

August 20, 2014

Senator Claire McCaskill
506 Hart Senate Office Building
Washington, D. C.
20510 Washington

Dear Senator McCaskill,

As a physician who has spent my time since medical school hopefully "...being part of the solution.." as you put it, it appears to me that your recent televised conversation with Dr. Mehmet Oz was one of a great missed opportunity to bring attention to the lack of effective medical consumer protection, which is so urgently needed.

Let me introduce myself. My name is Dr. Paul Lynn. I graduated from Louisiana State School of Medicine in 1967. After I completed my internship at Charity Hospital in New Orleans, Louisiana, I went on to serve as Naval Medical Officer, Second Lieutenant with the 1st Marine Division in Vietnam, gaining a greater understanding of battlefield trauma, tropical diseases, parasitical infections and other related medical issues. I was awarded the Combat Action Medal and the South Vietnam Cross of Gallantry. Following this service I practiced as a medical Missionary in the Benedictine Monastery of Esquipulas, Guatemala, for two months. I then worked as an Emergency Room physician at various hospitals in California and Louisiana for more than two years. During a two-year stay in Madras, India, I gained more experience in the treatment of tropical diseases, and learned about different approaches of Natural Medicine. Today, I am the Medical Director of San Francisco Preventive Medical Group with more than 35 years of experience in Natural Medicine.

I believe we agree that the major part of the problem in medicine today is the loss of an effective medical consumer protection in the United States. You are trying to address this issue in your committee, which is commendable.

This loss of protection is occurring at the same time when there is greater need of it, when TV and the Internet are filled with sophisticated medical marketing and infomercials of dubious value. Pharmaceutical companies have aggressively employed the infomercials in prime time, offering pain relievers, heart disease protection, cures for serious autoimmune disease, Viagra and so on.

Why? Because, marketing to a worried medical consumer is often an easy path to huge profits.

In the past, family doctors served as 'guardians', careful to protect patients in their use of prescription drugs. However, the number of people who have family doctors in the USA has

diminished dramatically, according to research done by Barbara Starfield MD, MPD, and a former director of Johns Hopkins University Primary Care Policy Center.¹ Two thirds of physicians are now specialists who only spend a few minutes with their patients and will never again see them after treatment or surgery is concluded. These doctors are much more costly to the whole system, as they are trained to find rare disease through the use of extensive batteries of expensive tests. The person-focused care of yesterday has been decreasing, replaced by a disease-focused care, which often overlooks the fact that most people are affected by a variety of conditions occurring simultaneously.

Adding to the problem, the FDA has compromised its function as supervisor of our medical system and of the safety of commercialized drugs, by allowing drug research to be funded and performed by pharmaceutical companies, and not by an independent entity.

Can these companies really produce unbiased research? It is difficult to imagine how.

We know that when research studies report findings which do not support pharma company claims, the FDA allows the pharma company in charge of a study to stop a trial without reporting the results, and then restart a new one designed to obtain their desired outcome. We also know that even in the case of supporting trials for FDA-approved drugs, over half of them remained unpublished 5 years after approval, and there is evidence pointing out a selective reporting of results, from trials in which a new drug works better than an old one.² This has created a bias in favor of literature reporting only positive benefits.

Moreover, both the pharmaceutical and weight-loss advertisements fail to mention that the NIH, or another objective agency, no longer does the research they quote. It is being done by the pharmaceutical companies or by a subcontracted foreign company. As you know, these companies, called Contract Research Organizations, are wholly dependent on those pharmaceutical companies for their livelihood. Meanwhile, this unfiltered system of marketing has helped increase the profits of the pharmaceutical giants to almost unbelievable levels.

Thus, unique to developed countries, the family doctor and the FDA in the U.S. have both ceased functioning as credible, trustworthy guardians, through which medical consumers can get information they can rely upon, while the TV commercials, billboards, and mail solicitations are telling consumers of a dire need for a procedure or medication. All of this advertising only adds to consumer confusion as to what their actual medical needs are. Because of this loss of consumer protection and the disappearance of family doctors, consumers end up paying the highest cost for medications and treatment procedures, while receiving health care that compares poorly with that of other developed countries.

¹ Marcille, John "A conversation with Barbara Starfield, MD, MPH: An evidence base for primary care," *Managed Care*, 2008 managedcaremag.com/archives/0806/0806.qna_starfield.html. Chen, Pauline W., "Where have all the primary care doctors gone?" *New York Time*, December 20, 2012.

² Public Library of Science "Half of trials supporting FDA applications go unpublished," *Science Daily*, September 22, 2008, sciencedaily.com/releases/2008/09/080922205031.htm

This explanation is to remind us really of what medical consumers are up against. This is also why the “DR OZ” show is being viewed by such a large audience in search of a much more person-focused care. They consider his program an opportunity, now rare, to get medical information from a source they can trust. Dr. Mehmet Oz does, overall, convey information in an easily understandable manner.

My response to his program is mostly relief. I am thankful that there is a doctor in our medical community with his extensive skill who is trying to communicate information to consumers in a non-marketing format. As a daily practicing doctor I see the urgent need and desire in patients to have access to unbiased information. Patients increasingly are aware of the aggressive marketing by the best ad agencies money can buy on medical matters, which include even life and death decisions.

Presently, where can we get medical opinion free of this mega-profit motive marketing? Along with Dr. Oz and your committee, it concerns me greatly that this excessive marketing has now even penetrated deeply into medical schools, and ultimately in the decisions made by private practitioners. A small portion of the huge profit is being recycled back into medical education, research and practice, in order to gain such an overall influence that eventually the student doctor learns to prescribe only what this mega-profit system provides. Most doctors today are simply unaware of how the profits associated with the breakdown of the medical consumer protections now limit their options for patient care. In my experience patients have sensed these changes.

It is not clear to me why congressional committees such as yours, funded by tax-paying medical consumers, do not take action with regard to the work of Dr. Barbara Starfield and others. Why does her work remain unchallenged yet unheeded by agencies such as the FDA? Remember that the FDA was largely founded 80 years ago to improve the weak and biased doctor-funded system then in practice. Now the pharmaceutical companies have been allowed by Congress to fund their own consumer protection agency. Should we assume that these companies will exhibit better ethics than the doctors did? Are you aware that 25% of total operating expenses of the FDA and 100% of funds used to regulate pharmaceutical companies are now provided by those same companies?

To your credit, more than most, you are making the attempt to address this problem. But it appears your advisors are guiding you in the wrong direction. Dr. Oz is obviously not an example of a medical doctor corrupted into taking advantage of the laws of consumer protection. On balance it does seem that Dr. Oz, in his dual role as concerned physician and entertainer, did make an error in judgment in the enthusiastic communication on air about the herbal weight-loss products he as a doctor had earnestly investigated hoping to help people with obesity. He acknowledged this over-enthusiasm to your committee. But unless you really have evidence that Dr. Oz is ‘on the take’, in your own zeal to be of help it seems you have also made an error in judgment, during your committee hearing on national TV, when you intimated that Dr. Oz was possibly part of the problem, rather than a target of convenience of this type of corruption.

Looking objectively at his body of work on air for the past 5 years, hasn't he clearly acted as an agent of change, bringing out ways consumers can help themselves medically through lifestyle, diet or supplements? He seems to have been able to help some people reduce their dependence on our current always expensive and sometimes exploitive medical system.

The research I have studied says that if consumers are encouraged to attempt to help themselves they will probably be successful. The Nurses' Health Study and the Caerphilly Heart study, among other well performed studies, prove the huge potential of lifestyle in this area of medicine.³ In view of their research, wouldn't you agree that overall Dr. Oz' efforts have a strong statistical probability of saving lives and reducing medical cost to those consumers who have put some of his suggestions into practice? His recommendations for lifestyle alone could warrant that conclusion it seems to me.

Those doctors who join with pharmaceutical and weight-loss herbal companies in an attempt to defraud and sometimes injure the consumer do exist. Dr. Oz, on the other hand, has never endorsed any product! He obviously could have been receiving millions for endorsements by now.

In other ways, we could someday find ourselves in a similar position as Dr. Oz, of appearing to be in an involuntary collusion. For example, Senator McCaskill, you have received a small donation from Pfizer Pharmaceuticals, and have not returned it.⁴ Are you aware that Pfizer, purely for profit, is bankrupting and injuring women far beyond what the diet pill industry is doing? Of course, I am assuming at this time that you do not know the details regarding the drugs called Provera. Just as Dr. Oz did not recognize in that moment during his program what would happen in his attempt to encourage his viewers to try something new.

However, you also didn't and still do not recognize that your acceptance of Pfizer contribution to you, while you are chairwomen of a consumer protection committee, places you and your reputation in a vulnerable position. Pfizer, of course, needs to influence people like yourself in order to continue their life-threatening breach of consumer protection. Unfortunately, because of your reputation as an honest, no-nonsense Senator, you seem to have been placed in a compromised position, somewhat similar to Dr. Oz. With the unquestioned acceptance of a donation from Pfizer, in a small way you are now appearing to condone a great tragedy in the making, permitted by the breakdown of consumer safeguards.

Here are some of the details about Pfizer and Provera. The drugs Provera is being actively marketed to menopausal women, while Pfizer has had proof for 12 years that it causes breast cancer. The conclusive proof that it causes breast cancer was established in 2002, with the publication of the Women's Health Initiative (WHI) and in a 2010 article by Dr. Rowan

³ The Nurses' Health Study established in 1976 is still ongoing. The results can be consulted in: www.channing.harvard.edu/nhs/

See also: Elwood, P. et al. "Healthy lifestyles reduce the incidence of chronic diseases and dementia: Evidence from the Caerphilly Cohort Study," *PLoS ONE* 2013, 8(12): e81877.

⁴ OpenSecret.Org Center for Responsive Politics, "Sen. Claire McCaskill", July, 21, 2014, <http://www.opensecrets.org/politicians/pacs.php?cycle=2014&cid=N00027694§or=H&seclong=Health&cat=H04&induslong=Pharmaceuticals%2FHealth+Products&newMem=N>

Chlebowski MD, PhD, confirming those results.⁵ Pfizer does not attempt to challenge the findings! Unfortunately for women, Pfizer has discovered that they do not even have to challenge such damning findings because of the breakdown in consumer protection.

Apparently Pfizer has chosen not to make the terrible research findings an issue, and hope people like you, me, Dr. Oz, and the public will not notice. They are using a small portion of their enormous profits from the sale of Provera to post-menopausal women to continue to quietly settle over 10,000 lawsuits from women who have developed breast cancer while taking Provera.⁶ Pfizer has paid out \$850 million to date for these settlements. They also publicly assure the investment funds which own their stock that they already hold another \$350 million in escrow for future settlements, and are ready to add to that total if necessary. Isn't it outrageous that Pfizer has so little fear of the FDA and Consumer Protection Congressional committees such as yours, that they can even publicly reassure investors that the proven cancer-causing breast cancer drug they are marketing will continue to be sold for a huge profit to unsuspecting women for an indefinite period of time?

Where is the outrage?

From everything I know, what occurred between Dr. Oz and the diet pill industry was not collusion on his part. The entire diet pill industry is a very real danger. However, as a breach of the Consumer Safety Net it is 'minor league' in comparison to what is occurring with Pfizer and its exploitation of the breakdown of the consumer protection that should be provided by your committee, the FDA, physician groups, etc. This breakdown is a 'major league' breach, where thousands of women are dying unnecessarily, with nobody to stop it, in spite of voices like Chlebowski from the WHI.

Hopefully, you and your committee will use this letter as a wake-up call as to how serious the problem of corruption from mega-profitable medical businesses of all types has become. The flood of money appears to even have arrived at your doorstep, and I would really be interested that you respond to my question about your own non-return of Pfizer contributions.

It seems some form of public statement absolving Dr. Oz of any intentional involvement in the diet pill scam is in order. Also, giving him credit for making great efforts to expose on national TV the very companies in the diet pill industry who misuse his comments. After all, wasn't he doing some of the investigative work your committee should have taken as its responsibility?

⁵ WHI "Risks and benefits of estrogen plus progestin in healthy menopausal women. Principal results from the Women's Health Initiative randomized controlled trial," *JAMA* 2002, 288: 321-333, and Chledowski, R. T. et al., "Estrogen alone in postmenopausal women and breast cancer detection by means of mammography and breast biopsy," *J. Clin. Oncol.* 2010, 28(16): 2690-2697 Doi: 10.1200/JCO.2009.24.8799

⁶ Prempro contains a combination of the drugs Provera and Premarin. Feeley, Jef "Pfizer loses Prempro ruling, must pay \$10.4 million," *Bloomberg*, July 21, 2012 bloomberg.com/news/2012-07-21/pfizer-must-pay-10-4-million-in-prempro-lawsuit-court-rules.html

Finally, isn't it time for you to bring the CEO of Pfizer before your committee and ask the tough questions he hopes he will never have to answer in public? This is the missed opportunity to which I am referring. I am ready, willing and able to be of help to you in this endeavor. Do not hesitate to ask for my assistance.

I remain,

Sincerely yours,

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