#1381

COX COMMENTS

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Joan Claybrook, President

December 5, 1995

Honorable Joe Barton
Chairman, Subcommittee on Oversight and Investigations
Committee on Commerce, U.S. House of Representatives

Dear Chairman Barton:

On November 15th of this year during a hearing involving the FDA and medical devices, explicit references and innuendos were made by Congressman Cox of California concerning me and Public Citizen's Health Research Group, of which I am the Director. I hereby request that this letter be included in the official record of the hearing in order to correct these errors.

1. *McCarthy-like tactics*

It is unfortunate and deplorable that a member of Congress, groping for straws, would stoop to tactics quite reminiscent of the late Senator Joseph McCarthy in order to try to establish some sort of cabal involving the FDA and me. Asking Dr. Kessler do you know and have you ever had lunch with Sidney Wolfe is the sort of probing which should have vanished long ago.

2. *Meeting with FDA Device Staff and Health Research Group Staff on October 6, 1995.*

Although it is correct, as the hearing record indicates, that such a meeting occurred on October 6th and that one of the topics discussed was pedicle screws, I can not think of any specific device about which our organization and the FDA are or have ever been at greater odds with each other than the pedicle screw. At that meeting, we voiced strong disapproval of FDA's previously announced plans to deregulate pedicle screws even more than we thought they were going to a year ago when we became involved in this issue.

3. *Funding of Public Citizen's Health Research Group*

Congressman Cox's question to Drs. Kessler and Burlington concerning our funding is inaccurate. "Do you have any knowledge...that the Health Research Group is funded by plaintiffs' lawyers?"implies some knowledge on Mr. Cox's part that this is so. Almost all of Public Citizen's funding is from members--mainly small donors whose identities and professions are generally unknown to us, from the sale of publications such as *Worst Pills, Best Pills* concerning prescription drug dangers for older people and from foundations. We do not, as a matter of policy, take any money from any organizations, such as the Association of Trial Lawyers of America and we are currently quite at odds with plaintiffs' attorneys in 14 class action lawsuits in which they have struck deals with defense attorneys which are not adequate from the plaintiffs' perspective. Our litigation group is, amongst other efforts in these class action suits, attempting to reduce the amount of fees that the plaintiffs' attorneys are trying to get.

We do have medical and technical information clearinghouses for plaintiffs' attorneys in which we provide publicly available information about drugs or devices in which we have been involved. We operate these by charging attorneys for the costs of running the clearinghouses. In the case of one we have for pedicle screws, at present, our costs of running it probably exceed the amount of money we have charged the plaintiffs' attorneys.

4. *The documents which were inadvertently provided by FDA to plaintiffs' attorneys*

Until the hearing on November 15th, I was unaware that the documents containing information about the seriously flawed study of safety and effectiveness of pedicle screws had been inadvertently provided to plaintiffs' lawyers. The notion that there was any connection between the meeting on October 6, 1995 involving the FDA and the Health Research Group and this disclosure is absurd.

Sincerely,

Sidney M. Wolfe, M.D.
Director, Public Citizen's
Health Research Group

cc: Peter Deutsch