From: Hohmann, Ann (HHS/OASH) < Ann. Hohmann@hhs.gov>

Sent: Wednesday, December 21, 2016 10:46 AM

To: jenstrom@ucla.edu

Cc: Garfinkel, Susan J (HHS/OASH) <Susan.Garfinkel@hhs.gov>; Trenkle, William (OS/OASH)

<William.Trenkle@hhs.gov>

Subject: DIO 6351

Dear Dr. Enstrom,

As the ORI expert in biostatistics and public health, Dr. Garfinkel gave me the materials that ORI has regarding your November 7 conversation with Dr. Trenkle about the Jerrett et al. 2013 paper and your emailed materials to AskORI on November 11, 2016. I have read and reviewed all of the materials. I understand your concern about the way the data were presented in the paper and used elsewhere. Though I have no clinical training, it appears that the relative risks reported do not seem to rise to the level of clinical significance and do not provide evidence that air pollution is directly responsible for mortality. Presenting this data as such, may be a question only of bad science.

However, "bad" or sloppy science is not the same as research misconduct. ORI's regulation (42 CFR 93.103) defines research misconduct, as you know, as "fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results." While it is true that Dr. Jerrell and colleagues did not cite all the research showing that the relative risk is very, very close to 1 and only emphasized specific numbers, they did not, as far as I can tell, change their data to get a statistically and clinically significant result. The weak results are there for all to see. Thus, there does not appear to be falsification.

To overinterpret one's data is certainly inappropriate, but would be a matter to raise with the reviewers and the journal editors, who apparently did not insist that the authors tone down their conclusions. ORI is aware that the research on the effects of air pollution is certainly not the only area of science where there is open controversy. Just this morning, *The Scientist* ran an article on the controversy regarding the effects of sugar intake (<a href="http://www.the-scientist.com/?articles.view/articleNo/47819/title/Industry-Funded-Sugar-Study--Don-t-Trust-Other-Sugar-Studies/&utm_campaign=NEWSLETTER_TS_The-Scientist-Daily_2016&utm_source=hs_email&utm_medium=email&utm_content=39616948&_hsenc=p2ANqtz-8Q5JhLgCWe4CJboPROHvuwP0x1fr3XLwxkrNXixW4tqdO_29UCNh4fj6q1lwpolH0ferca7iYMwC0oyjX7kTTvwmW8_mA&_hsmi=39616948). Unfortunately, we all are aware that science loses when research is influenced by special interest groups.

The Public Health Service (PHS) regulation, under which ORI acts, is not meant to be a way to put the brakes on controversial science. The mission of our Office is to protect PHS research funds from researchers who knowingly and intentionally make up data or change them to serve their purposes. In the documents you provided, there does not appear to be evidence that Dr. Jerrell and his colleagues have done that. Without clear evidence of fabrication and/or falsification of data (and not just failing to cite contrary data), ORI is unable to further pursue your allegations. What you do and have been doing for decades – promoting your own research results – in scientific and other venues may be the best way to combat opposing viewpoints. Good luck in the future.

Ann A. Hohmann, Ph.D., MPH Division of Investigative Oversight Office of Research Integrity (ORI) 1101 Wootton Parkway, Suite 750 Rockville, MD 20852

Phone: 240 453-8431 **Ann.Hohmann@hhs.gov**