IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

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| AMERICAN TRADITION INSTITUTE ENVIRONMENTAL LAW CENTER, | ) | |
| Plaintiff, | ) | |
| v. | ) | Civil Action No. 1:12-cv-1066-AJT-TCB |
| UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, et al., | ) | |
| Defendants. | ) | |

DECLARATION OF MARTIN W. CASE

I, Martin Wendell Case, pursuant to 28 U.S.C. § 1746, declare, under penalty of perjury, that the following statements are true and correct based upon my personal knowledge and experience:

1. I am the Clinical Research Studies Coordinator for the CAPTAIN controlled human exposure study

2. As a Clinical Research Studies Coordinator, my duties include training, testing, monitoring, and coordinating human clinical research studies for the Environmental Public Health Division of the US EPA.

3. I received a BA in Chemistry from the University of North Carolina at Chapel Hill, Chapel Hill, NC in 1980. I also hold a Bachelor of Science degree in Public Health from the same university (1983). My clinical research experience consist of 28 years of performing and carrying out human subject testing for the Environmental Protection Agency and 21 years Medical Technology Clinical Laboratory testing in the area of Hematology/Coagulation for the University of North Carolina Healthcare System.

4. I have reviewed the Complaint and exhibits filed in the captioned case and the Motion for a Temporary Restraining Order.

5. My first approach after being introduced to the subject by the medical station staff is to ask the subject if they have read the consent form. The subjects for CAPTAIN have been given the informed study consent form on a previous visit, and, they are also given the same consent to read again if they have not read the consent the day of the training.

6. My next approach is to ask the question: "Do you have any questions about what you have read, and do you understand what you have read?" Based on their response, this gives me the opportunity for me to judge whether I may need the principal investigator for the scientific aspect of the study, or, one of the medical doctors to answer anything that I think I may not be able to explain to the satisfaction of myself and to the subject.

7. Then based on my comfort level from that point, I go to what I consider the main assurance to the subject that he or she is not committed or obligated in anyway to what they have read or will sign about their participation for being in this study. I state very clearly that "their participation in this study and any study here at EPA is strictly and completely volunteer, and that they may stop their participation at anytime for any reason without any coercion whatsoever."

8. Next I go into the details of the study (purpose). I always have a copy of the identical consent form in front of me as guidance. I explain what they will be receiving in the way of air pollution, how they will receive the air pollution, and describe how the air pollution is delivered in the chamber. I will explain to them that they will be receiving clean air on one day of the study, concentrated particles from the air outside the test building on the second day of the study, and the third day is a follow-up day. I will state in lay terms how they will be exposed to the particles for 2 hours, and explain what this is similar to (comparable to) as compared to going about their everyday activities based on where they live.

9. Next I go over the CAPTAIN medical screening questions about any reasons they should not participate in this study, and their requirements and compliance restrictions for being in this study.

10. Then I explain a very detailed timeline for all the things they will have to do each day in the study, stepping them through what will be happening or being performed on or to them in each phase. As always, I pause, and ask for questions as I step them through the different

events/procedures. Next I discuss discomforts, risks, and symptoms they may incur from doing procedures we will do on them. Again, this is the time I always add: "if you do like doing or feel uncomfortable with any procedure, then don't hesitate to say 'I don't want to do this', the subject always has the avenue to say no."

11. At this point I do a more scripted presentation of the consent where I may read or follow closely the sections of the consent dealing with: "possible benefits from being in the study, how their privacy is protected, what will happen if they are injured by or while in the study, and their rights as a research subject. " I inform that EPA will reimburse them up to $5,000.00 if is it determined by our on-call duty doctor that we have injured them in any way or caused illness by participating in this study. I always assure them that by signing this consent they are not signing away their right to sue if they feel they have been injured or wrongfully damaged by lack of reasonable care or neglect on our part.

12. Then, I go over thoroughly their payment for being in the study, their different types of reimbursement, and the our method of determining reimbursement that can be affected by scheduling conflicts, the weather, their level of or lack of performance, their cancellation, our cancellation, and our ability to notify them when scheduling problems arise due to equipment failures or facility type issues.

13. Finally, I assure them of our concern for their safety first and foremost. Specifically, I tell them of the safe guards we have in place for monitoring their vitals signs, (e.g. EKG telemetry, blood pressure, and oxygen saturation; 'especially while in the chamber'). I show the subject that they are always on camera, that they can just speak up to be heard, and that I am always just several feet away at the console watching them. As I am performing the training, I physically show them the controlled testing chambers and point out all of these features and safe guards that we have in place. In addition, I informed them of our emergency medical equipment, our overhead paging capability, immediate emergency response by our nurses, and that a dedicated on-call physician is always in the facility at all times when any study is taking place. I state again, "any questions."

14. I provide participants with information about fine particles ($PM_{2.5}$). I say that $PM_{2.5}$ are particles so small that they are able past through your airways and go deep into your lungs, these

particles are so small that your usual lining and cilia of your airways are not able to prevent these particles from passing into your lungs. Therefore, if you are a person that for example lives in a large city like Los Angeles or New York, and it's been a very hot day, and you can see the haze in the air, and you happen to be someone that works outside, and if you have an underlying unknown health condition, or, you may be older in age; the chances are that you could end up in the emergency room later on that night, wondering what's wrong, possibly having cardiac changes that could lead to a heart attack; there is the possibility you may die from this.

15. I make sure they have initialed and dated every page of the consent form, printed and signed their name in the proper place, and correctly dated the consent. I in turn do the same as the person obtaining their consent. I file this copy in their study chart, and I also make sure they have a signed identical copy to take with them as reference, with contact telephone numbers of the PI, study personnel, our EPA approval medical officer (who oversees our research protocols), and the telephone number with contact information for the Internal Review Board of the University of North Carolina at Chapel Hill who oversees and approves this and all of our studies.

Dated: October 3, 2012

Martin W. Case

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