Exposing Corruption Exploring Solutions

Project On Government Oversight

August 3, 2011

The Honorable Margaret A. Hamburg
Commissioner
U.S. Food and Drug Administration
White Oak Building I
10903 New Hampshire Avenue
Silver Spring, MD 20993

Via Email: Margaret.Hamburg@fda.hhs.gov

Dear Commissioner Hamburg:

The Project On Government Oversight is a nonpartisan independent watchdog that champions good government reforms. As such, we take a keen interest in the U.S. Food and Drug Administration (FDA), which receives around $4 billion a year in federal taxpayer dollars to regulate aspects of almost 25 percent of the U.S. economy.

We are writing with concerns about Dr. Janet Woodcock, Director of the Center for Drug Evaluation and Research (CDER) at the FDA. Dr. Woodcock has made comments in recent months that seem to support a loosening of the conflict-of-interest rules for scientists serving on FDA advisory panels. For several reasons, her statements do not seem to accurately portray the situation and appear to ignore relevant information.

The facts indicate that FDA is not having difficulty recruiting experts without conflicts of interest, that there are large numbers of qualified experts without industry ties, and that CDER appears to have significant leeway to issue waivers for researchers with financial conflicts. The current conflict-of-interest rules do not create an unreasonable burden and are not preventing the agency from getting expert advice.

- The number of conflict of interest waivers granted for FDA advisory members has never exceeded 5 percent, well below the legal cap of around 13 percent. (Attachment A)

- The vacancy percentage for CDER advisory members continues to fall, from 30 percent in 2009 to the mid-20s now. (Attachment B)

- Federally funded research gathered by Harvard University's Dr. Eric Campbell, published in *Health Affairs*,[1] and presented in June at a Georgetown University conference finds that almost 50 percent of research academics have no ties to industry; approximately one-third of these researchers are full professors.

- A study in the *Archives of Internal Medicine*[2] surveyed participants who created clinical care guidelines for cardiology. These guidelines were published by the American College of Cardiology and the American Heart Association. Of those participants, 44 percent had no financial conflicts of interest.

- Two journalists published a list of nearly 100 medical experts with no corporate ties in the *British Medical Journal* in 2008.[3]

These rules do create an additional hurdle, but that is exactly the point: we want expert advice that is as free as possible from the influence of industry.

In light of this information, we are troubled that Dr. Woodcock is making public statements that it is difficult to find experienced, unconflicted experts to serve on FDA advisory panels. It also alarms us that, in a talk you gave last week at Public Citizen, you have repeated Dr. Woodcock's misleading statements. According to *Bloomberg*, you said, "Patient-advocacy groups and academic researchers have expressed 'valid concerns' about the conflict-of-interest policy, prompting an agency rules review."[4] We would like to add that press accounts have found that patient advocacy groups,[5] professional societies,[6] and academic physicians[7] receive a great deal of funding from pharmaceutical groups. It is not surprising that those with conflicts of interest would argue for a loosening of the rules.

Last year, you raised concerns in a letter to FDA staff about the possibility for conflicted experts to undermine the public's confidence in your agency. You wrote:

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[1] Darren E. Zinner, et al., "Participation of academic scientists in relationships with industry," *Health Affairs*, Vol. 28, Issue 6, November 1, 2009, pp. 1814-1825. http://content.healthaffairs.org/content/28/6/1814.abstract (Downloaded August 2, 2011) (hereinafter *Health Affairs* study)

[2] Todd B. Mendelson, et al., "Conflicts of Interest in Cardiovascular Clinical Practice Guidelines." *Archives of Internal Medicine*, Vol. 171, No. 6, March 28, 2011, pp. 577-585. http://www.bioethics.upenn.edu/documents/COICardio-ArchIntMed.pdf (Downloaded August 2, 2011) (hereinafter *Archives of Internal Medicine* study)

[3] Jeanne Lenzer and Shannon Brownlee, "Naming names: is there an (unbiased) doctor in the house?" *British Medical Journal*, 337:a930, July 23, 2008. http://www.bmj.com/content/337/bmj.a930.full?ijkey=51VaCZNnRtCQvUz&keytype=ref (Downloaded August 2, 2011) (hereinafter *British Medical Journal* study)

[4] Jeffrey Young, "Conflict-of-Interest Rules May Be Relaxed in 2012, Hamburg Says," *Bloomberg*, July 25, 2011. http://www.bloomberg.com/news/2011-07-25/conflict-of-interest-rules-may-be-relaxed-in-2012-hamburg-says.html (Downloaded August 2, 2011)

[5] Gardiner Harris, "Drug Makers Are Advocacy Group's Biggest Donors," *The New York Times*, October 21, 2009. http://www.nytimes.com/2009/10/22/health/22nami.html (Downloaded August 2, 2011)

[6] Charles Ornstein and Tracy Weber, "Financial Ties Bind Medical Societies to Drug and Device Makers," *ProPublica*, May 5, 2011. http://www.propublica.org/article/medical-societies-and-financial-ties-to-drug-and-device-makers-industry/single (Downloaded August 2, 2011)

[7] "Dollars for Doctors: How Industry Money Reaches Physicians," *ProPublica*. http://www.propublica.org/series/dollars-for-docs (Downloaded August 2, 2011)

> Conflict-of-interest waivers for scientific advisers have been controversial, however. If FDA is perceived to rely heavily on conflicted experts, then confidence in the agency's decision making can be undermined.
>
> In my view, it is clearly better for the agency in fulfilling its public health mission when advisors have no conflicts of interest. FDA staff should search far and wide for experts who have the requisite knowledge without conflicts of interest.[8]

We agree wholeheartedly with these statements, and ask that you maintain FDA's high standards in this area. In the following pages we lay out our concerns in greater detail.

Dr. Woodcock's Statements and Evidence to the Contrary

At the Reuters Health Summit back in May, Dr. Woodcock told reporters, "There is no doubt it is difficult finding highly experienced people who do not have conflicts."[9]

Dr. Woodcock made a similar statement during a congressional hearing in early July. She responded to a question from Congressman John Shimkus (R-IL). He asked if she knew of cases where someone was disqualified from serving on an advisory committee because they worked on a clinical trial for an unrelated product, and if that caused a "time lag" in drug approval. Dr. Woodcock responded:

> Yes, it is true. It is also true, we have difficulty recruiting qualified people and having highly qualified panels. And in some cases we've had to delay advisory committees because of difficulty—because once we go through in great detail all the financials of the individuals we've nominated, we find that they have to be excused from participating. [10]

We feel that these statements run contrary to FDA's own data on advisory committees and statements you made in a letter sent last year to FDA officials. In that letter, you wrote:

> The law permits FDA to grant waivers for experts on its advisory committees. FDA may not exceed a cap set in the law on the number of waivers to be granted. For fiscal year 2010, this cap is set at about 13% of all advisory committee members participating in advisory committee meetings; we currently are granting waivers for less than 5%.[11]

According to FDA's published data on waivers for this year, the Agency is still granting waivers below 5 percent, which is well below the 12.78 percent target. (Attachment A)

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[8] Letter from Dr. Margaret A. Hamburg, Commissioner, Food and Drug Administration, to FDA staff, "Commissioner's letter to FDA staff on disclosure of financial conflicts of interest," April 21, 2010. http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm209001.htm (Downloaded August 2, 2011) (hereinafter Hamburg letter)

[9] Lisa Richwine, "FDA official sees drug approvals rising," *Reuters*, May 9, 2011. http://www.reuters.com/article/2011/05/09/us-summit-fda-approvals-idUSTRE7485B120110509 (Downloaded August 2, 2011)

[10] House Energy and Commerce Committee, "Hearing: PDUFA V: Medical Innovation, Jobs, and Patients," July 7, 2011. http://energycommerce.house.gov/hearings/hearingdetail.aspx?NewsID=8765 (Downloaded August 2, 2011)

[11] Hamburg letter

If FDA is not close to exceeding the cap for granting waivers (therefore has many non-conflicted experts) then why is Dr. Woodcock making statements to the contrary?

Furthermore, FDA's published data finds that the vacancy rate for advisory committees fell another 2 percent this year, and has fallen 10 percent overall, from 33 percent in 2009 to the present rate of 23 percent. (Attachment C) This indicates that FDA is having fewer problems finding experts without industry ties—maintaining the current rules and undermines Dr. Woodcock's argument.

According to a federally funded study of 2914 academics published in *Health Affairs*[12] and presented at Georgetown University in June, almost half of U.S. academic researchers have no relationship with industry. Around one-third of these researchers are full professors. Furthermore, a study published in the *Archives of Internal Medicine*[13] surveyed hundreds of experts who helped create clinical care guidelines published by the American College of Cardiology and the American Hearth Association. Forty-four percent of those participants had no financial conflicts.

Three years ago, journalists Jeanne Lenzer and Shannon Brownlee compiled a list of medical experts with no ties to industry. While some of these experts are former reporters, many have advanced degrees. Lenzer and Brownlee published their list in the *British Medical Journal* in 2008.[14] If these two reporters are capable of finding experts without ties to industry, then why can't the FDA? We have attached that article along with the names for your perusal. (Attachment D)

The facts at this time do not support a loosening of the FDA's conflict of interest rules, despite Dr. Woodcock's statements to the contrary. If anything, the FDA should work harder to find unconflicted experts to serve on advisory committees. To gain the public trust, we must ensure that the FDA relies on the best available information for its policies, rather than personal opinions and biases.

I appreciate your review of this letter and the attached documents. If you have any questions, please do not hesitate to contact Paul Thacker at thacker@pogo.org or (202) 347-1122.

Sincerely,

Danielle Brian
Executive Director

Enclosures: 4

cc: Chair and Ranking Member, House Energy and Commerce Committee
Chair and Ranking Member, Senate Finance Committee
Chair and Ranking Member, Senate Aging Committee
Chair and Ranking Member, Senate HELP Committee
Public Citizen
Union of Concerned Scientists

[12] *Health Affairs* study
[13] *Archives of Internal Medicine* study
[14] *British Medical Journal* study

Attachment A

Percent of advisory committee members participating in meetings in the month who were granted waivers

Download XML file | Related Links

Dictionary: When FDA determines that an advisory committee member has a financial conflict of interest, the agency may grant a waiver that allows the member to participate in an advisory committee meeting if certain criteria and policies are met. In general, FDA may grant a waiver if the member's expertise is considered essential to the committee's discussions and recommendations. FDA must also take into consideration a cap on the number of waivers that can be granted each year. FDA searches for experts who have the necessary expertise without conflicts of interest; yet, in some cases, many of the top authorities in specialized scientific fields may have a conflict of interest. When FDA grants a waiver, the financial interests associated with the waiver are posted on FDA's website along with the reasons for granting the waiver.

Change Fiscal Year 2011

Fiscal Year - 2011

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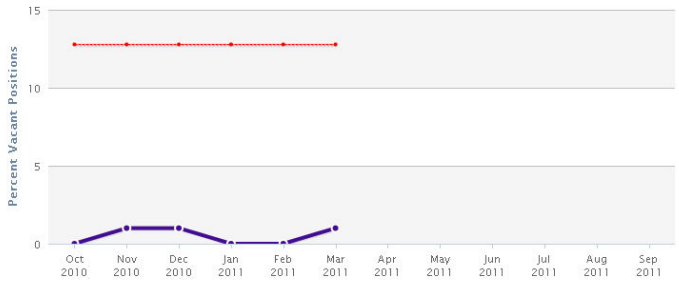

Overlay measure(s):

- ☐ Total number of advisory committee members participating in meetings in the month who were granted waivers
- ☐ Total number of advisory committee members participating in meetings in the month

FY 2011 Target: Less than 12.78%

Time	Target	Percent Vacant Positions
Oct 2010	12.78	0
Nov 2010	12.78	1
Dec 2010	12.78	1
Jan 2011	12.78	0
Feb 2011	12.78	0
Mar 2011	12.78	1
Apr 2011	N/A	TBD
May 2011	N/A	TBD
Jun 2011	N/A	TBD
Jul 2011	N/A	TBD
Aug 2011	N/A	TBD
Sep 2011	N/A	TBD

Total number of advisory committee members participating in meetings in the month who were granted waivers

Fiscal Year - 2011

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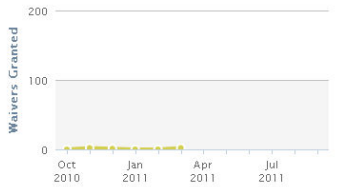
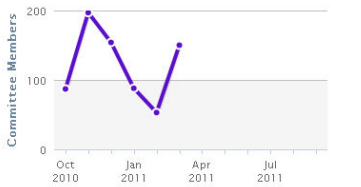


Time	Target	Waivers Granted
Oct 2010	N/A	0
Nov 2010	N/A	2
Dec 2010	N/A	1
Jan 2011	N/A	0
Feb 2011	N/A	0
Mar 2011	N/A	2
Apr 2011	N/A	TBD
May 2011	N/A	TBD
Jun 2011	N/A	TBD
Jul 2011	N/A	TBD
Aug 2011	N/A	TBD
Sep 2011	N/A	TBD

Total number of advisory committee members participating in meetings in the month

Fiscal Year - 2011

Change chart type:



Time	Target	Committee Members
Oct 2010	N/A	87
Nov 2010	N/A	197
Dec 2010	N/A	154
Jan 2011	N/A	88
Feb 2011	N/A	53
Mar 2011	N/A	150
Apr 2011	N/A	TBD
May 2011	N/A	TBD
Jun 2011	N/A	TBD
Jul 2011	N/A	TBD
Aug 2011	N/A	TBD
Sep 2011	N/A	TBD

Related Links

- FDA-TRACK Advisory Committees Dashboard

Note: The data provided on this website is produced on an ongoing basis for performance management purposes and is subject to change due to updates of preliminary estimates, corrections, or other reasons. In addition, FDA may change the type or amount of data provided on this website at any time.

Attachment B

Percent of CDER advisory committee member positions vacant at the end of the month

Download XML file | Related Links

Dictionary: Access to state-of-the-art, scientific expert advice to support agency decision making processes is imperative to the FDA advisory committee process. Having the fewest vacancies on our committees allows the agency to have ready access to those experts and supports the ability of FDA to meet its public health mission. For more information about FDA advisory committees, please visit http://www.fda.gov/AdvisoryCommittees/default.htm

Change Fiscal Year: All

Fiscal Year - All

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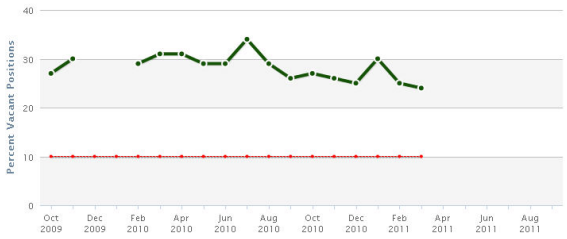


Overlay measure(s):

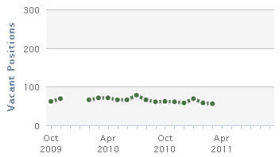
- ☐ Number of CDER advisory committee member positions vacant at the end of the month
- ☐ Total number of CDER advisory committee member positions at the end of the month

Time	Target	Percent Vacant Positions
Oct 2009	10	27
Nov 2009	10	30
Dec 2009	10	TBD
Jan 2010	10	TBD
Feb 2010	10	29
Mar 2010	10	31
Apr 2010	10	31
May 2010	10	29
Jun 2010	10	29
Jul 2010	10	34
Aug 2010	10	29
Sep 2010	10	26
Oct 2010	10	27
Nov 2010	10	26
Dec 2010	10	25
Jan 2011	10	30
Feb 2011	10	25
Mar 2011	10	24
Apr 2011	N/A	TBD
May 2011	N/A	TBD
Jun 2011	N/A	TBD
Jul 2011	N/A	TBD
Aug 2011	N/A	TBD
Sep 2011	N/A	TBD

Number of CDER advisory committee member positions vacant at the end of the month

Fiscal Year - All

Change chart type:

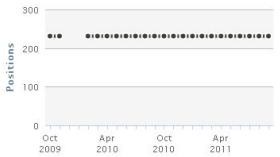


Time	Target	Vacant Positions
Oct 2009	N/A	62
Nov 2009	N/A	69
Dec 2009	N/A	TBD
Jan 2010	N/A	TBD
Feb 2010	N/A	66
Mar 2010	N/A	71
Apr 2010	N/A	71
May 2010	N/A	66
Jun 2010	N/A	66
Jul 2010	N/A	78
Aug 2010	N/A	66
Sep 2010	N/A	61
Oct 2010	N/A	62
Nov 2010	N/A	61
Dec 2010	N/A	58
Jan 2011	N/A	69
Feb 2011	N/A	58
Mar 2011	N/A	56
Apr 2011	N/A	TBD
May 2011	N/A	TBD
Jun 2011	N/A	TBD
Jul 2011	N/A	TBD
Aug 2011	N/A	TBD
Sep 2011	N/A	TBD

Total number of CDER advisory committee member positions at the end of the month

Fiscal Year - All

Change chart type:



Time	Target	Positions
Oct 2009	N/A	231
Nov 2009	N/A	231
Dec 2009	N/A	TBD
Jan 2010	N/A	TBD
Feb 2010	N/A	231
Mar 2010	N/A	231
Apr 2010	N/A	231
May 2010	N/A	231
Jun 2010	N/A	231
Jul 2010	N/A	231
Aug 2010	N/A	231
Sep 2010	N/A	231
Oct 2010	N/A	231
Nov 2010	N/A	231
Dec 2010	N/A	231
Jan 2011	N/A	231
Feb 2011	N/A	231
Mar 2011	N/A	231
Apr 2011	N/A	231
May 2011	N/A	231
Jun 2011	N/A	231
Jul 2011	N/A	231
Aug 2011	N/A	231
Sep 2011	N/A	231

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Attachment C

U.S. Food and Drug Administration

About FDA

May 24, 2011: FDA-TRACK Advisory Committees Quarterly Briefing Summary

Sign up to receive FDA-TRACK email updates [1]

Advisory Committees Dashboard [2]

- In the last 12 months, the FDA advisory committee vacancy rate has been reduced from 34% to 23%. During this time, 71 net advisory committee positions were filled.
- FDA has 49 advisory committees and panels and held 18 advisory committee meetings in FY 2011 Q2. For more information about upcoming FDA advisory committee meetings please see the advisory committee calendar website: http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm [3].
- FDA advisory committee staffs reported on several successful outreach events in FY 2011 including posting notices in the Federal Register, meeting with professional organizations, and participating in conferences. FDA receives an average of 57 nominations per month from individuals interested in becoming members of FDA's advisory committees. Additional information about vacancies on advisory committees [4] and the nomination process [5] can be found on the FDA website.
- FDA product Centers reported having several nomination packages in the final stages of the clearance and review process. The Center for Devices and Radiological Health (CDRH) [6] reported that 15 nominations are in the clearance process to fill vacancies on the Technical Electronic Product Radiation Standards Advisory Committee [7]. This committee advises FDA about proposed performance standards for electronic products which emit radiation. The Center for Drug Evaluation and Research (CDER) [8] and the Center for Biologics Evaluation and Research (CBER) [9] reported that nine and three nomination packages, respectively, are also in the clearance process to fill vacancies on multiple CDER and CBER committees. Each of these packages contains multiple individual nominations. Nominees have been identified to fill seven of the eight current vacancies on the Science Board to the Food and Drug Administration [10].
- Approximately 20 appointments will be made over the next couple of months for Consumer Representatives, who historically take longer to recruit due to their unique role in understanding scientific data while representing the voice of the consumer.

Contact Us

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Percent of FDA advisory committee member positions vacant at the end of the month

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Dictionary: Access to state-of-the-art, scientific expert advice to support agency decision making processes is imperative to the FDA advisory committee process. Having the fewest vacancies on our committees allows the agency to have ready access to those experts and supports the ability of FDA to meet its public health mission. For more information about FDA advisory committees, please visit http://www.fda.gov/AdvisoryCommittees/default.htm

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Fiscal Year - All

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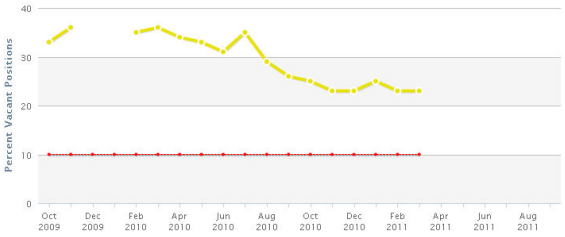


Overlay measure(s):

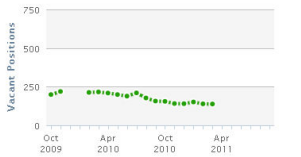
- Number of FDA advisory committee member positions vacant at the end of the month
- Total number of FDA advisory committee member positions at the end of the month

Time	Target	Percent Vacant Positions
Oct 2009	10	33
Nov 2009	10	36
Dec 2009	10	TBD
Jan 2010	10	TBD
Feb 2010	10	35
Mar 2010	10	36
Apr 2010	10	34
May 2010	10	33
Jun 2010	10	31
Jul 2010	10	35
Aug 2010	10	29
Sep 2010	10	26
Oct 2010	10	25
Nov 2010	10	23
Dec 2010	10	23
Jan 2011	10	25
Feb 2011	10	23
Mar 2011	10	23
Apr 2011	N/A	TBD
May 2011	N/A	TBD
Jun 2011	N/A	TBD
Jul 2011	N/A	TBD
Aug 2011	N/A	TBD
Sep 2011	N/A	TBD

Number of FDA advisory committee member positions vacant at the end of the month

Fiscal Year - All

Change chart type:



Time	Target	Vacant Positions
Oct 2009	N/A	199
Nov 2009	N/A	219
Dec 2009	N/A	TBD
Jan 2010	N/A	TBD
Feb 2010	N/A	213
Mar 2010	N/A	216
Apr 2010	N/A	209
May 2010	N/A	199
Jun 2010	N/A	189
Jul 2010	N/A	210
Aug 2010	N/A	177
Sep 2010	N/A	157
Oct 2010	N/A	155
Nov 2010	N/A	141
Dec 2010	N/A	140
Jan 2011	N/A	151
Feb 2011	N/A	139
Mar 2011	N/A	138
Apr 2011	N/A	TBD
May 2011	N/A	TBD
Jun 2011	N/A	TBD
Jul 2011	N/A	TBD
Aug 2011	N/A	TBD
Sep 2011	N/A	TBD

Total number of FDA advisory committee member positions at the end of the month

Fiscal Year - All

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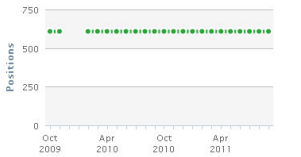

Time	Target	Positions
Oct 2009	N/A	608
Nov 2009	N/A	608
Dec 2009	N/A	TBD
Jan 2010	N/A	TBD
Feb 2010	N/A	608
Mar 2010	N/A	608
Apr 2010	N/A	608
May 2010	N/A	608
Jun 2010	N/A	608
Jul 2010	N/A	608
Aug 2010	N/A	608
Sep 2010	N/A	608
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Apr 2011	N/A	608
May 2011	N/A	608
Jun 2011	N/A	608
Jul 2011	N/A	608
Aug 2011	N/A	608
Sep 2011	N/A	608

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Attachment D

MEDICINE AND THE MEDIA

Is there an (unbiased) doctor in the house?

Journalists often forget that conflicts of interest might bias the opinions of their expert sources. **Jeanne Lenzer** and **Shannon Brownlee** explain how, in a bid to disentangle commercial messages from science, they have compiled a list of around 100 independent medical experts that reporters can turn to

Ho hum, another medical scandal in the news. Earlier this month US Senator Chuck Grassley announced his intention to investigate Alan Schatzberg, chairman of the psychiatry department at Stanford University and the incoming president of the American Psychiatric Association, about his multimillion dollar interest in Corcept Therapeutics, a company that is seeking to market a drug that Dr Schatzberg is researching with federal funding, and the extent to which he disclosed and was required to disclose that interest to Stanford.[1] In June the *New York Times* broke a front page story about the alleged failure of three top research psychiatrists at Harvard, each of them a proponent of drug treatment for psychiatric conditions in children, to report that since 2000 they had collectively received more than $4.2m (£2.1m; €2.6m) from various drug companies.[2]

After ignoring the growing controversy over conflict of interest for years, journalists now seem only too happy to expose wrongdoing in medicine. Yet when it comes to reporting medical news, those self same reporters often seem to forget that conflicts of interest might also bias the opinions of their expert sources. The media are filled with happy talk about "medical breakthroughs" that is based on information gathered from sources with ties to the industry. Yet simply knowing that conflicts of interest can create bias doesn't answer the question of which studies we ought to believe. Because journalists fail to seek out sources who can offer an independent perspective, many medical stories in the popular media are either unbalanced or simply wrong.

"Because journalists fail to seek out sources who can offer an independent perspective, many medical stories in the popular media are either unbalanced or simply wrong"

In an attempt to disentangle commercial messages from science and to contribute to better reporting we took a drastic step that we believe can go to the heart of the problem: we decided to name names. We created a list of nearly 100 international medical experts in a wide variety of disciplines. But contrary to the "gotcha" tradition of journalism, the list's members are not physicians on the take but rather the reverse: they are leading independent experts, many of them sources we have cultivated over years of reporting. It includes, from journal publishing, two former editors of the *New England Journal of Medicine*, the former editor of the *Western Journal of Medicine*, and a senior editor of *PLoS Medicine*; former advisers to the US Food and Drug Administration; physician educators; researchers; bioethicists; epidemiologists, methodologists, geneticists, and clinicians from various specialties; medical whistleblowers; and several medical journalists.

Where do the media get their medical stories from?

Those applying to be on the list fill out a form affirming that they have not received "any financial support in any form from pharmaceutical or medical device manufacturers during the past five years" and that they don't have other affiliations or financial involvements that would present a conflict of interest. A three member board decides whether to accept applicants. We also maintain a "page 2" list of experts who willingly disclose their conflicts of interest or have ended their industry ties but only within the past five years. Despite their recent commercial ties, these experts are included in the list because they have provided key insights into the inner workings of partnerships between physicians and the industry—and thus have bitten the hand that feeds them, in effect.

The reaction to the list, which has been embraced enthusiastically by our fellow reporters and roundly condemned by several allies of the drug industry, suggests that the effect of simply gathering these names together could well go beyond making life a little easier for our fellow journalists.

Seeking unbiased sources

The need for such a resource is evident from studies showing that bias and poor reporting on medical topics are widespread in the popular media. Gary Schwitzer, a professor of journalism at the University of Minnesota, publishes HealthNewsReview.org, a website that reviews healthcare news for balance, accuracy, and completeness. Schwitzer and a team of academic researchers analysed 500 stories published in top outlets between April 2006 and April 2008 for two key criteria: did the journalist quote an independent expert, someone not involved in the relevant research; and did they make some attempt to report potential conflicts of interest. The result? Half the stories failed to meet these two very basic requirements.[3]

In another study Alan Cassels, a pharmaceutical policy researcher at the University of British Columbia, and his colleagues analysed media coverage of five prescription drugs published in 193 Canadian newspapers in 2000.[4] Cassels, who is on our list, found that the stories were overwhelmingly positive towards the drugs: all 193 articles included at least one drug benefit, while 68% (132/193) failed to mention any potential harm. Two thirds of the stories quoted a source by name, but only a scant 3% (5/164) included information about conflicts of interest for sources who were not government or industry officials.

In the view of one list member, Arnold

The list

John Abramson, clinical instructor, Harvard Medical School

Marcia Angell, former editor in chief, *New England Journal of Medicine*

David Antonuccio, professor, Department of Psychiatry and Behavioral Sciences, University of Nevada

Michael J Barry, chief of general medicine unit, Massachusetts General Hospital, Harvard Medical School

Ken Bassett, professor of family practice, pharmacology, and therapeutics, University of British Columbia

Lisa Bero, professor, University of California, San Francisco

Stephen Bezruchka, Department of Health Services and Department of Global Health, School of Public Health and Community Medicine, University of Washington, Seattle

Laura Boylan, assistant professor, Department of Neurology, New York University

Phil Brewer, university medical director, Quinnipiac University, Connecticut; and past medical safety fellow, US National Highway Traffic Safety Administration

Howard Brody, director, US Institute for the Medical Humanities

Steven R Brown, Banner Good Samaritan family medicine residency, University of Arizona College of Medicine

Daniel Carlat, assistant clinical professor of psychiatry, Tufts University School of Medicine, and editor in chief, *The Carlat Psychiatry Report*

Alan Cassels, pharmaceutical policy researcher, University of Victoria, British Columbia

Robert Cook-Deegan, director, Center for Genome Ethics, Law and Policy, Duke Institute for Genome Sciences and Policy

Sam S Dahr, Retina Center of Oklahoma

John M Davis, Gilman professor of psychiatry, University of Ilinois at Chicago

Raymond De Vries, professor, bioethics programme, University of Michigan Medical School

Richard Deyo, Kaiser Permanente professor of evidence based family medicine, Department of Family Medicine, Oregon Health and Science University

Kay Dickersin, director, US Cochrane Center

Mark Ebell, deputy editor, *American Family Physician*, and professor, University of Georgia

Carl Elliott, University of Minnesota Center for Bioethics

David J Elpern

Margaret Ewen, Health Action International, Netherlands

Anne Rochon Ford, coordinator, Women and Health Protection, Canada

Adriane Fugh-Berman, professor, Department of Physiology and Biophysics, Georgetown University Medical Center, and director, PharmedOut.org

Joseph Glenmullen, clinical instructor in psychiatry, Harvard Medical School

Robert Goodman, founder and director of No Free Lunch and general internist at Montefiore Medical Center, New York

Merrill Goozner, director, Integrity in Science, US Center for Science in the Public Interest

Peter Gøtzsche, director, Nordic Cochrane Centre, Denmark

Mark E Helm, medical director, EBRx, Arkansas Evidence-Based Prescription Drug Program, and assistant professor, College of Pharmacy, University of Arkansas for Medical Sciences

David Himmelstein, associate professor of medicine, Harvard University

Jerome Hoffman, professor of medicine and emergency medicine, University of California, Los Angeles

John P A Ioaniddis, professor and chairman, Department of Hygiene and Epidemiology, University of Ioannina School of Medicine, Ioannina, Greece, and Institute for Clinical Research and Health Policy Studies, Department of Medicine, Tufts-New England Medical Center, Tufts University School of Medicine

Peter Juni, head of division, Institute of Social and Preventive Medicine, University of Bern, and director, Clinical Trials Unit, Bern University Hospital

Jon Jureidini, head, Department of Psychological Medicine, Children's Youth and Women's Health Service, Adelaide, and associate professor, disciplines of psychiatry and paediatrics, University of Adelaide

Scott Kim, assistant professor of psychiatry

Peter D Kramer, clinical professor of psychiatry and human behaviour, Brown University, Providence, Rhode Island

Barnett Kramer, associate director for disease prevention, US National Institutes of Health

Sheldon Krimsky, Tufts University, and Council for Responsible Genetics

Stefan Kruszewski, Stefan P Kruszewski and Associates

Richard A Lange, professor of medicine, Johns Hopkins Hospital, Baltimore

Jeffrey Lacasse, assistant professor, Department of Social Work, College of Human Services, Arizona State University at West Campus

Dara K Lee, staff cardiologist, Presbyterian Heart Group, Albuquerque, and vice president, Medical Staff Affairs, Presbyterian Hospital, Albuquerque

Gretchen LeFever, director of patient safety and performance excellence, Sentara, US

Trudo Lemmens, associate professor, Canada

Jonathan Leo, associate professor of neuroanatomy, US

Joe Lex, emergency physician, US

Joel Lexchin, professor, School of Health Policy and Management, York University, Toronto

Abby Lippman, professor, McGill University, Montreal

Peter Lurie, Health Research Group at Public Citizen, United States

William K Mallon, associate professor of clinical emergency medicine, Keck School of Medicine at the University of Southern California, and director, Division of International, LAC+USC Medical Center, Los Angeles

Peter R Mansfield, director, Healthy Skepticism, Australia

Linda Marsa, freelance journalist, US

Charlea Massion, Center for Education in Family and Community Medicine, Stanford University School of Medicine, and member of board of directors, American College of Women's Health Physicians

Charles Medawar, Social Audit, UK

Steven Miles, professor of medicine, Center for Bioethics, University of Minnesota

Barbara Mintzes, assistant professor, Department of Anesthesiology, Pharmacology and Therapeutics, University of British Columbia

Steven Morgan, associate professor and associate director, Centre for Health Services and Policy Research, School of Population and Public Health, University of British Columbia

Ray Moynihan, journalist, Australia

Vijaya Musini, assistant professor, Department of Anesthesiology, Pharmacology and Therapeutics, University of British Columbia, and Therapeutics Initiative, Canada

Thomas L Perry, clinical assistant professor, Department of Anesthesiology, Pharmacology and Therapeutics and Department of Medicine, University of British Columbia

Bruce Psaty, professor of medicine and epidemiology, University of Washington Cardiovascular Health Research Unit

Arnold Relman, former editor in chief, *New England Journal of Medicine*

David Rind, senior deputy editor, *UpToDate*, and assistant clinical professor of medicine, Harvard Medical School

Charles Rosen, clinical professor of surgery, University of California, Irvine, and founding director, US Association for Ethics in Spine Surgery

Haya Rubin, director, research and evaluation, Palo Alto Medical Research Institute, California, and adjunct professor of medicine, Johns Hopkins University, Baltimore

Larry Sasich

John Schumann, assistant professor of medicine, University of Chicago, and MacLean Center for Clinical Medical Ethics, Chicago

Lisa Schwartz, Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, New Hampshire

Gary Schwitzer, director, health journalism, MA programme, University of Minnesota School of Journalism and Mass Communication

Vera Hassner Sharav, Alliance for Human Research Protection, US

Allen Shaughnessy, professor, Tufts University School of Medicine, Boston, Massachusetts

Anthony So, programme on global health and technology access, Terry Sanford Institute of Public Policy, Duke University, Durham, North Carolina

Robert C Solomon, American College of Emergency Physicians, and medical editor in chief, ACEP News, US

Des Spence, general practitioner, Glasgow, and UK spokesman of No Free Lunch

Sydney Z Spiesel, clinical professor of paediatrics, Yale University School of Medicine, and regular commentator for Slate and US National Public Radio

Alex Sugerman, attorney, Prescription Access Litigation, US

Leonore Tiefer, New View Campaign, and New York University School of Medicine

Alexander Tsai, residency training programme, Department of Psychiatry, University of California at San Francisco

Jennifer Washburn, journalist, US

H Gilbert Welch, Dartmouth Institute for Health Policy and Clinical Practice, Lebanon, New Hampshire

Michael Wilkes, professor of medicine and director of global health, University of California, and former vice dean of education and former editor in chief, Western Journal of Medicine, University of California, Davis

Sidney Wolfe, director, Health Research Group of Public Citizen, US

Steven Woloshin, Veterans Affairs Outcomes Group

Alastair Wood, US

Steffie Woolhandler, associate professor of medicine, Harvard University

James Wright, managing director, Therapeutics Initiative, Canada

Gavin Yamey, senior editor, *PLoS Medicine*, US

The list can also be viewed at www.healthnewsreview.org/independentexperts.php

"Industry knows that buying doctors is an effective marketing tool . . . far more effective than the dollars they spend on drug representatives"

List member Peter Gøtzsche

Relman, former editor in chief of the *New England Journal of Medicine* and professor emeritus of medicine and of social medicine at Harvard Medical School, such bias fails to serve the public good. "People who have a financial stake in the results of clinical research can well be biased in the way research is conducted, in the way they report it, and what they say about it when interviewed by the media."

Changing the status quo

The question is why reporters seem unable to grasp the connection between the large body of evidence showing that financial conflicts of interest create bias in medical research and the need for the media to seek out independent sources. To be fair, journalists face a daunting task when trying to sift through medical research, and many are as yet unaware of the profound influence the drug industry has over research results and the ways in which the industry shapes medical "truths." Many reporters also fail to realise that the individuals and organisations they turn to for expert commentary, such as professional groups and charities, professional guideline authors, federal advisory panellists, and patients' groups, often depend financially on the industry. Thus there is a self reinforcing process in which commercially sponsored researchers, whose prominence is enhanced by the industry's public relations machine, are dubbed "experts," while independent sources are cited less often.

From informal conversations with colleagues we also know that other factors are at work when reporters fail to take conflicts of interest into account. Some confess that they hesitate to ask sources about any potential conflicts for fear that the source will take umbrage and refuse to be interviewed. Others assume that if a study appears in a peer reviewed journal it must be valid.

One of the solutions to the problem of biased news reporting, in the view of Michael Wilkes, professor of medicine and director of global health at the University of California, Davis, is greater transparency.[5] We think the list is a step in that direction. The chief requirement for membership, besides a recognised area of expertise, is that the expert must not have taken any industry funding for at least the past five years. Beliefs about certain drugs or treatments were not criteria for inclusion or exclusion. Indeed, the list includes experts who sit at opposite poles of the spectrum of beliefs on certain issues.

Backlash and honour

Within days of our announcing that we would make our list available to reporters the requests began pouring in. Thus far we have sent a copy of the list to 105 reporters, authors, and editors from such media outlets as the New York Times, Newsweek, Forbes, Fortune, Bloomberg News, the Washington Post, US News & World Report, the Canadian Broadcasting Corporation, Medscape, and many other publications across the US and several other nations. Senators and a state attorney general have also requested it.

Surprisingly, we are also receiving requests from recognised experts who wanted to be on the list. Being a member, it seems, is a badge of honour, say several of the list members we interviewed for the *BMJ*. Others, like list member Barnett Kramer, want to improve the quality of medical reporting. Kramer, a medical oncologist and associate director for disease prevention at the US National Institutes of Health, said, "Working journalists can be overwhelmed by PR."

The other surprise came after the publication of a story we wrote in the online magazine Slate that mentioned the list.[6] Within days bloggers were furiously accusing us of everything from biased, sloppy reporting to being members of the Church of Scientology (which is opposed to psychiatric drugs). Many of our critics—virtually all of them backed by the industry—opined that our list was undoubtedly filled with experts who were on the payrolls of plaintiffs' attorneys. (A few have testified in court cases, and those who have been paid for their testimony have disclosed it for the list.) This venom was unexpected, as we imagined that the list would be viewed as a positive step towards helping reporters identify doctors and other experts who can address thorny and complex medical issues without having competing financial interests. Now we think we understand the backlash a little better.

One of the problems recognised by Schwitzer is that many journalists rely for story ideas on news releases from the industry's public relations departments, and some even use releases as the sole source of information on experts to interview. By offering an alternative list of highly credible, independent experts, the industry may fear that its paid key opinion leaders[7] and the professional societies whose favour they cultivate will no longer be the first source of medical news.

Peter Gøtzsche, director of the Nordic Cochrane Centre and a member of the Danish group Doctors Without Sponsors, described why he joined the list: "Industry knows that buying doctors is an effective marketing tool . . . far more effective than the dollars they spend on drug representatives. This leads to less than optimal health care for patients."

Beyond the list's usefulness to journalists, we hope that it will also be used by government agencies, medical journal editors, and professional societies as they seek out experts to serve as editorialists and members of clinical guideline and advisory panels. The FDA, for example, has a copy of the list. We would be pleased to send it to other agencies and professional societies.

Readers can decide for themselves whether our list of independent experts includes any experts with "something worth saying."

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Shannon Brownlee is a senior fellow at the New America Foundation, Washington, DC

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Cite this as *BMJ* 2008;337:a930

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