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7/27/92 (reminder) iom

Re Women (and minorities) in clinical trials.

Dear Ruth - (Bolger)

I've not been tracking this closely, but I did quickly read the revised draft white paper (under covering memo of 10/28/92)

I fear the argument will not be very clear to the intended (political) audience. The first two paragraphs are OK. They should be briefly expanded in some more intelligible summary.

I am also struck that nothing is said about minorities' tout pis!

The idea that "minorities" collectively are a biologically significant subgroup is absurd. But if we are to entertain the hypothesis that clinical response differences may obtain (as well they might!) among all the diverse subpopulations, consider how that will paralyze every study - with a presumed obligation to test significant numbers of blacks, hispanics, asians, etc... And of course it is the polymorphisms within these that will really count.

I concur that genetic polymorphisms (including but not confined to those connected with sex and race) are woefully neglected in therapeutic research. I also concur that automatic inclusion of every subgroup in clinical trials is a heavy handed and counterproductive approach

Is "gender" now the PC term for "sex"?

Is there a difference in meaning between "gender-specific" and "sex-specific"? Is the population "of female gender" congruent with "the female sex"?

"Gender" still has some connotation of psychic affinity (as in "gender-identity problems of children") as opposed to biological sex. Are all those subtleties now ignored? I suspect (if the semantics still holds) the report does intend sex-specific, not gender-specific, throughout its discussion. If synonymy, sex ≡ gender, is intended, perhaps that should be footnoted.