ACCUSATIONS OF UNETHICAL TREATMENT OF HUMANS BY THE EPA RESULTS IN UNPLEASANT IMPLICATIONS

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INTRODUCTION

On September 24, 2012, the American Tradition Institute Environmental Law Center[1] (ATI) filed a lawsuit against the United States Environmental Protection Agency (EPA) in the U.S. District Court for the Eastern District of Virginia.[2] The complaint asked the court to find that the EPA failed to comply with laws controlling human experimentation. Ultimately, the ATI sought to "immediately halt EPA's human experimentation which intentionally exposes human subjects, including some 'more susceptible to the effects of air pollutants' to 'fine particles' such as those 'produced by car and coal-fired power plants.'"[3] The ATI also sought declaratory relief, asking the court to find that the EPA failed to adequately inform participants that the pollution they would be inhaling as part of the experiment posed a serious risk to their health and that there is absolutely no benefit to participating.[4] These unpleasant implications constitute a violation of national standards limiting human experimentation, as well as international standards originally found in the Nuremberg Code.

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1. At the time of the writing of this note, the American Tradition Institute (ATI) had not yet changed its name to the Energy and Environment Legal Institute (E&E Legal). As such, E&E Legal is referred to as ATI throughout the body of this work. "The Energy and Environment Legal Institute (E&E Legal) is a 501(c)(3) organization engaged in strategic litigation, policy research, and public education on important energy and environmental issues. Primarily through its strategic litigation efforts, E&E Legal seeks to address and correct onerous federal and state governmental actions that negatively impact energy and the environment." *Mission*, ENERGY & ENV'T LEGAL INST., http://www.eelegal.org/?page_id=1657 (last visited Oct. 8, 2013).

2. *See* Verified Complaint, Am. Tradition Inst. Envtl. Law Ctr. v. U.S. Envtl. Prot. Agency (No. 1:12-cv:1066), *available at* http://epahumantesting.files.wordpress.com/2012/09/2012-09-21-complaint-as-filed.pdf.

3. *Id.* at 1-2.

4. *Id*. at 2.

After World War II, the Allies created the Nuremberg Code which set forth ethical research principles regarding human experimentation.[5] The Code was the result of the Doctors' Trials, which followed the Nuremberg Trials and addressed human experimentation performed by Nazi doctors on human subjects.[6] Here, in essence, the ATI's lawsuit alleges the EPA has violated set standards created for the protection of human participants in scientific experiments by failing to adequately inform them of the dangers associated with participation.[7] Failure to provide participants with necessary information renders participants unable to give valid informed consent, therefore, making these experiments illegal.[8]

On January 31, 2013, the ATI's case against the EPA was thrown out by Judge Anthony Trenga who determined the EPA's alleged actions did not constitute "final agency action"[9] under the Administrative Procedure Act.[10] Judge Trenga also determined that because the ATI was not personally being harmed by the ex-

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5. *See Nuremberg Code*, U.S. HOLOCAUST MEMORIAL MUSEUM, http://www.ushmm.org/information/exhibitions/online-features/special-focus/doctors-trial/nuremberg-code (last visited Jan. 18, 2014).

6. Manny Bekier, *The Ethical Considerations of Medical Experimentation on Human Subjects*, CITY U. N.Y. (Nov. 18, 2010), http://www.qcc.cuny.edu/socialsciences/ppecorino/MEDICAL_ETHICS_TEXT/Chapter_7_Human_Experimentation/Reading-Nazi-experimentation.htm.

7. Verified Complaint, *supra* note 2.

8. Informed consent requires "full disclosure of the nature of the research and the participant's involvement[.]" *See Required Components of Informed Consent*, INSTITUTIONAL REV. BOARD FOR HUM. PARTICIPANTS, http://www.irb.cornell.edu/forms/consent.htm (last visited Jan. 18 2014).

9. In order to constitute final agency action, the EPA's conduct must violate rights or obligations that have been determined or from which legal consequences can flow. Am. Tradition Inst. Envtl. Law Ctr. v. U.S. Envtl. Prot. Agency, No. 1:12-cv-1066 (E.D. Va. Jan. 31, 2013), http://elr.info/litigation/43/20029/american-tradition-institute-environmental-law-center-v-united-states.

10. Steve Milloy, *Federal Judge Overturns EPA Human Experiments Case: Illegal Testing Continues to Endanger Lives*, WASH. TIMES, Feb. 13, 2013, http://www.washingtontimes.com/news/2013/feb/13/milloy-federal-judge-overturns-epa-human-experimen/. The APA governs the process by which federal agencies develop and issue regulations. It also provides standards for judicial review if a person has been adversely affected or aggrieved by an agency action. *See generally Summary of the Administrative Procedure Act*, U. S. ENVTL. PROT. AGENCY, http://www2.epa.gov/laws-regulations/summary-administrative-procedure-act (last visited Sept. 7, 2013); Administrative Procedure Act 5 U.S.C. §§551-559 (2006).

periments, it did not have standing to pursue the case.[11] However, the allegations this lawsuit brings against the EPA, a United States government agency, are far too serious to disregard. Although the United States has come a long way and evolved over the years, it does not have a clean record when it comes to experiments involving humans.[12] In order to ensure that current regulations are effective at preventing human rights violations, serious allegations, such as these against the EPA, cannot be taken lightly. If the allegations are true, allowing conduct like this by a government agency as influential as the EPA is unacceptable and could have devastating consequences for human rights in the United States. It is crucial for the legal system to allow the ATI's lawsuit to proceed in order to guarantee that the EPA is following regulations and to ensure individual participant's safety in future experiments.

Part I of this note will discuss in more detail the allegations against the EPA, ignoring the procedural reasons for why the current lawsuit was thrown out and focusing on the substantive allegations as if the case were going forward.

Part II of this note will discuss the legitimacy of the ATI's claim and explain why these allegations, if true, violate medical ethical standards and should therefore be illegal. This will include a discussion of current and historical ethical standards in medicine, based upon an examination of the Nuremberg Code and the doctrine of informed consent. Part II will also delve into the text of the Common Rule, the governing standard for experiments involving human subjects by government agencies, and the role it plays in this lawsuit.

Part III of this note will explain the importance of addressing these allegations and the possible consequences for society if they are true and the EPA's actions go unchecked. This will include a discussion of the seriousness of the offenses and demonstrate how past violations of humans rights have affected society.

Part IV of this note will conclude by discussing why the EPA is not taking these allegations as seriously as it should and why the ATI's lawsuit, and other suits like it, should be permitted to pro-

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11. Verified Complaint, *supra* note 2, at 7-13. The fact that Judge Trenga found the ATI was not a proper plaintiff is not wholly relevant to this discussion.

12. *See* Abigail Perkiss, *Public Accountability and the Tuskegee Syphilis Experiments: A Restorative Justice Approach*, 10 BERKELEY J. AFR.-AM. L. & POL'Y 70 (2008).

ceed in our courts of law as they constitute potential violations of human rights in contravention of the Nuremberg Code.

I. THE ATI ALLEGES THE EPA FAILED TO INFORM HUMAN SUBJECTS PARTICIPATING IN THEIR EXPERIMENTS THAT THEY WERE GOING TO BE EXPOSED TO LETHAL PARTICULATE MATTER.

The ATI alleges the EPA intentionally exposed human test subjects to fine particles, such as those produced by cars and coal-fired power plants, which the EPA itself has described as lethal and concluded there is no exposure level below which there is no risk at all.[13] "Fine particles"[14] are found in gaseous substances, like smoke and haze, which are 2.5 micrometers in diameter and smaller.[15] These particles can be directly emitted from sources such as forest fires, or they can form when gases emitted from power plants, industries, and automobiles react in the air.[16] The apparent goal of these experiments was to test the effects of the inhalation of this particulate matter on individuals more susceptible to harm from it, such as those with asthma or other respiratory illnesses.[17] Landon Huffman, a member of the ATI, participated in one of these experiments and said he believed the personal benefit to participating in the experiment was that it could actually help with his asthma, not worsen it.[18] He had no idea the pollution the EPA was forcing into his lungs was actually putting his health in serious danger and greatly increasing his chances of getting ill or even dying.[19]

Long ago, the EPA determined any exposure to these particles could cause an array of serious health consequences, or even

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13. Lorraine Bailey, *EPA Tests Lethal Fine Particles on Human Subjects, Think Tank Says*, COURTHOUSE NEWS SERVICE (Sept. 26, 2012), http://www.courthousenews.com/2012/09/26/50640.htm.

14. The EPA categorizes "fine particles" as a type of "particulate matter." The EPA states, "'Particulate matter,' also known as particle pollution or PM, is a complex mixture of extremely small particles and liquid droplets. Particle pollution is made up of a number of components, including acids (such as nitrates and sulfates), organic chemicals, metals, and soil or dust particles." *Particulate Matter (PM)*, U.S. ENVTL. PROT. AGENCY, http://epa.gov/airquality/particlepollution/ (last visited Dec. 27, 2013).

15. *Id.*

16. *Id*.

17. Verified Complaint, *supra* note 2, at 12-13.

18. *Id*. at 3.

19. *Id*.

death, within hours or days of inhalation.[20] Steve Milloy,[21] one of the individuals responsible for filing this complaint, states EPA researchers failed to properly warn participants that this particulate matter was deadly and extremely harmful; instead, the study subjects unknowingly risked their lives for $12 per hour.[22] In addition to the lawsuit, Milloy also filed a complaint with the North Carolina Medical Board,[23] accusing three doctors of "intentionally exposing test subjects to inhalable pollutants that the agency considered both cancer—and death—causing."[24] The complaint states, "During these experiments, the study subjects were intentionally exposed to airborne fine particulate matter ("PM 2.5") at levels ranging from 41.54 micrograms per cubic meter to 750.83 micrograms per cubic meter for periods of up to two hours."[25] The problem is the EPA has determined that even in low levels PM 2.5 is ultra-hazardous and can be potentially lethal within hours of exposure, and no exposure to PM 2.5 is safe.[26] With this knowledge there is no justification for why the EPA should be able to continue conducting experiments that purposely introduce PM 2.5 to humans, regardless of whether or not the participants were fully informed of the harmful consequences of the experiment. The EPA's own website summarizes the health risks of particulate matter, stating:

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20. Milloy, *supra* note 10.

21. Steve Milloy is the publisher of JunkScience.com, a columnist for FoxNews.com and the New York Sun, and an adjunct scholar at the Competitive Enterprise Institute. *See generally* Steven J. Milloy, COMPETITIVE ENTERPRISE INSTITUTE, http://cei.org/adjunct-scholar/steven-j-milloy (last visited Dec. 27, 2013).

22. Milloy, *supra* note 10.

23. The complaint was filed with the North Carolina Medical Board because the purportedly illegal experimentation was being carried out at an EPA laboratory on the Chapel Hill campus of the University of North Carolina School of Medicine. In addition, Milloy asserts that EPA researchers and grantees have carried out dozens of similar experiments over the past ten years at schools such as Rutgers University, the University of Michigan, University of Rochester, University of Southern California, and University of Washington. Steve Milloy, *EPA's Illegal Human Experiments Could Break Nuremberg Code: Agency Claims Unfettered Discretion in Treatment of Test Subjects*, WASH. TIMES, Dec. 31, 2012, http://www.washingtontimes.com/news/2012/dec/31/epas-illegal-human-experiments-could-break-nurembe/.

24. Paul Chesser, *EPA in a Bind over Hazardous Experiments on Humans*, NAT'L LEGAL & POL'Y CENTER (June 18, 2012, 11:10 AM), http://nlpc.org/stories/2012/06/15/epa-bind-over-hazardous-experiments-humans.

25. *Id.*

26. *Id.*

> Particle pollution – especially fine particles – contains microscopic solids or liquid droplets that are so small that they can get deep into the lungs and cause serious health problems. Numerous scientific studies have linked particle pollution exposure to a variety of problems, including: premature death in people with heart or lung disease, nonfatal heart attacks, irregular heartbeat, aggravated asthma, decreased lung function, and increased respiratory symptoms, such as irritation of the airways, coughing or difficulty breathing.[27]

The EPA also states that those with heart or lung disease, children, and older adults are at the most risk when exposed to particulate matter.[28] On September 22, 2011, EPA Administrator Lisa Jackson addressed Congress and told the Oversight and Investigations Subcommittee of the House Energy and Commerce Committee, "Particulate matter causes death. It doesn't make you sick. It's directly causal to dying sooner than you should."[29] In its 2009 assessment, the EPA stated there was in fact evidence suggesting a causal relationship between PM 2.5 exposure and cancer.[30] At university laboratories, the EPA has employed or funded researchers who have been intentionally exposing a variety of people to concentrated levels of different air pollutants, including soot and dust, diesel exhaust, ozone and chlorine gas.[31] In 2009, the EPA clearly established the dangers linked with particulate matter. Yet, the EPA still proceeded to expose individuals, especially those who already suffer from health issues, and fails to see the abuse in doing so.

II. IF THE ALLEGATIONS ARE TRUE, THE EPA'S EXPERIMENTS SHOULD BE ILLEGAL DUE TO THE FACT FAILURE TO GIVE A TEST SUBJECT FULLY INFORMED CONSENT VIOLATES THE CODE OF MEDICAL ETHICS.

The American Medical Association's (AMA) Code of Medical Ethics is a guide for practicing physicians regarding ethical issues and policies. The Principles of Medical Ethics (hereinafter "Common Rule") adopted by the AMA are not laws but rather "standards of conduct which define the essentials of honorable behavior

27. *Particulate Matter*, *supra* note 14.
28. *Id.*
29. Chesser, *supra* note 24.
30. *Id.*
31. Milloy, *supra* note 23.

for the physician."[32] Physicians have a duty to treat their patients in accordance with these well-accepted medical and ethical principles, or else they could be subject to discipline or even to lawsuits, as is the case here.[33]

In the first half of the 1900s uniform regulation of human experiments was virtually nonexistent. It was not until 1946, when news of experiments performed by Nazi doctors during World War II drew attention to the lack of international standards on research with human participants, that the need for universal standards was realized.[34] This resulted in the formulation of the Nuremberg Code. One of the major principles emphasized in the Nuremberg Code[35] was the idea of informed consent, a phrase often used in law to indicate that an individual's approval meets certain minimum standards and is said to have been given based upon a clear appreciation and understanding of the facts, implications, and future consequences of an action.[36] There are three requirements for valid informed consent: (1) the person must have the ability to understand the information they are given and the consequences of the decision they are making, (2) the physician must disclose relevant information to allow the person to make an educated decision, and (3) the person must be able to make their decision voluntarily, without any coercion.[37]

The doctrine of informed consent was originally created to target experiments by Nazi doctors during World War II who were known for their unethical experiments on prisoners without their

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32. *See generally Principles of Medical Ethics*, AM. MED. ASS'N, http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/principles-medical-ethics.page? (last visited Dec. 27, 2013).

33. For example, in *Horne v. Patton*, a physician was sued for breach of fiduciary duty after revealing patient information to the patient's employer, contrary to instructions of the patient. 291 Ala. 701, 704 (1973). The court held there was a confidential relationship between the doctor and the patient which imposed a fiduciary duty upon the doctor not to disclose information concerning his patient obtained in the course of treatment unless the public interest or the private interest of the patient demands otherwise. *Id.* at 711.

34. *History of Ethics*, CLAREMONT GRADUATE U., http://www.cgu.edu/pages/1722.asp (last visited Dec. 27, 2013).

35. For a list of the Nuremberg Code principles *see The Nuremberg Code*, U.S. NAT'L INST. HEALTH, *available at* http://history.nih.gov/research/downloads/nuremberg.pdf (last visited Dec. 27, 2013).

36. *Informed Consent Law & Legal Definition*, USLEGAL, *available at* definitions.uslegal.com/i/informed-consent (last visited Dec. 27, 2013).

37. Douglas Andrew Grimm, *Informed Consent for All! No Exceptions*, 37 N.M. L. REV. 39, 40-41 (2007).

consent.[38] The concern was that because of the risks associated with experiments, patients had the right to be informed of the possible consequences of their participation. As stated above, one of the crucial elements of giving valid informed consent is the idea that individuals are furnished with the required information to make a knowledgeable decision. Here, the contention is that the test subjects were not given all of the information they needed in order to make a well-informed decision. Without knowledge of exactly how dangerous inhalation of particulate matter is, participants cannot give valid consent.

The Nuremberg Code marked the beginning of regulations regarding the ethical use of human participants in research. Today, the Common Rule governs all U.S. government-funded human subjects research.[39] This sets forth requirements for review by an Institutional Review Board (IRB), informed consent, and additional protections for vulnerable populations.[40] The central requirements for the Common Rule are:

> 1. That people who participate as subjects in covered research are selected equitably and give their fully informed, fully voluntary written consent; and
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> 2. That proposed research be reviewed by an independent oversight group referred to as an Institutional Review Board (IRB), and approved only if risks to subjects have been minimized and are reasonable in relation to anticipated benefits, if any, to the

38. For example, Nazi doctors performed various operations without anesthesia, carried out malaria inoculation experiments, had healthy individuals injected with bacterial cultures, performed plastic surgery experiments, dietary experiments, and experiments with poisoned ammunition. Many of these experiments were fatal or extremely debilitating. *See* Capt. Edgar G. Boedeker & 1st Lt. Nicholas R. Doman, *War Crimes and Crimes Against Humanity Part IV*, Donovan Nuremberg Trials Collection, Vol. IX Section 16.02, *available at* http://library2.lawschool.cornell.edu/donovan/pdf/Nuremberg_3/Vol_IX_16_02.pdf (last visited Dec. 27, 2013). For a list of experiments that were done and the doctors, *see, e.g.*, *The Nuremberg Trials: The Doctors Trial*, U. MO.-KAN. CITY SCH. L,, http://law2.umkc.edu/faculty/projects/ftrials/nuremberg/NurembergDoctorTrial.html (last visited Dec. 27, 2013).

39. *Information on Protection of Human Subjects in Research Funded or Regulated by U.S. Government*, U.S. DEPT. OF HEALTH & HUMAN SERVS, http://www.hhs.gov/1946inoculationstudy/protection.html (last visited Dec. 27, 2013).

40. *Id.*

> subjects, and the importance of the knowledge that may reasonably be expected to result.[41]

The Common Rule clearly states the need for fully informed voluntary consent. As this information is taken from the EPA's own website, it is clear that the EPA is aware of the guidelines. If the allegations are true and the EPA failed to inform study subjects of the dangers associated with the matter they were inhaling, then it could not have obtained valid consent because consent that is the result of misrepresentation or fraud is not valid.[42] Particulate matter is known to be extremely dangerous which brings into question the validity of experimenting on human subjects if the possible benefits are so heavily outweighed by the associated risks and no problems seem to be solved by them.[43] The following is the warning Steve Milloy asserts the test subjects were actually given:

> PM exposure: During the exposure to the concentrated air pollution particles, you may experience some minor degree of airway irritation, cough, and shortness of breath or wheezing. These symptoms typically disappear 2 to 4 hours after exposure, but may last longer for particularly sensitive people. You will be monitored continuously during the exposure session.[44]

If this is truly the extent of the warning given to participants, the shortcomings are obvious. This notice clearly downplays the significant negative impact exposure to PM 2.5 can have on a person, and especially on those already more inclined to health issues.[45]

The Common Rule requires the following in order to receive IRB approval of research:

> (1) Risks to subjects are minimized:

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41. *Human Subjects of Research (the "Common Rule")*, U.S. ENVTL. PROT. AGENCY, http://www.epa.gov/oppfead1/guidance/cr-require.htm (last visited Dec. 27, 2013).

42. Verified Complaint, *supra* note 2, at 2.

43. *Id.* at 1-2.

44. Steve Milloy, *EPA Human Testing Blog*, JUNKSCIENCE.COM, *available at* http://epahumantesting.files.wordpress.com/2012/08/omegacon-pm-disclosure.gif (last visited Dec. 27, 2013).

45. The lack of full disclosure or a formal piece of paper that clearly comes from the experiments affects the credibility of this excerpt.

> (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and
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> (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes
>
> (2) Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result . . .
>
> (3) Selection of subjects is equitable . . .
>
> (4) Informed consent will be sought from each prospective subject or the subject's legally authorized representative.[46]

Under the Common Rule, once the EPA had knowledge of the danger of the toxic fumes inhaled by test subjects, it was their obligation to stop immediately. From the information at hand through this complaint and other information available to the public, there is no sufficient justification that outweighs the harm this experiment causes.

III. IF THE EPA IS EXEMPT FROM FOLLOWING ETHICAL GUIDELINES, CONGRESS NEEDS TO TAKE ACTION AGAINST THE CURRENT POLICIES.

The ethical issue surrounding these experiments is centered on the allegation that the EPA continued to expose human test subjects to PM 2.5, knowing the severe risks associated and not fully informing them of these dangers. In his complaint, Milloy states the EPA requires researchers to minimize risk to subjects, and in addition, the risks must be reasonable compared to anticipated benefits.[47] The EPA's response to these allegations has basically been to say that as an organization it is "above the law" and the federal court system is not the proper venue to decide any wrongdoing under the Clean Air Act (CAA).[48] The EPA claims:

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46. Criteria for IRB Approval of Research, 40 C.F.R § 26.111 (2013).
47. Verified Complaint, *supra* note 2, at 15.
48. Milloy, *supra* note 23.

> Nothing in the CAA provides a meaningful standard to evaluate what air pollution the EPA chooses to study or how. To the contrary, the CAA gives the EPA broad discretion in the subject matter of its research program. Congress broadly mandated that the EPA study the health effects of air pollution.[49]

Even so, it does not follow that the EPA should be permitted to put individuals at risk without giving absolute disclosure so that they can fully understand the danger that is involved in participation.

Given proper disclosure, as there are no documented benefits to inhaling PM 2.5 and the health risks are so severe, the likelihood of public participation in the study would be significantly diminished, if present at all.[50] Perhaps that is one motivation for why the EPA may have failed to disclose the negative effects of the experiments to their test subjects. If individuals fully aware of the risks would no longer partake, then that could have caused serious roadblocks for the EPA's research.

Mr. Milloy comments on the need for congressional action, alluding to the EPA's implied immunity:

> [B]ecause Congress has not enacted a law that expressly forbids the agency from violating the Nuremberg Code and federal regulations governing human testing or that expressly guides judges in evaluating the conduct of agency researchers who experiment on their fellow human beings, the agency has unfettered discretion to do as it pleases with the young, old, sick and anyone else who falls into its clutches.[51]

Although he argues the EPA is immune, the organization does have its own regulations regarding protection of human research subjects that incorporates much of the Common Rule.[52] This would mean that contrary to Mr. Milloy's statements, the EPA should be bound by violations of their own adopted code of ethical experimentation. Failure to enforce legally binding guidelines with re-

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49. *Id.*

50. As stated earlier, the EPA has determined that inhalation of particulate matter can cause death or an array of other serious medical issues within hours or days.

51. Milloy, *supra* note 23.

52. *Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research*, U.S. ENVTL. PROT. AGENCY, *available at* http://www.epa.gov/osa/phre/pdf/epa-order-1000_17-a1.pdf.

gards to human experimentation could lead to dangerous consequences, as might be the case with the EPA's alleged experiments.

IV. THE ALLEGATIONS OF HUMAN RIGHTS VIOLATIONS BY THE EPA LACK NECESSARY CREDIBILITY

The biggest issue for the ATI is that its complaint has not been taken seriously. The EPA has not taken it seriously.[53] Universities, such as North Carolina, where these experiments took place have not taken it seriously.[54] When notified of the experiments, officials at the University of North Carolina stated they would "investigate further if warranted."[55] A look at the letter gives the impression that the university is brushing the allegations aside without seriously examining what has taken place on their campus.[56]

A likely reason for this is a lack of concrete evidence from multiple sources. The allegations have merit, considering participants have come forward, however, the complaint lacks the "final nail in the coffin," so to speak. As it stands, there are holes in Steve Milloy's arguments, and as such it is difficult not to be skeptical. The EPA is a widely reputed organization; to successfully make unsettling claims against it requires additional substantiation. The ATI could achieve this goal by locating additional study participants, have them confirm their lack of knowledge of the risks involved with participation in the experiment and show how they were negatively impacted by their involvement.

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53. For example, Steve Milloy states, "Rather than defending itself against the serious allegations made by the institute, the EPA instead has said it is essentially above the law and the federal court has no business hearing those serious charges." Steve Milloy, Op-Ed., *EPA's Illegal Human Experiments Could Break Nuremberg Code: Agency Claims Unfettered Discretion in Treatment of Test Subjects*, WASH. TIMES, Dec. 31, 2013, http://www.washingtontimes.com/news/2012/dec/31/epas-illegal-human-experiments-could-break-nurembe/?page=all.

54. Steve Milloy, *UNC to Investigate Ghastly EPA Human Experiments,* JUNKSCIENCE.COM (July 2, 2012), http://junkscience.com/2012/07/02/unc-to-investigate-ghastly-epa-human-experiments/.

55. Letter from William L. Roper, Dean and Vice Chancellor for Medical Affairs, UNC-Chapel Hill, to Steve Milloy, (June 28, 2012), *available at* http://junksciencecom.files.wordpress.com/2012/07/unc-response-062812.pdf.

56. *Id.*

The information currently available lacks credibility. Mr. Milloy has posted pictures of these said EPA experiments.[57] However, some critics assert that the machine depicted looks awfully similar to a machine used to monitor breathing in patients with emphysema.[58] Mr. Milloy also posts an excerpt he declares was taken directly from the consent forms filled out by test subjects, yet he fails to display a complete form.[59] This again leads one to question the credibility of the information. There are individuals who believe experiments such as these are commonplace and frequently practiced by government agencies, the military, universities, other research entities, as well as pharmaceutical companies.[60] They argue these experiments are guided by strict rules and safety regulations under the Common Rule and assert that this is basic scientific process.[61] If this is a common practice, then the United States has not evolved as far as society would like to believe with regard to their ethical treatment of human test subjects. If the allegations against the EPA are true, it has a lot to answer for. Unfortunately, without additional corroboration, the complaint is going nowhere.

V. CONCLUSION

The argument certainly exists that the work the EPA is performing under the Clean Air Act is extremely important and has helped advance society's knowledge and awareness with regard to pollution and its negative impact on human health. However, the question becomes: at what point do the benefits of the EPA's experiments outweigh the health risks to the participants? The EPA's current practices do not make the health of participants their primary concern, resulting in dangerous consequences. The importance of having guidelines in place, such as the Common

57. For an image of the alleged testing that the EPA is performing, *see* Steve Milloy, EPA HUMAN TESTING BLOG, http://epahumantesting.files.wordpress.com/2012/08/epa-makes-de-from-smw.jpg (last visited Dec. 27, 2013).

58. *Compare id.* (alleging the EPA testing involves pumping diesel exhaust through piping into an exposure chamber), *with Spirometry*, MAYO CLINIC, http://www.mayoclinic.com/health/medical/IM01608 (last visited Dec. 27, 2013) (showing a patient using a spirometer to test lung function).

59. Milloy, *supra* note 57.

60. Ben Jervey, *Irony Alert: Tobacco Apologist Steve Milloy's EPA Human Testing Scare Campaign*, DESMOGBLOG.COM (Oct. 24, 2012, 1:36 PM), http://www.desmogblog.com/2012/10/11/irony-tobacco-apologist-steve-milloys-epa-human-testing-scare-campaign.

61. *Id.*

Rule, is evident as history has shown us that without regulation the rights of human test subjects can easily be infringed. Regulation ensures that the safety and well-being of the test subject is the number one priority when conducting human experiments. Otherwise, experiments like those performed in Nazi concentration camps and even in the United States are able to occur.[62] Unfortunately, a major issue for the ATI and Steve Milloy is a lack of credible concrete evidence of these experiments and lack of proof of the extent of knowledge participants really had before they agreed to partake. Much of the information found comes from articles or blogs written by Milloy himself. While the complaint filed with the district court in Virginia seems legitimate, in order for such allegations to be taken seriously more proof of the experiments needs to be unearthed. As it stands, without such evidence, the courts are not going to persecute a large and influential organization like the EPA.

62. *See, e.g.*, *Bad Blood: The Tuskegee Syphilis Study*, U. VA. HEALTH SYS., http://www.hsl.virginia.edu/historical/medical_history/bad_blood/report.cfm (last visited Dec. 27, 2013).