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To: Open Public Hearing
Endocrinologic and Metabolic Drug Safety and
Risk Management Advisory Committees to the
Food and Drug Administration
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Good Afternoon.

I am Richard Ralston, Executive Director of Americans for Free Choice in Medicine. We are a non-profit organization providing public education on free market approaches to health care. We advocate the principles of individual rights of physicians and patients and personal choice as the only proper basis for health-care policy. We support the economic and moral rights of businesses to make profits as the result of developing and producing medications, and of their investors to obtain a substantial return on their investments. We hold that this provides the best hope for the development of new drugs for America and the world.

I need to disclose that my organization received a contribution of fifty dollars from an employee of Pfizer a few years ago which was later matched with a gift of fifty dollars from Pfizer. No other gift from a pharmaceutical firm or organization has been received, nor any reimbursement for travel expenses.

I should also say that I have been managing my own Type II Diabetes for some years. I have previously taken Avandia, but now rely on insulin. I once participated in a clinical trial of Lantus.

I have no qualifications to evaluate the safety or efficacy of any prescription drug. I am not a physician or a scientist. I do not know how to conduct a clinical trial, or how to evaluate the results of such a trial. I do not know how to evaluate a "meta-analysis" of multiple clinical trials.

I have been told that it is possible to compile the apples of one clinical trial conducted under one set of criteria and controls with the oranges of another clinical trial conducted under another set of criteria—but exclude the

grapefruits of another clinical trial because it reported no adverse events—and then somehow come to conclusions not reached by any of those who actually conducted the clinical trials.

But I don't understand it.

In other words, my limited understanding of these methodologies puts me at approximately the same level of competence as the Chairman and members of the House Committee on Oversight and Government Reform.

But I was not born yesterday.

When results of a meta-analysis claim that a drug is killing people and should be taken from the market, why is it first reviewed with the majority staff of a committee of the House of Representatives as a part of discussing "pending legislation?" On what basis did the Chairman of that committee instantaneously issue a press release evaluating the findings of the meta-analysis and describe it as "a case study of the need for reform of the nation's drug safety laws?"

Was this press release based on the Chairman's vast clinical experience? Or on his mature understanding of the human endocrine system? If not, was his press release itself a "case study," but a case study of how to distort, manipulate and manufacture research data to support a political agenda?

If patients taking the drug are presumably dropping in the streets from heart failure, why does a prestigious medical journal first take the time to write an editorial in pursuit of a political agenda as a part of publishing the research?

Lastly, why would someone who has been publishing clinical research make the statement on a national television program—broadcast to the general public—that "the deaths caused by Avandia could dwarf the carnage of September 11, 2001?" As I am not familiar with the austere technical terminology of reports on

clinical trials, can someone explain to me what were the exact clinical results and what were the precise metrics that justified such a statement? And from the perspective of objective peer review, what could have been the purpose of such a statement? Is there something going on here besides science?

I am concerned that the tremendous power of the Food and Drug Administration over our health and daily lives has become a magnet for those with another agenda.

To mention only two:

There are those with so much antipathy for private business as such, that they would rather see people suffer and die for want of new medications than allow anyone, anywhere to make money from developing them.

There are some law firms—already hovering over Avandia as a contingency fee jackpot of billions of dollars—who would prefer to see <u>any</u> drug driven off the market—no matter how many people it helps—if it presents an opportunity for a litigation bonanza that will only result in increased drug prices.

My chief concern is what happens to patients in this process. What happens when patients are frightened away from drugs that are helping them? Or when physicians are intimidated from prescribing approved drugs? Do politicians issuing press releases, or researchers making polemical statements on television care about what they are doing to the countless patients that have been helped by a drug without adverse effect?

There are two distinct issues here to which I would like to draw your attention. First is the politicization of research. Secondly, and more importantly, is what the use of such tactics implies about the core skills of the researchers and the reliability of their conclusions. Why are such tactics necessary if the science speaks for itself? When should publishing research be turned into a political and public relations campaign in the general media? And why? And do researchers who behave in this way employ the same tactics with the same zeal against the drug companies that fund their research as against those that don't?

I am sure that I do not need to tell the members of this committee that there are those who would like to preempt or manipulate their advice to the FDA. Nor do I need to remind you that your advice must be based exclusively on sound science and the objective evaluation of clinical trials—and not on statements made on ABC's Nightline.

Those who manipulate research for the purpose of increasing the powers of the FDA—which they can then further manipulate to achieve their political objectives—must not be allowed to control this process.

Please rest assured that many of us realize all of these factors and how you have to contend with them.

Thank you. ***Americans for Free Choice in Medicine*** ***www.afcm.org***