vioxx—but only 36 of these articles (50%) included a disclosure of Merck sponsorship or a disclosure of whether the author had received any financial compensation from Merck.

- David Healy and Dinah Cattell examined documents produced by a medical publishing company called Current Medical Directions (CMD), which had been contracted by the drug company Pfizer to ghostwrite articles about the antidepressant drug Zoloft (setraline). David Healy and Dinah Cattell, *Interface Between Authorship, Industry and Science in the Domain of Therapeutics*, 183 British J. Psychiatry 22, 22–27 (2003) (attached as Exhibit 5). The documents, which were produced in 1999 and were made public in litigation against Pfizer, listed all the articles about Zoloft that CMD had produced for Pfizer. Healy and Cattell compared this list with the published medical literature on Zoloft over a 3-year period to see what had happened to the papers written by CMD. They

found that 55 out of the 96 published articles on Zoloft in the peer-reviewed medical literature had originated from CMD.

7. Given the relatively few research articles in this area, much of our knowledge of ghost writing has necessarily come from a small number of personal anecdotes:

- Some academic authors have described their experiences of having been approached by drug companies to put their names to a ghostwritten article. For example, the academic physician Dr Adriane Fugh-Berman at Georgetown University School of Medicine has described how the drug company AstraZeneca asked her to put her name to a ghostwritten article. Adriane Fugh-Berman, *Not In My Name*, THE GUARDIAN, April 21, 2005, available at http://www.guardian.co.uk/science/2005/apr/21/science.research (attached as Exhibit 6).
- Some medical writers have admitted that they were paid by drug companies to ghostwrite articles. For example, in the British medical journal *The Lancet*, Marilynn Larkin shared her experiences of being a ghost writer: "I recently had my first and last experience as a 'ghostwriter' for a medical communications company. I agreed to do two reviews for a supplement to appear under the names of respected 'authors.' I was given an outline, references, and a list of drug-company-approved phrases. I was asked to sign an agreement stating that I would not disclose anything about the project. I was pressured to rework my drafts to position the product more favourably, and was shown another company-produced review as an example —it read like bad promotional writing." Marilynn Larkin,

Whose Article Is It Anyway?, 354 THE LANCET 136, 136 (1999) (attached as Exhibit 7).

8. The editors of *PLoS Medicine* consider ghostwriting to be an unacceptable and deceptive practice. This view is held by other editors. The World Association of Medical Editors considers ghostwriting to be "dishonest and unacceptable." World Association of Medical Editors, *Ghost Writing Initiated by Commercial Companies*, J. GEN. INTERN. MED., vol. 20(6) at 549 (2005) (attached as Exhibit 8). Writing in *PLoS Medicine* recently in a commissioned debate about ghostwriting, Jerome Kassirer, the former editor-in-chief of the *New England Journal of Medicine*, noted the potential of medical ghostwriting to distort the medical literature, which occurs by "a pharmaceutical company's marketing department promoting one of its products by carefully selecting positive reports and deemphasizing the product's risks, and then paying a well-known academic author to submit the paper for publication without attribution." Jerome Kassirer *et al. What Should Be Done To Tackle Ghostwriting in the Medical Literature?*, PLoS Med., vol. 6(2) at e1000023 (2009) (attached as Exhibit 9). Doctors rely largely on medical journals to obtain up-to-date information on which treatments work and which do not. Medical journal articles—particularly those published in prestigious journals—are perceived by doctors as being authoritative and these articles have a major impact on how doctors treat patients. Ghostwriting has the potential to substantially distort the scientific record, and hence threaten the validity and credibility of medical knowledge. In an invited lecture given to the American Medical Writers' Association (a group that includes professional writers who have been employed by drug companies to ghost write articles),

Gavin Yamey, a former assistant editor at the *British Medical Journal* (BMJ) and now a Senior Editor at *PLoS Medicine*, said that ghostwriting is a "shadowy practice that has little to do with improving health care, and everything to do with profit." Gavin Yamey, *Who Stands Behind the Word? A Journal Editor's View of Ghostwriting*, available at http://www.bibalex.org/Supercourse/SupercoursePPT/15011-16001/15071.ppt (attached as Exhibit 10).

9. *PLoS Medicine* has an interest in documenting ghostwriting and its negative effects. We believe that the scientific integrity of any medical journal article depends not just on the quality of the science being reported, but on the honesty and transparency of the authorship. In other words, our faith in the scientific record depends a great deal upon our faith in honest authorship. Ghostwriting is a deceitful and manipulative practice that threatens the scientific record. The World Association of Medical Editors states: "The scientific record is distorted if the primary purpose of an article is to persuade readers in favor of a special interest, rather than to inform and educate, and this purpose is concealed." World Association of Medical Editors, *Ghost Writing Initiated by Commercial Companies*, J. GEN. INTERN. MED., vol. 20(6) at 549 (2005) (attached as Exhibit 8). *PLoS Medicine* has published a number of articles on the practice of ghost writing (such as Sergio Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, PLOS MED., vol. 4(9) (2007); Peter Gøtzsche *et al.*,*Ghost Authorship in Industry-Initiated Randomised Trials*, PLOS MED., vol. 4(1) (2007); Jerome Kassirer *et al. What Should Be Done To Tackle Ghostwriting in the Medical Literature?*, PLOS MED., vol. 6(2) (2009); Elizabeth Wager, *Authors, Ghosts, Damned Lies, and Statisticians*, PLOS MED,, vol. 4(1)

at e34-0005 (2007) (attached as Exhibit 11)), including a recent editorial written by the editors called "An Unbiased Scientific Record Should Be Everyone's Agenda." The *PLoS Medicine* Editors, *An Unbiased Scientific Record Should Be Everyone's Agenda*, PLOS MED. vol. 6(2) at e1000038 (2009) (attached as Exhibit 12). *PLoS Medicine* has also signed up to a policy statement aimed at uncovering the use of ghost writers in articles submitted to the journal, while at the same time allowing the legitimate use of appropriately acknowledged medical writers. Adam Jacobs and Elizabeth Wager, *European Medical Writers Association (EMWA) Guidelines on the Role of Medical Writers in Developing Peer-Reviewed Publications* (2005), available at http://www.emwa.org/Mum/EMWAguidelines.pdf (attached as Exhibit 13). This policy statement was written by the European Medical Writers Association (EMWA), which developed the statement to "provide guidance for medical writers and to outline the legitimate role of professional writers in developing publications." The EMWA statements declares: "The involvement of medical writers and their source of funding should be acknowledged. Identifying the writer, either as an author or contributor or in the acknowledgements section, helps readers, reviewers, and journal editors to understand how the manuscript was developed, and recognises the writer's involvement. Identifying the writer's funding source ensures transparency and makes readers aware of any potential conflicts of interest." *Id.*

10. Despite the evidence above, the exact details of how drug companies coordinate and orchestrate their ghostwriting campaigns remain unclear. Moffatt and Elliott argue that so far we've only had "glimpses" of the details of corporate ghostwriting through a few anonymous surveys and a handful of lawsuits. Barton

Moffatt and Carl Elliott, *Ghost Marketing: Pharmaceutical Companies and Ghostwritten Journal Articles*, 50 PERSPECTIVES IN BIOLOGY & MED. 18 (2007) (attached as Exhibit 14). Three of these glimpses include:

- Healy and Cattell's study of medical articles about Zoloft. *See* Exhibit 5. Healy and Cattell found that the articles about Zoloft that were ghostwritten by CMD for Pfizer were uniformly positive about the drug and under-reported its side effects.
- Evidence of ghostwriting that was produced in litigation surrounding the diet drug Fen-Phen (fenfluramine-phentermine), made by Wyeth-Ayerst. *See* Exhibit 14. The drug was withdrawn from the market in 1997 after being linked to valvular heart disease. One year previously, in 1996, Wyeth-Ayerst had hired ghostwriters at Excerpta Medica Inc, a New Jersey-based medical communications firm, to write ten articles for medical journals promoting Fen-Phen. Wyeth paid Excerpta Medica $15,0000 - $20,000 per article and, in turn, Excerpta Medica paid prominent university researchers $1,000 to $1,500 to edit drafts of their articles and put their names on the published product. Subsequent lawsuits filed by injured Fen-Phen users unearthed internal company documents showing that Wyeth-Ayerst had "edited the draft articles to play down and occasionally delete descriptions of the drug's side effects." Testimony of Sheldon Rampton, Research Director, Center for Media and Democracy, before the U.S. House of Representatives Committee on Science and Technology, March 28, 2006, available at http://www.prwatch.org/node/5899 (attached as Exhibit 15).

- The example of potential distortion of the literature shown in documents released after litigation related to rofecoxib (Vioxx). *See* Exhibit 4. This case study is probably the most compelling reason why it is essential to document the extent and effects of ghostwriting.

The three cases listed above show how important litigation has been at revealing the extent and public health harms of ghostwriting.

11. We now have a tremendous opportunity to find out more about corporate ghostwriting and its influence upon the medical literature and on public health. According to an article published in the *New York Times*, significant ghostwriting has occurred with respect to the prescription drug Prempro. Duff Wilson, *Drug Maker Said to Pay Ghost Writers for Journal Articles*, N.Y. TIMES, December 12, 2008, available at http://www.nytimes.com/2008/12/12/business/13wyeth.html (attached as Exhibit 16). In that article, James Szaller, an attorney involved in a multidistrict litigation regarding the hormone replacement therapy Prempro (combination conjugated equine estrogens plus medroxyprogesterone acetate), states: "For the last three years, I've looked at ghostwriting at Wyeth . . . . There is a mammoth amount of material. The problem is that almost all of it is still under seal." This *New York Times* article suggests that the sealed documents contain evidence of an orchestrated ghostwriting campaign. *PLoS Medicine* believes that it is crucially important to unseal these documents so that we can see the extent of this campaign—did it involve ghostwriting, ghost authorship, ghost management, or all three, and did public health harms result from these 'ghost' activities? We cannot know until the documents are unsealed.

12. On July 9, 2002, the National Heart, Lung, and Blood Institute announced that it was stopping its study of Prempro (a study that was part of the Women's Health Initiative [WHI] trial). Center for Drug Evaluation and Research, *FDA Statement on the Results of the Women's Health Initiative* (Aug. 2002), available at http://www.fda.gov/cder/drug/safety/WHI_statement.htm (attached as Exhibit 17). The study was initially conducted to assess whether long term Prempro use would reduce the risk of coronary heart disease in postmenopausal women. The study was stopped early because the risks of Prempro, particularly the risks for "invasive breast cancer and coronary heart disease, exceeded the benefits of the drug, which included a lower rate of fractures and a reduction in the risk of colorectal cancer." *Id.* A recent follow-up study by Rowan Chlebowski and colleagues, on behalf of the WHI investigators, in the *New England Journal of Medicine* states: "The Women's Health Initiative (WHI) trial of conjugated equine estrogens plus medroxyprogesterone acetate was stopped when health risks were shown to exceed the benefits of combined hormone therapy. The incidence of breast cancer was higher in the hormone-therapy group, and the cancers were larger and more advanced; in addition, the frequency of abnormalities on mammograms and of breast biopsies was increased in the hormone-therapy group." Rowan Chlebowski *et al.*, *Breast Cancer After Use of Estrogen Plus Progestin in Postmenopausal Women*, 360 NEW ENG. J. MED. 573, 573-87 (2009) (attached as Exhibit 18). Chlebowski and colleagues note that, after the early stopping of the WHI trial, the use of menopausal hormone therapy in the United States decreased substantially, and subsequently the incidence of breast cancer also dropped. Based on their research, these authors conclude:

"The increased risk of breast cancer associated with estrogen-plus-progestin therapy declined markedly soon after discontinuation of the therapy and was unrelated to a change in the use of mammography. This finding supports the hypothesis that the recent reduction in the incidence of breast cancer among women in certain age groups in the United States is predominantly related to a decrease in the use of combined estrogen plus progestin." *Id.*

13. Mr Szaller has publicly stated that the sealed discovery materials contain evidence of an extensive ghostwriting campaign orchestrated by Wyeth designed to conceal the risks associated with taking Prempro. *See* Exhibit 16. *PLoS Medicine* seeks to intervene in the Prempro case in order to unseal these discovery materials. According to a *New York Times* article on Senator Charles Grassley's investigation of Wyeth's use of ghostwriters, some documents showing evidence of ghostwriting in this case have been publicly released. These documents, says the *New York Times*, "show company executives came up with ideas for medical journal articles, titled them, drafted outlines, paid writers to draft the manuscripts, recruited academic authors and identified publications to run the articles — all without disclosing the companies' roles to journal editors or readers." *Id.* The public documents, however, only appear to give glimpses of Wyeth's orchestrated ghostwritten campaign.

14. As noted above, although there is some evidence that ghost writing is a pervasive practice, this evidence is largely anecdotal and sporadic. The documentation of a systematic campaign by a company, especially one that may have led to the concealment of serious side effects, will lead to further calls to bring this practice to an end.

PLos Medicine believes that there is now a very strong public health case to be made for unsealing the sealed documents—we have a rare opportunity to make public a documented example of a coordinated ghostwriting campaign.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on: 14 May, 2009

VIRGINIA BARBOUR
Chief Editor, *PLoS Medic ine*

Attachments

1. Serg io Sismondo, *Ghost Management: How Much of the Medical Literature Is Shaped Behind the Scenes by the Pharmaceutical Industry?*, PLOS MED., vol. 4(9) (2007).
2. Anne tte Flanagin *et al.*, *Prevalence of Articles With Honorary Authors and Ghost Authors in Peer-Reviewed Medical Journals*, 280 JAMA 222 (1998).
3. Pete r Gøtzsche *et al.*,*Ghost Authorship i n Industry-Initiated Randomised Trials*, PLOS MED., vol. 4(1) (2007).
4. J oseph Ross *et al.*,*Gue st Authorship and Ghostwriting in Publications Related to Rofecoxib: A Case Study of Industry Documents from Rofecoxib Litigation*, 299 JAMA 1800 (2008).
5. Da vid Healy and Dinah Cattell, *Interface Between Authorship, Industry and Science in the Domain of Therapeutics*, 183 British J. Psychiatry 22 (2003).
6. Adr iane Fugh-Berman, *Not In My Name*, THE GUARDIAN, April 21, 2005.
7. Mar ilynn Larkin, *Whose Article Is It Anyway?*, 354 THE LANCET 136 (1999).
8. W orld Association of Medical Editors, *Ghost Writing Initiated by Commercial Companies*, J. GEN. INTERN. MED., vol. 20(6) (2005).
9. J erome Kassirer *et al. What Should Be Done To Tackle Ghostwriting in the Medical Literature?*, PLOS MED., vol. 6(2) (2009).
10. Gavin Yamey, *Who Stands Behind the Word? A Journal Editor's View of Ghostwriting*, available at http://www.bibalex.org/Supercourse/SupercoursePPT/15011-16001/15071.ppt.
11. Elizabeth Wager, *Authors, Ghosts, Damned Lies, and Statisticians*, PLOS MED., vol. 4(1) (2007).
12. The *PLoS Medicine* Editors, *An Unbiased Scientific Record Should Be Everyone's Agenda*, PLOS MED., vol. 6(2) (2009).
13. Adam Jacobs and Elizabeth Wager, *European Medical Writers Association (EMWA) Guidelines on the Role of Medical Writers in Developing Peer-Reviewed Publications* (2005), available at http://www.emwa.org/Mum/EMWAguidelines.pdf.
14. Barton Moffatt and Carl Elliott, *Ghost Marketing: Pharmaceutical Companies and Ghostwritten Journal Articles*, 50 PERSPECTIVES IN BIOLOGY & MED. 18 (2007).
15. Testimony of Sheldon Rampton, Research Director, Center for Media and Democracy, before the U.S. House of Representatives Committee on Science and Technology, March 28, 2006, available at http://www.prwatch.org/node/5899.
16. Duff Wilson, *Drug Maker Said to Pay Ghost Writers for Journal Articles*, N.Y. TIMES, December 12, 2008, available at http://www.nytimes.com/2008/12/12/business/13wyeth.html.
17. Center for Drug Evaluation and Research, *FDA Statement on the Results of the Women's Health Initiative* (Aug. 2002), available at http://www.fda.gov/cder/drug/safety/WHI_statement.htm.
18. Rowan Chlebowski *et al., Breast Cancer After Use of Estrogen Plus Progestin in Postmenopausal Women*, 360 NEW ENG. J. MED. 573 (2009).