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Could You Repeat That Please? Forty-Five years of Pesticide Experiments on People

Barbara Leiterman*

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I. Introduction

In October of 2004 approximately thirty Florida parents were offered \$970.00, a camcorder, a bib, and a t-shirt in exchange for the right to measure the development of their young children who were exposed to household chemicals and pesticides on a routine basis.¹ The children were exposed to household chemicals through furniture or fabric in their homes that contained the chemicals² and they were exposed to pesticides through

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1. Kirkpatrick, E.P.A. *Halts Florida Test on Pesticides*, N.Y. TIMES, Apr. 9, 2005, at A15; Michael Janofsky, *Nominee Challenged Over Program On Pesticides*, N.Y. TIMES, Apr. 7, 2005, at A19.

2. Kirkpatrick, *supra* note 1; Janofsky, *supra* note 1.

routine application of household pesticides in their homes.³ The recruitment of test subjects for this study was the beginning of the Children's Environmental Exposure Study, otherwise known as CHEERS.⁴

In order to participate in CHEERS, the families involved needed to live in Duval County, Florida, have children less than one year of age,⁵ and "spray [] pesticides inside [their] home routinely."⁶ Subsequently, families that signed up to participate agreed to allow the United States Environmental Protection Agency ("EPA") to monitor the development of their children for the next two years.⁷

CHEERS will serve as an introduction to the practical and ethical quandaries of testing pesticides on people. The story of its cancellation will be examined, as it reveals not only the lack of public knowledge of this field, but also the dangers exacerbated by this lack of public knowledge. Part I (Section II) will describe pesticide tests on people that occurred between 1967 and 2004 for products aimed at the American market, and the ethical violations found within those experiments.

Part II (Section III) will explore two pesticide tests on people since 2005: the Agricultural Health Study and the Endosulfan Study. Both experiments share many of the qualities of good science. In fact, they may represent ethical tests of pesticides on people. However, they also raise the deeper questions of consent and necessity implicit in pesticide tests on people.

Part III (Section IV) will briefly analyze some of the laws and regulations that govern pesticides in the United States, focusing on their relationship with pesticide tests on people. In general, when this article refers to pesticide tests on people, it is referring to those tests whose results were submitted, or were intended to be submitted, to U.S. regulators. Part III will also describe human health risk assessments, and incentives for testing pesticides on people.

II. Testing Pesticides on People

A. The Children's Environmental Exposure Study (CHEERS)

The Children's Environmental Exposure Research Study ("CHEERS") was designed to study the effects, if any, of the pesticides DEET and pyrethrin, as well as phthalates, brominated flame-retardants, and

3. Janofsky, *supra* note 1.

4. *Id.*

5. *Id.*

6. Kirkpatrick, *supra* note 1.

7. *Id.*; see Juliet Eilperin, *Chemical Industry Funds Aid EPA Study: Effect of Substances on Children Probed*, WASH. POST, Oct. 26, 2004, at A23.

perfluorinated compounds on children between birth and three years of age.⁸ Phthalates, brominated flame-retardants, and perfluorinated compounds are all commonly found in modern household products.⁹ Brominate flame retardants are “found in polyurethane foam products, foam padding in furniture, textiles, electrical appliances, televisions and computers.”¹⁰ Regarding phthalates, “80–90% of [p]hthalates are used in

8. Eilperin, *supra* note 7, at 23; *see also* Kara Sissell, EPA Cancels Controversial Children’s Health Study, CHEM. WEEK, Apr. 20, 2005, at 27.

Before CHEERS was proposed, the following was already known by the U.S. government regarding the health risks of some of the chemicals being studied:

In 2001 the Department of Health and Human Services described the pesticide group pyrethrins interfering with nerve and brain function. Department of Health and Human Services, Agency for Toxic Substances & Disease Registry, *ToxFAQs for Pyrethrins and Pyrethroids*, <http://web.archive.org/web/20030417165632/http://www.atsdr.cdc.gov/tfacts155.html> (last visited Aug. 10, 2012).

Pyrethrins and pyrethroids interfere with the normal way that the nerves and brain function. Exposure to very high levels of these compounds for a short period in air, food, or water may cause dizziness, headache, nausea, muscle twitching, reduced energy, changes in awareness, convulsions and loss of consciousness. Changes in mental state may last several days after exposure to high levels of pyrethroids has ended. *Id.*

The same webpage also addressed the effect of pyrethrins on children:

It is likely that health effects seen in children exposed to high levels of pyrethrins or pyrethroids will be similar to the effects seen in adults. We do not know whether children differ from adults in their susceptibility to these chemicals. *Id.* Birth defects have not been observed in humans exposed to pyrethrins or pyrethroids. Offspring of animals that ingested pyrethrins or pyrethroids while pregnant showed signs of possible damage to the immune system. Some animals that were exposed to pyrethrins or pyrethroids right after birth showed altered behavior as adults. *Id.*

9. PAT COSTNER ET AL., SICK OF DUST: CHEMICALS IN COMMON PRODUCTS A NEEDLESS HEALTH THREAT IN OUR HOMES (2005), *available at* <http://www.cleanproduction.org/library/Dust%20Report.pdf> (last visited Oct. 9, 2012).

10. COSTNER, *supra* note 9, at 11; *see also* LINDA S. BIRNBAUM & DANIELE F. STASKAL, BROMINATED FLAME RETARDANTS: CAUSE FOR CONCERN? 12 ENVIRONMENTAL HEALTH PERSPECTIVES 1, 9-10 (2004) *available at* <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1241790/pdf/ehp0112-000009.pdf> (last visit-

flexible PVC (vinyl) products such as wall coverings, flooring, furniture, shower curtains, clothing, raincoats, shoes, and toys.”¹¹ And lastly, the perfluorinated compound PFOA is “used to make Teflon, Goretex, and . . . materials that are used in . . . nonstick frying pans, utensils, stove hoods, stain proofed carpets, furniture, and clothes.”¹²

CHEERS was to be funded by the EPA and the American Chemistry Council (“ACC”).¹³ The ACC is a trade group of American chemical corporations including pesticide manufacturers.¹⁴ To help fund the study, the EPA accepted two million dollars from the ACC.¹⁵

CHEERS aimed to recruit sixty test subject families.¹⁶ The parents or guardians of the test subjects in those families would be instructed to videotape their babies and/or young children (hereinafter “children”), collect urine samples from their children, attach “activity sensors” to them for one week every three to six months¹⁷ and allow two EPA researchers to visit their

ed Oct. 9, 2012). Note that while Costner uses the term “brominate flame retardants” and Birnbaum & Staskal use the term “brominated flame retardants,” their descriptions of the chemicals and the uses of those chemicals make it evident that they are referring to the same class of chemicals.

11. COSTNER, *supra* note 9, at 11.

12. *Id.* Costner and her co-authors reported on a study of dust samples taken from 70 homes in seven U.S. states. They found that “[a]ll composite samples were contaminated by all six of the chemical classes we investigated: phthalates, pesticides, alkylphenols, brominated flame retardants, organotins and perfluorinated compounds.” *Id.* at 5.

13. Kirkpatrick, *supra* note 1; *see also* Janofsky, *supra* note 1.

14. Kirkpatrick, *supra* note 1.

15. *Id.*; *see also* Eilperin, *supra* note 7, at 23. However the Organic Consumers website lists the ACC’s contribution as 2.1 million. ORGANIC CONSUMERS, EPA & Chemical Industry To Study Effects Of Known Toxic Chemicals On Children: Study Launch Date Suspended Until Summer 2005, Offers Public Comment Period, <http://www.organicconsumers.org/epa-alert.htm> (last visited Aug. 13, 2011).

The two million dollars accepted from the American Chemistry Council helped fund a study that was expected to cost nine million dollars in total. Johanna Neuman, *Acting EPA Chief Withdraws Controversial Pesticide Project; Canceling the Study on Children Clears the Way for a Senate Vote on His Nod to Head the Agency*, L.A. TIMES, Apr. 9, 2005, at A31.

16. Eilperin, *supra* note 7, at 23.

17. Videotape: Senator Barbara Boxer, Press Conference of Senator Bill Nelson and Senator Barbara Boxer at the Senate Radio/TV Gallery: EPA’s Children’s Environmental Exposure Research Study and Nomination of

homes up to four times a year for the duration of the two-year study.¹⁸ The EPA and the ACC would use the videotapes, urine samples, sensor data, and researchers' observations to study the development of the children in these families. The children would be studied in order to measure the effects of pesticide and household chemical exposure on their developing bodies.¹⁹ It appears that the parents or guardians of the test subjects would receive the promised money, clothing, and video camera only after fulfilling their obligations to the study for the full two years.²⁰

Pesticide tests on people can be roughly divided between observational tests and intentional dosage tests. An observational test is one where "researchers collect data on exposures that occur in the course of routine activities."²¹ An intentional dosage test is one where human test subjects are intentionally given a specific dose of a substance (for example five milligrams of a pesticide in a pill, an injection, or an inhaled vapor).²²

Can CHEERS be considered an observational study?²³ The CHEERS test subjects lived in environments where, theoretically, they were already exposed to the chemicals being studied and their exposure was not intended to change as a result of the study. Arguably, proposing to take blood samples and attach activity sensors to the test subject children may take CHEERS out of the realm of observational testing. Whether or not CHEERS was a purely observational test, it was not an intentional dosage test because the test subjects were not intentionally given a specific dose of a substance. These distinctions are necessary when delving into the ethics of experimentation on people.

Stephen Johnson to be EPA Administrator (Apr. 7, 2005) (on file with author).

18. *Id.*

19. Janofsky, *supra* note 1.

20. Kirkpatrick, *supra* note 1. David B. Resnik agrees that parents of test subjects "could remain in the study even if they decided to reduce or eliminate their pesticides use; they would also be free to withdraw from the study at any time." David B. Resnik, *Lessons Learned From the Children's Environmental Exposure Research Study*, 97 AM. J. PUB. HEALTH 414, 415 (Mar. 2007).

21. *Id.*

22. The Code of Federation Regulation defines intentional exposure research on humans as "a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study." 40 C.F.R. § 26.1102(i).

23. Resnik, *supra* note 20, at 415.

Six health clinics and three hospitals in Jacksonville, Florida were chosen as recruitment sites for CHEERS.²⁴ According to the study's proposal, "[a]lthough all Duval County citizens are eligible to use the [health care] centers, [the clinics and hospitals] primarily serve individuals with lower incomes. In the year 2000, seventy five percent of the users of the clinics for pregnancy issues were at or below the poverty level."²⁵ The national poverty level for a family of four in 2005 was \$19,157.00.²⁶

The compensation offered to the parents of CHEERS test subjects (a video camera, \$960.00 cash, and a t-shirt and bib) may seem like small compensation to some. The Acting Administrator for the Human Exposure and Atmospheric Sciences Division of the EPA's Office of Research and Development said that it was unlikely that anyone would volunteer for CHEERS out of financial need²⁷ and that "[n]obody can go into this study just for that amount of money."²⁸ However, framing the CHEERS rewards as a percentage of the annual budget of the CHEERS recruits reveals that the benefits offered (\$960.00 cash, two clothing items of minimal value, and a video camera with a value of approximately \$150.00 = \$1,110.00) represent approximately seventeen percent of the annual budget of a family of four living at the poverty line in 2005.²⁹ Seventeen percent of any person's budget is a considerable incentive.

Why were clinics and hospitals that primarily serve working class people (seventy five percent of the users of the clinics for pregnancy issues were at or below the poverty level),³⁰ chosen as recruitment sites? Some researchers believe that low-income test subjects in low-income neighborhoods are less likely to "make a fuss" to the public, the press, or their political representatives about an environmental risk or siting decision. In 1984 a political consulting firm called Cerrell Associates wrote a report for

24. ORGANIC CONSUMERS, *supra* note 15; Videotape: Senator Bill Nelson, Press Conference of Senator Bill Nelson and Senator Barbara Boxer at the Senate Radio/TV Gallery: EPA's Children's Environmental Exposure Research Study and Nomination of Stephen Johnson to be EPA Administrator (Apr. 7, 2005) (on file with author), *supra* note 17.

25. ORGANIC CONSUMERS, *supra* note 15.

26. David Leonhardt, U.S. Poverty Rate Was Up Last Year, N.Y. TIMES, Aug. 31, 2005.

27. Juliet Eilperin, EPA to Study Pesticides' Effect on Kids Spurs Backlash within Agency, S.F. CHRON., Oct. 31, 2004.

28. *Id.*

29. There is at least a 75% chance that the families recruited for CHEERS were living at or below the poverty line. ORGANIC CONSUMERS (quoting EPA Study Proposal, at 23), *supra* note 15.

30. *Id.*

the California Waste Management Board.³¹ The report recommended siting waste incinerators in neighborhoods that would “offer the least potential of generating public opposition.”³² It described such neighborhoods as:

[s]mall, rural communities whose residents are low income, older people, or people with a high school education or less; communities with a high proportion of Catholic residents Officials and companies should look for lower socioeconomic neighborhoods that are also in a heavy industrial area with little, if any commercial activity.³³

Fifty-one percent of the births at the medical facilities at which the CHEERS test subjects were recruited were to women of color, and sixty-two percent of those mothers had ended their education at elementary or secondary school.³⁴ The CHEERS proposal also purportedly said “[t]he percentage of births to individuals classified as black in the U.S. Census is higher at these three hospitals than for the County as a whole.”³⁵ Luke Cole and Sheila Foster’s description of the influence of race when choosing toxic waste sites is relevant:³⁶

Rarely does a “smoking gun” – explicit racial criteria or motivation – exist behind the decision to locate a toxic waste facility in a community of color. The reasons frequently given by companies for siting facilities are that such communities have low-cost land, sparse populations, and desirable geological attributes. Notably, however, there is evidence that portions of the waste industry target neighborhoods that possess the attributes of many poor communities of color, using “race-neutral criteria.”³⁷

31. LUKE COLE & SHEILA FOSTER, FROM THE GROUND UP: ENVIRONMENTAL RACISM AND THE RISE OF THE ENVIRONMENTAL JUSTICE MOVEMENT (2000), *reprinted in* 34 ENVIRONMENTAL JUSTICE: LAW, POLICY & REGULATION 70-74 (Clifford Rechtschaffen & Eileen Gauna eds., 2002).

32. *Id.*

33. ORGANIC CONSUMERS (*quoting* EPA Study Proposal), *supra* note 15.

34. *Id.* (*quoting* EPA Study Proposal, at 23), *supra* note 15.

35. *Id.*

36. COLE & FOSTER, *supra* note 31, at 70-74.

37. *Id.* at 35.

Public policy as it concerns race is subject to strict scrutiny, both culturally and politically,³⁸ by sensitized people and communities.³⁹ This is one of many reasons why choosing to recruit the CHEERS test subjects from health clinics primarily serving less educated working class people of color was a poor choice. However, when looked at in the historical context of human testing, it was not necessarily a surprising choice.

Pesticide testing is a relatively new type of human experimentation, born of a culture typified by human rights abuses.⁴⁰ While some grizzly

38. U.S. CONST. amend. V, amend. XIV, § 1. The first two definitions of “discrimination” in Black’s Law Dictionary are:

1. “The effect of a law or established practice that confers privileges on a certain class or that denies privileges to a certain class because of race, age, sex, nationality, religion or handicap.”

2. “Differential treatment; esp., a failure to treat all persons equally when no reasonable distinction can be found between those favored and those not favored.” BLACK’S LAW DICTIONARY 534 (9th ed. 2009).

39. Harriet A. Washington describes the political and cultural responses of African Americans to medical experimentation:

Historically, African Americans have been subjected to exploitative, abusive involuntary experimentation at a rate far higher than other ethnic groups. Thus, although the heightened African American wariness of medical research and institutions reflects a situational hyper-vigilance, it is neither a baseless fear of harm nor a fear of imaginary harms. A “paranoid” label is often affixed to blacks who are wary of participating in medical research. However, not only is paranoid a misnomer but it is also symbolic of a dangerous misunderstanding. That is why I refer to African American fears of medical professionals and institutions as iatrophobia, coined from the Greek words iatro (“healer”) and phobia (“fear”).

HARRIET A. WASHINGTON, *MEDICAL APARTHEID: THE DARK HISTORY OF MEDICAL EXPERIMENTATION ON BLACK AMERICANS FROM COLONIAL TIMES TO THE PRESENT* 21 (2006).

40. “An important theme of human experimentation before World War II is that many of the subjects were from vulnerable populations: Children, mentally ill people, poor people, prisoners, minorities, and desperately ill people were often harmed or exploited in research After World War II, vulnerable subjects continued to suffer harm or exploitation in research.” ADIL SHAMOO & DAVID B. RESNIK, *RESPONSIBLE CONDUCT OF RESEARCH* 245, 265 (2d ed. 2009) (hereinafter “RESPONSIBLE CONDUCT”). *RESPONSIBLE CONDUCT*

examples are well known (i.e. Nazi experiments on prisoners in concentration camps), what may be less well known is the consistency with which certain groups are used as test subjects. Prisoners,⁴¹ soldiers,⁴² the mentally ill,⁴³ children,⁴⁴ poor people,⁴⁵ and people of color⁴⁶ have all been

describes many of the worst abuses of human test subjects in Chapter 13 “Protecting Vulnerable Human Subjects in Research,” pages 265 – 288.

41. RESPONSIBLE CONDUCT, *supra* note 40, at 244 (“[i]n Oregon State Prison from 1963 to 1971, researchers X-rayed the testicles of 67 male prisoners, who were mostly African Americans, to study the effects of radiation on sperm function”); *id.* at 266 (“[p]rior to 1973, pharmaceutical companies conducted about 70% of their phase I clinical trials on prisoners”) (internal citations omitted); *see also* Valerie H. Bonham & Jonathan D. Moreno, *Research With Captive Populations: Prisoners, Students, and Soldiers* OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 461 (Ezekiel J. Emanuel et al. eds., 2008).

42. RESPONSIBLE CONDUCT, *supra* note 40, at 244 (“[f]rom the 1940s to the 1960s, researchers injected encapsulated radium into the nostrils of more than 1,500 military personnel; many developed nosebleeds and severe headaches after exposure”); *id.* at 266 (“[t]housands of military personnel were used in LSD experiments in the 1950s”) (internal citations omitted); *see also* Valerie H. Bonham & Jonathan D. Moreno, *Research With Captive Populations: Prisoners, Students, and Soldiers* OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 461 (Ezekiel J. Emanuel et al. eds., 2008).

43. The Willowbrook hepatitis experiments were conducted from 1956 to 1980 on mentally retarded children living in the Willowbrook State School in Staten Island, New York. RESPONSIBLE CONDUCT, *supra* note 40, at 265 – 266; *see also* Alan R. Fleischman & Lauren K. Collogan, *Research with Children*, OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 437, 438 (Ezekiel J. Emanuel et al. eds., 2008) (otherwise healthy children were infected with hepatitis in order to study the effects of a possible antibody and the possibility of inducing immunity against the disease); *see also* Walter M. Robinson & Brandon T. Unruh, *The Hepatitis Experiments at the Willowbrook State School*, OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 80, 84 (Ezekiel J. Emanuel et al. eds., 2008). Robinson and Unruh argue that the Willowbrook experiments, when seen in their historical and social context, are not the ethical violations that history has claimed, but rather that the scientists involved “did what they could to improve the chances that institutions were safer for their child residents.” *Id.* at 80.

44. Fleischman and Collogan describe scientific research in the United States in the early 1900s: “the subjects in these studies were often poor or abandoned children who were provided to researchers by doctors working in orphanages and asylums.” Fleischman & Collogan, *supra* note 43, at 437, 447.

victims of human experimentation. The latter two categories may suffer from this exploitation disproportionately because they face double and triple jeopardy when they fall into multiple categories.

1. CHEERS is Cancelled

CHEERS was abruptly cancelled on April 8th, 2005.⁴⁷ The study had recruited half its test subjects, and a pilot study had taken wipe samples for organic compounds on household surfaces.⁴⁸ As far as it is known, that is as far as it got. One of the most instructive aspects of CHEERS is why it was cancelled. Prior to its cancellation CHEERS was the subject of internal dissent in the EPA, external criticism by environmental and public health organizations, and faint though dogged critical press coverage. But it appears that none of those were enough to stop it - CHEERS was cancelled primarily because of the well-timed ultimatum of a U.S. Senator.

The dissent within the EPA became known through internal emails obtained by the press.⁴⁹ Troy Pierce, an EPA scientist in Atlanta at the time, said that CHEERS sounds like it “goes against everything we recommend at EPA concerning use of [pesticides] related to children.”⁵⁰ He continued by stating that, “[p]laying families in Florida to have their homes routinely treated with pesticides is very sad when we at EPA know that [pesticide management] should always be used to protect children.”⁵¹ Suzanne Wuerthele, the EPA’s regional toxicologist in Denver at the time, wrote to her colleagues and proclaimed that after reviewing the project’s design she

Fleischman and Collogan also describe Nazi experiments on child prisoners in concentration camps. *Id.* at 447.

45. Carol Levine, *Research Involving Economically Disadvantaged Participants*, OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 431 (Ezekiel J. Emanuel et al. eds., 2008).

46. Lo and Garan found that “[e]gregious misconduct in clinical research has often centered on ethnic and minority populations.” Bernard Lo & Nesrin Garan, *Research with Ethnic and Minority Populations* OXFORD TEXTBOOK OF CLINICAL RESEARCH ETHICS 423 (Ezekiel J. Emanuel et al. eds., 2008); *see* Washington, *supra* note 39; *see also* Denise Grady, *White Doctors, Black Subjects: Abuse Disguised as Research*, N.Y. TIMES, Jan. 23, 2007, at F5.

47. Stephen L. Johnson, *This Study was Cancelled April 8, 2005*, U.S. ENV’T’L PROTECTION AGENCY, <http://www.epa.gov/cheers> (last visited July 4, 2010).

48. NAT’L EXPOSURE RESEARCH LAB., U.S. ENV’T’L PROTECTION AGENCY, A LITERATURE REVIEW OF WIPE SAMPLING METHODS FOR CHEMICAL WARFARE AGENTS AND TOXIC INDUSTRIAL CHEMICALS 10 (Jan. 2007).

49. Eilperin, *supra* note 27.

50. *Id.*

51. *Id.*

feared poor families would not understand the dangers associated with pesticide exposure and that “EPA researchers will not tell participants that using pesticides always entails some risk, and not using pesticides will reduce that risk to zero.”⁵² Wuerthele wrote, “[i]t is important that EPA behaves ethically, consistently, and in a way that engenders public health. Unless these issues are resolved, it is likely that all three goals will be compromised and the agency’s reputation will suffer.”⁵³

External criticism came from a collection of environmental and public health groups, most notably Organic Consumers.⁵⁴ In addition, several journalists frequently cited in this piece followed CHEERS closely.⁵⁵ They and their editors deserve praise for tenacious coverage.⁵⁶ But the story never became a national story, nor did public knowledge of CHEERS ever reach a critical mass.⁵⁷

On April 7, 2005 California U.S. Senator Barbara Boxer called a press conference with Florida U.S. Senator Bill Nelson.⁵⁸ Senator Boxer denounced CHEERS and declared her intent to stall the appointment of Stephen L. Johnson as the EPA Administrator until CHEERS was cancelled.⁵⁹ Within seventy-two hours of the press conference, Stephen Johnson announced that he was canceling CHEERS.⁶⁰ A spokesman for the EPA acknowledged that Johnson canceled CHEERS in part because of the threat to his confirmation.⁶¹ In regards to Boxer’s press conference that was quickly followed by Johnson’s cancellation of CHEERS, the EPA spokesman

52. *Id.*

53. *Id.*

54. ORGANIC CONSUMERS (*quoting* EPA Study Proposal), *supra* note 15.

55. The reporters include Juliet Eilperin and Catherine Komp, and their editors at the Washington Post, the San Francisco Chronicle, and the (no longer published) New Standard.

56. *Id.*

57. This statement is based on anecdotal evidence. Former classmates, EPA interns, and academics in the environmental field did not know about CHEERS until discussing it with the author. The phenomenon continues to the present day with friends, family, and peers. In fact, most people the author has discussed this piece with in the past six years are shocked to learn that pesticides are tested on human subjects.

58. Boxer, *supra* note 17; *see also* Boxer, Nelson To “Hold” Stephens Nomination Until EPA Cancels Pesticide Program, WHITE HOUSE BULL., Apr. 7, 2005; Kirkpatrick, *supra* note 1; Janofsky, *supra* note 1.

59. Boxer, *supra* note 17.

60. Kirkpatrick, *supra* note 1.

61. *Id.*

quipped, “[t]hey are pretty juxtaposed in time, aren’t they?” and then said “[t]here is clearly a connection.”⁶²

Six years later, many ambiguities remain about CHEERS. The EPA and the ACC have little substantive information about the study on their websites. Five months after CHEERS was cancelled the EPA CHEERS web page turned an accusatory eye towards critics of CHEERS.⁶³ Under the title, “This study was cancelled April 8, 2005,” the EPA Administrator wrote:

Last fall, in light of questions about the study design, I directed that all work on the study stop immediately and requested an independent review. Since that time, many misrepresentations about the study have been made. EPA senior scientists have briefed me on the impact these misrepresentations have had on the ability to proceed with the study. I have concluded that the study cannot go forward, regardless of the outcome of the independent review. EPA must conduct quality, credible research in an atmosphere absent of gross misrepresentation and controversy.⁶⁴

The website has - to the best of the author’s knowledge - had the same message posted on this webpage ever since.⁶⁵ Additionally, the author believes that in April 2005 the ACC website had two press releases regarding CHEERS, but they are no longer available on the ACC’s website using the site’s search function.⁶⁶

62. *Id.*

63. Johnson, *supra* note 47.

64. *Id.*

65. *Id.*

66. In 2005 the author wrote about these two press releases:

The first press release announced the beginning of CHEERS. It was on EPA stationery, it began and ended with names and numbers for contacts at the EPA and the ACC, and it concluded with short descriptions of the missions of the EPA and the ACC. BARBARA LEITERMAN, AMERICAN CHEMISTRY COUNCIL, EPA PARTNERS WITH AMERICAN CHEMISTRY COUNCIL TO STUDY YOUNG CHILDREN’S EXPOSURES TO HOUSEHOLD CHEMICALS (2004). The press release begins, “[t]he U.S. Environmental Protection Agency and the American Chemistry Council (ACC) announced today a Cooperative Research and Development Agreement (CRADA) to conduct a landmark study to learn more about how young children come into contact with household pesticides and other chemicals in their homes.” The second press release on the ACC website was from the day CHEERS was cancelled. It was on ACC stationery. BARBARA

In part because the ACC and the EPA have become virtually silent on the subject of CHEERS, the substantive information readily available to the public is largely from its critics. Therefore, many questions cannot be answered. For example, the *Sarasota Herald-Tribune* wrote that CHEERS was “seriously flawed” in part because it “astonishingly – contained no provision for intervening if the children showed signs of health damage.”⁶⁷ The *New York Times* reported that a recruiting flier for CHEERS offered the financial and material benefits previously listed (\$960.00, the video camera, and CHEERS clothing) “to parents whose infants or babies were exposed to pesticides if the parents completed the two – year study.”⁶⁸ This implies that if parents decided to change or discontinue their use of pesticides (perhaps wondering why the EPA was studying their child’s development in reference to pesticides at all), they might not get the material rewards promised at the end of the two years.⁶⁹ As far as is known, neither the EPA nor the ACC directly addressed these assertions, thus these as well as many other questions about CHEERS remain unanswered.

2. CHEERS Exemplifies Ethical Quandaries in the Field

What type of human experiment did CHEERS propose? Was the CHEERS proposal an observational study, as previously described, or is the fact that CHEERS proposed taking blood and urine samples from the test subject children, as well as attaching activity sensors to them, enough to take it out of the realm of observational studies?

If CHEERS was not an observational study, it also was not an intentional dosage test.⁷⁰ CHEERS manages to skirt these distinctions, as

LEITERMAN, AMERICAN CHEMISTRY COUNCIL, CHEMICAL MAKERS BACK EPA DIRECTION ON EXPOSURE RESEARCH (2005).

67. *Test of Ethics: Pesticide-study Proposal Lacks Adequate Safeguards*, SARASOTA HERALD-TRIB., July 5, 2005, at A10.

68. *Id.* (emphasis added); see also Eilperin, *supra* note 27.

69. A less credible report regarding CHEERS came from *The Baltimore Sun*, which reported that according to internal EPA critics of the program, it had planned to give teething rings and cheese slices to test subject infants because “researchers knew that infants dropped them and then placed them in their mouths.” Andrew Schneider, *New Rules For Testing On Humans Denounced; Senior EPA Staff Criticize Agency Proposal As Flawed*, BALTIMORE SUN, July 7, 2005, at A1. Supposedly this method would more effectively introduce pesticides or pesticide residue on the floor into the bodies of the test subject children through the teething rings and food.

70. See 40 C.F.R. § 26.1102(i), *supra* note 22 (An intentional dose test is where a test subject is given a specific dosage of a substance through ingestion, injection, or inhalation).

well as ably demonstrating several of the ethical questions implicit in observational tests of pesticides on people.

For example, when scientists “passively observe” human conduct in order to determine the health risks of such conduct, what are the scientists’ moral obligations when if the scientist told the test subject the suspected risks of that conduct, the subject might choose to discontinue the conduct altogether?⁷¹ Suzanne Wuerthele, the EPA scientist previously cited, objected to CHEERS on exactly this basis when she expressed her concern that the test subjects might not know about the risks of pesticide use because EPA researchers would not inform participants about the risk, and that they could “reduce that risk to zero” by not using pesticides.⁷²

Another ethical question implicit in observational tests of pesticides on people involves the Hawthorne Effect.⁷³ The Hawthorne Effect shows that if human test subjects are aware that they are being studied, that awareness alone affects their conduct, possibly making it abnormal and invalidating the scientific results.⁷⁴ Paying people with money or goods to “do what they normally do” may have this effect. Therefore, paying people to take part in a pesticide study may influence them to expose their bodies (or the bodies of their children or others in their care) to pesticides, even though they will not directly benefit from the pesticide exposure and the exposure may in fact cause negative health consequences. The *New Yorker’s* article on “guinea pigging” describes a small distinct group of people who appear to make their living as human test subjects in medical trials.⁷⁵ At least one test subject profiled in the story took intentional doses of experimental drugs knowing that he was “not going to get the benefit of the health care [that was] developed by [the] research . . . because [he was] not in the economic class to get health insurance.”⁷⁶ In another case first reported by the *Wall Street Journal* and described in the *New Yorker*:

[T]he Eli Lilly company was using homeless alcoholics from a local shelter to test experimental drugs at budget rates at its testing site in Indianapolis The Lilly clinic, the *Journal* reported, had developed such a reputation for admitting the

71. Eilperin, *supra* note 27.

72. *Id.*

73. RESPONSIBLE CONDUCT, *supra* note 40, at 245. With thanks to Anne Fried who first explained the Hawthorne Effect to the author.

74. *Id.*, *supra* note 40, at 245.

75. Carl Elliot, *Guinea-Pigging*, *NEW YORKER*, Jan. 7, 2008.

76. *Id.*

down-and-out that subjects traveled to Indianapolis from all over the country to participate in studies.⁷⁷

Extrapolating from the conduct of human test subjects of medical trials to human test subjects of pesticide trials, it is feasible that parents or guardians of child test subjects could change their conduct in order to receive the financial and material benefits of participating in CHEERS. For example, the parents or guardians of test subjects might change the amount or type of pesticide(s) they use in order to enroll their children in the study, or they might maintain a level of use or loyalty to a particular pesticide in order to receive compensation from the study. In short, the pesticide exposure of the child test subjects could have been affected by CHEERS recruiting their parents or guardians.

Lastly, like many pesticide tests on people profiled in this article, CHEERS may have threatened to violate ethical standards because it was simply bad science. In 1998 the EPA appointed a joint subcommittee of the Science Advisory Board and the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”) Scientific Advisory Panel (“SAB/SAP”) to advise it on the ethics of using data from the pesticide tests on people being presented for its consideration.⁷⁸ SAB/SAP was so internally divided that its final report was emphatically rejected by two committee members.⁷⁹ Those committee members wrote a scalding Minority Report that was included as an Appendix to the final Majority Report.⁸⁰

Despite the substantive disagreements between the SAB/SAP Majority and Minority Reports,⁸¹ and the Minority Report’s troubling accusations of misrepresentation and distortion in the Majority Report,⁸² it appears that all parties agreed that “[b]ad science is always unethical; research protocols that are fundamentally flawed, such as those with sample sizes inadequate

77. *Id.*

78. Heidi Gorovitz Robertson, *How Many Times Do I Have to Tell You?!*: EPA’s Ongoing Struggle with Data from Third Party Pesticide Toxicity Studies Using Human Subjects, 28 WM. & MARY ENVTL. L. & POL’Y REV. 205, 222 (2004).

79. COMMENTS ON THE USE OF DATA FROM THE TESTING OF HUMAN SUBJECTS: A REPORT BY THE SCIENCE ADVISORY BOARD AND THE FIFRA SCIENTIFIC ADVISORY PANEL, EPA-SAB-EC-00-017, A-1 (Sept. 2000) (hereinafter “SAB/SAP Report”); available at <http://www.epa.gov/scipoly/sap/meetings/1999/november/ec0017.pdf>.

80. *Id.* at C-1.

81. *Id.*

82. *Id.* at C-1, C-2.

to support reasonable inferences about the matter in question, are unjustifiable.”⁸³

CHEERS was an example of “bad science” for two reasons. First, its proposed sample size was inadequate to support reasonable inferences about the matter in question. CHEERS proposed examining the effects of certain pesticides by studying thirty test subjects over two years.⁸⁴ In order for the results of CHEERS to be applicable to the general population, it would need a far larger number of test subjects. The SAB/SAP Minority Report stated:

[S]trong documentation [was found] that the human studies done by the pesticide manufacturers were scientifically invalid. They showed that to find a small effect, at least 2500 subjects in each group were necessary. They also showed that the sample sizes used by the [pesticide] manufacturers, (7 to 50 subjects) to report no effect [from the pesticide exposure] had a 3% to 4% chance to find an effect.⁸⁵

Second, CHEERS proposed to study chemicals that have long-term effects over a short term. SAB/SAP’s Majority Report described this as a common limitation of pesticide experiments on people:

[A]lthough volunteer experiments typically involve brief exposure, many real world questions about safety involve chronic exposures. This is particularly relevant with pesticide exposures. In one case from the insecticide literature, investigators studying a sample of farmers exposed while treating sheep with organophosphates . . . reported that the chronic effects of exposure, primarily neurobehavioral in character, are not predicted by sensitivity to any acute warning signs.⁸⁶

The SAB/SAP Majority Report asserted that this scientific weakness could be “addressed by careful experimental design,”⁸⁷ but one SAB/SAP

83. *Id.* at 1.

84. See Kirkpatrick, *supra* note 1; Janofsky, *supra* note 1; Eilperin, *supra* note 7, at A23.

85. *Id.* at C-2. The paragraph quoted ends with: “[t]his was initially placed in the body of the [SAB/SAP Majority Report] draft, then removed and buried in the appendix, despite the repeated protest of members of the committee.” *Id.*

86. SAB/SAP Report, *supra* note 79, at 12 – 13.

87. *Id.* at 13.

committee member “disagreed, noting that chronic effects, such as the neurobehavioral changes seen for the [organophosphates] would be very difficult, possibly impossible, to detect in acute studies regardless of the design.”⁸⁸

In her testimony to the Senate Environment and Public Works Committee, Senator Barbara Boxer described some of the potential long-term health effects of pesticide exposure:

Pesticides can cause cancer and adversely affect a child’s neurological, reproductive, respiratory, immune, and endocrine systems, even at low levels. It is also my understanding that EPA’s new cancer risk assessment guidelines for early life exposure finds that children under two may have a tenfold increase in risk from cancer causing substances.⁸⁹

It is important to remember that (other than the promise of the exchange of money between the EPA and the ACC, taking wipe samples from household surfaces, and recruiting half its test subjects)⁹⁰ the pesticide tests on human subjects proposed by CHEERS did not actually begin. However, it is possible that that is only because, as previously described, fortuitous timing enabled Senator Boxer to bring CHEERS to the level of presidential politics.

88. *Id.* ORGANIC CONSUMERS puts this scientific weakness into layperson’s terms:

The trick here is that these products are known to have negative long-term health effects. This is a short two-year study. In other words, the results of the study are already known . . . there will be little to no obvious short-term negative effects on these children at the end of the two-year period. The seemingly positive results of the study will allow the ACC to announce positive ‘EPA study results’ to the public, which will allow the ACC to more effectively lobby Congress to weaken regulations on these products.

ORGANIC CONSUMERS, EPA & CHEMICAL INDUSTRY TO STUDY EFFECTS OF KNOWN TOXIC CHEMICALS ON CHILDREN: STUDY LAUNCH DATE SUSPENDED UNTIL SUMMER 2005, OFFERS PUBLIC COMMENT PERIOD, <http://www.organicconsumers.org/epa-alert.htm> (last visited Aug. 13, 2011).

89. Videotape: Senator Barbara Boxer, Testimony to the U.S. Senate Env’t & Pub. Works Comm. (Apr. 6, 2005) (on file with author).

90. See Kirkpatrick, *supra* note 1, at A15; Janofsky, *supra* note 1, at A19; Eilperin, *supra* note 7, at A23; ORGANIC CONSUMERS, *supra* note 15, at A23; NAT’L EXPOSURE RESEARCH LAB., *supra* note 48, at 10.

B. Pesticide Tests on People Between 1967 and 2004

In 2005 the United States Congress received a report it had commissioned called Human Pesticide Experiments (the “Congressional Report”).⁹¹ The Congressional Report describes twenty-two tests of pesticides on humans between 1967 and 2004.⁹²

Of the pesticide tests on people described in the Report, six were conducted in the U.S., sixteen in foreign nations.⁹³ The EPA was considering every test described in the Congressional Report in order to evaluate the safety of the pesticide tested.⁹⁴

This is a crucial point, which runs through this paper: when this article refers to pesticide tests on people, it is usually only referring to those tests whose results were submitted, or were intended to be submitted, to US regulators. The submission of such tests to the EPA for its consideration automatically subjects them to the EPA’s regulations, thereby bringing them under U.S. legal scrutiny. Because the US is one of the largest users, if not the largest user of chemical pesticides in the world,⁹⁵ this lariat is wide enough to catch a meaningful percentage of the total number of pesticide tests on people.

Returning to the Congressional Report of pesticide tests on human subjects, perhaps the most significant common denominator of the twenty-two human pesticide experiments it described was their purpose:

[T]he strongest case for conducting human pesticide experiments can be made when the pesticide being tested offers the promise of significant health or environmental benefits compared to products already on the market. None of the 22 experiments being considered by EPA appear to meet this standard. To the contrary, the vast majority of the experiments were conducted for precisely the opposite reason: to justify keeping older and more dangerous pesticides on the market.⁹⁶

91. STAFF OF H.R. COMM. ON GOV’T REFORM, AND ENVTL. STAFF OF S. BOXER, 81ST CONG., HUMAN PESTICIDE EXPERIMENTS (2005) (hereinafter “CONGRESSIONAL REPORT”).

92. *Id.* at 9, 33 – 34 app. A.a.

93. *Id.* at 9.

94. *Id.* at intro, i. According to the CONGRESSIONAL REPORT every test had violations of ethical standards.

95. Eileen Gay Jones, *Forbidden Fruit: Talking About Pesticides and Food Safety in the Era of Agricultural Product Disparagement Laws*, 66 BKLYN L. REV. 823, 827 (2000/2001).

96. CONGRESSIONAL REPORT, *supra* note 91, at 10.

One of the earliest tests was a 1969 study of dichlorvos. The reader is asked to remember that “interpretations and applications of basic ethical principles as they are expressed in . . . rules on conduct do evolve over time,”⁹⁷ and many of these rules have become more strict.⁹⁸ Therefore, holding scientists from an earlier era to modern research ethics may be unfair. However, certain principles of scientific ethics are longstanding; “not treating others as mere means” to the scientist’s end-goal and accurately reporting results even when they are unfavorable are among those longstanding principles.⁹⁹

With these principles in mind:

EPA is considering [] a 1969 study involving the pesticide dichlorvos, an organophosphate pesticide manufactured by American Vanguard (AMVAC). In this experiment, 16 families in Tucson, Arizona, were exposed in their homes to resin strips containing the pesticide dichlorvos for a six-month period. Among the human subjects were 35 children (ranging in age from 2 to 19). The results of the experiment showed that cholinesterase levels dropped by up to 50% in test subjects, but the study concluded that the decrease “does not appear to be related to any adverse clinical responses. There are many factors other than dichlorvos which may produce lowering.”¹⁰⁰

In the same study, a seventeen year-old girl complained of headaches. The researchers removed the resin strip from the girl’s bedroom and her headaches stopped. Yet the researchers stated that, “[q]uestioning of the parent revealed the likelihood that the headaches were produced by other pressures.”¹⁰¹

Thirty-three years after the completion of this study, researchers sponsored by the manufacturer of dichlorvos reanalyzed the 1969 data to see if the old data could help establish a level at which chronic inhalation

97. Rep. Advisory Comm. on Hum. Radiation Experiments, Res. Ethics and Med. Prof., *reprinted in* BIOETHICS: HEALTH CARE, HUMAN RIGHTS, AND THE LAW 618 – 619 (Arthur B. La France ed., Mathew Bender & Co., Inc., 1999). This report on U.S. government Cold War radiation experiments was written decades after the experiments were conducted.

98. *Id.*

99. *Id.* at 883.

100. CONGRESSIONAL REPORT, *supra* note 91, at 31.

101. *Id.*

exposure had no effect on humans. The researchers found that much of the study's scientific data was so variable that it had to be discarded.¹⁰²

The Congressional Report describes a 1992 study in which thirty-six human subjects were given a pill with the pesticide aldicarb in it "with orange juice at breakfast."¹⁰³ Aldicarb is a "suspected endocrine, reproductive and neurotoxicant."¹⁰⁴ After swallowing the aldicarb pill, the test subjects were monitored for drops in cholinesterase in their nerve cells.¹⁰⁵ The test subjects were given doses already known to be dangerous: "in this experiment, human subjects were given doses sufficient to cause a 70% drop in cholinesterase levels, causing the subject to experience 'profuse whole body sweating.'"¹⁰⁶ Before the study began the EPA had already found that a 20% drop in cholinesterase in human nerve cells could reveal toxicity¹⁰⁷ and in 1998 industry representatives had described a 50% drop in cholinesterase as being "associated with adverse effects requiring treatment" with an antidote.¹⁰⁸

The Congressional Report depicts a 2004 study of the pesticide chloropicrin.¹⁰⁹ Chloropicrin is a suspected neurotoxicant that may damage DNA.¹¹⁰ In the study, 127 young people, many "college students and minorities"¹¹¹ were paid \$15 an hour to allow chloropicrin vapor to be "shot directly into their nostrils and eyes" or to go into a chamber filled with chloropicrin vapor "for up to one hour on four consecutive days."¹¹² The permissible exposure limit under the Occupational Safety and Health Administration is 100 parts per billion, and the vapor chamber repeatedly entered by the test subjects was filled with up to 1200 parts per billion of chloropicrin.¹¹³

An article in *Environmental Health Perspectives* described a study evaluated by the EPA in 2001, in which a contractor for Dow Chemical paid volunteers in Lincoln, Nebraska up to \$460 to swallow chlorpyrifos in concentrations up

102. CONGRESSIONAL REPORT, *supra* note 91, at 25.

103. *Id.* at 13.

104. *Id.* It was banned in the European Union in 2003. *Id.*

105. *Id.*

106. *Id.* at 14.

107. *Id.* at 13.

108. *Id.* at 13 – 14.

109. *Id.* at 14 – 16.

110. *Id.*

111. *Id.* at 15.

112. *Id.*

113. *Id.* at 15 – 16.

to 300 times higher than the EPA's "safe" level at the time.¹¹⁴ One of the test subjects, a woman who received the highest dose "reported numbness in her upper arms, which company officials ruled 'possibly' related to the pesticide."¹¹⁵

That same year, a contractor for the pesticide manufacturer Bayer submitted results of a test on humans of a pesticide called azinphos methyl to the EPA.¹¹⁶ Azinphos methyl is a pesticide that was derived from nerve gases used in World War II.¹¹⁷ The azinphos methyl study was conducted on

114. Oleskey et al., *Pesticide Testing in Humans: Ethics and Public Policy*, 112 ENVTL. HEALTH PERSP., 914, 916 (2004).

115. *Id.*

116. NATURAL RESOURCES DEFENSE COUNCIL, EPA REVERSES BAN ON TESTING PESTICIDES ON HUMAN SUBJECTS, Nov. 28, 2001 (hereinafter "NRDC REPORT"), available at <http://www.nrdc.org/media/pressReleases/011128a.asp>. There are two azinphos methyl tests the NRDC report could be referring to. Both are described in the CONGRESSIONAL REPORT. One has marked similarities to the test described the NRDC REPORT, therefore, that is the azinphos methyl test that is described in detail in this article.

Of the two azinphos methyl human tests in the CONGRESSIONAL REPORT, the first was in 1998, and involved thirty-five subjects being given doses of azinphos methyl twice as high as those at which animals were predicted to experience adverse effects. CONGRESSIONAL REPORT, *supra* note 91, at 36 app. B. "Every adverse effect reported by the human test subjects was dismissed as unrelated to the azinphos methyl and "attributed to 'viral illness' or 'ward conditions' or left unexplained." *Id.*

The second azinphos methyl study described in the CONGRESSIONAL REPORT took place in 1999. *Id.* at 35 – 36 app. B. It involved eight subjects receiving the same dose of azinphos methyl each day for 28 days, and being compensated \$2,400. These latter two details make the author believe that this 1999 study is the same azinphos methyl test described in the NRDC REPORT. Twenty-eight days can be the month's duration described by the NRDC, and the discrepancy between \$2,400 and the author's \$2,160 can be explained by mathematical quibbles over exchange rates and averages. For example, which average exchange rate applies? The rate of 1999 when the payment was made or of 2005 when the CONGRESSIONAL REPORT was written? These quibbles are particularly insignificant when it is remembered that the Congressional Report's review of the first azinphos methyl human test, conducted in 1998, mentioned neither compensation nor a period of days.

It is for these reasons that the author concludes that the 1999 azinphos methyl study described in the Congressional Report is the same as that described in the NRDC report, and has written about that test accordingly.

117. NRDC REPORT, *supra* note 116.

eight adult male volunteers in Scotland.¹¹⁸ The test subjects were hospitalized for a month and given the same dose of azinphos methyl each of the twenty-eight days of the study.¹¹⁹ They gave blood and urine samples and were paid for their participation.¹²⁰ Test subjects who did not complete the twenty-eight day study risked not receiving monetary compensation unless the supervising doctor approved.¹²¹ Every human test subject reported “adverse events” which were “universally dismissed as unrelated to the dosing.”¹²²

There have been six experiments between 1967 and 2004 that, in the words of the Congressional Report, “placed their human subjects at risk in order to attempt to identify a ‘no observed effects level’ (NOEL) in humans. These experiments exposed the test subjects to a pesticide in an attempt to identify the lowest exposure levels that would cause an effect.”¹²³

One of these tests was a 1996 experiment involving methyl isothiocyanate:

[The study] tested the NOEL of methyl isothiocyanate (MITC) . . . manufactured by several companies who sponsored [the] study as a consortium. MITC is similar in terms of structure and toxicity to methyl isocyanate, the chemical that killed thousands in Bhopal, India.

In this experiment, researchers modified laboratory goggles in order to allow MITC to be piped inside the goggles, exposing test subjects’ eyes to the fumigant for up to 8 hours The goal of the experiment was to determine the no observable effect levels for human eye irritation. At the higher levels of exposure, some subjects reported that the level of irritation in their eyes became so extreme that it approached or was at the “maximum” level, which would require the experiment to be terminated.¹²⁴

In the absence of a congressional report on the issue since 2005, it is difficult to know how many pesticide tests on people were conducted from 2005 to 2012. However, the EPA’s 2010 online summary of its protections for subjects of human studies research stated, “[h]istorically, EPA has

118. *Id.*

119. *Id.*; see CONGRESSIONAL REPORT, *supra* note 91, at 35 – 36 app. B.

120. See NRDC REPORT, *supra* note 116, at n. 110.

121. CONGRESSIONAL REPORT, *supra* note 91, at 21.

122. *Id.* at 36.

123. *Id.* at 11.

124. CONGRESSIONAL REPORT, *supra* note 91, at 12.

received approximately 33 intentional dosing studies of ALL [sic.] types annually.¹²⁵ Presumably these were all observational pesticide tests on people, because the EPA's proposed revised Human Studies Rule¹²⁶ asserts that the EPA has not received a single intentional dosage human testing study for review since 2006.¹²⁷

It is possible that the 2006 Human Testing Rule and the Human Studies Review Board¹²⁸ have reined in the most flagrant ethical violations found in intentional dosage pesticide tests on people. What, then, do ethical tests of pesticides on people look like? Two possible examples follow.

III. Is it Possible to Ethically Test Pesticides on People?

A. The Agricultural Health Study

The Agricultural Health Study is a largely observational study of over 89,000 farmers, commercial pesticide applicators and the adult members of their families in Iowa and North Carolina.¹²⁹ The National Institutes of Health and the EPA began studying the pesticide exposures and health of these farmers and their life partners in 1993,¹³⁰ specifically looking at why farmers appear to have higher rates of certain cancers than the general population, and why of all the potential contributing factors, there are strong links between pesticide exposure and cancer malignancies.¹³¹

The Agricultural Health Study, like CHEERS, observes and measures the pesticide exposure of people who are already exposed and theoretically will not change their exposure in response to the study. However, there are

125. EPA, *Expanded Protections for Subjects in Human Studies Research*, April 1, 2010, <http://web.archive.org/web/20100401013331/http://www.epa.gov/oppfead1/guidance/human-test.htm> (last visited Oct. 8, 2012).

126. *Revisions to EPA's Rule on Protections for Subjects in Human Research Involving Pesticides*, 76 Fed. Reg. 22 (Feb. 2, 2011). These revisions are outside the scope of this particular article.

127. *Id.*

128. The 2006 Human Testing Rule and the Human Studies Review Board are outside the scope of this particular article.

129. Michael C.R. Alavanja et al., *The Agricultural Health Study*, 104 ENVTL. HEALTH PERSP. 4, 362, April 1996 "Commentary"; see WELCOME TO THE AGRICULTURAL HEALTH STUDY, available at <http://aghealth.nci.nih.gov/> (last visited Aug. 15, 2011).

130. Alavanja, *supra* note 129; see also WELCOME TO THE AGRICULTURAL HEALTH STUDY, *supra* note 129.

131. Alavanja, *supra* note 129.

many other differences between the two studies that make the Agricultural Health Study more ethical than CHEERS. The Agricultural Health Study's test subjects are adults¹³² and are not paid in either money or goods.¹³³ The Study is funded and conducted by two federal agencies that have no known conflicts of interest.¹³⁴ At over 89,000 test subjects,¹³⁵ the sample size is large enough to achieve adequate statistical power to make its findings scientifically valid. Thus, the usual ethical concerns in regards to potential coercion of test subjects, conflicts of interest, and scientific integrity appear to be allayed.

The ethical questions that remain are:

(1) Was the information on the English-only Agricultural Health Study website that "agricultural workers . . . may experience higher rates of leukemia, myeloma, non-Hogkin's lymphoma, and [various] cancers"¹³⁶ given directly to the test subjects?

(2) If this information is on only one of the Agricultural Health Study's web pages, do all the test subjects (especially agricultural day laborers and their partners) have meaningful access to it if they are not English literate and/or do not have internet access?

(3) Were the test subjects (especially agricultural day laborers and their partners) told why they were chosen as subjects in a language that they could understand?

(4) Were the test subjects informed that they could reduce their health risk by discontinuing occupational or familial exposure to the pesticides being studied?

B. The Endosulfan Study

In Kerala India, two villages presented an ideal opportunity to research the effect(s), if any, of the pesticide endosulfan.¹³⁷ One of the two villages was in a valley below cashew plantations that had been sprayed with endosulfan for twenty years.¹³⁸ The other village was free of endosulfan exposure.¹³⁹ There already was "experimental evidence of adverse effects of

132. *Id.*

133. *Id.* at 363.

134. *Id.*

135. WELCOME TO THE AGRICULTURAL HEALTH STUDY, *supra* note 129.

136. *Id.*

137. H. Saiyed et al., *Effect of Endosulfan on Male Reproductive Development*, 111 ENVTL. HEALTH PERSP. 16, 1958-1962 (2003).

138. *Id.* at 1958-59.

139. *Id.*

endosulfan on the male reproductive system¹⁴⁰ but there was no human data on those effects when the study was undertaken.¹⁴¹ Researchers from the Indian Council of Medical Research, the Regional Occupational Health Research Center and an Indian medical college studied the reproductive development of 117 male schoolchildren in the first village, along with ninety in the second village, by taking blood samples and performing physical examinations.¹⁴² The physical examinations were performed by “pediatricians observing necessary privacy required for this delicate examination.”¹⁴³ Parents were asked to “accompany their children at the time of examination,”¹⁴⁴ which only occurred after they acquired (what appears to be) informed consent from parents.

The study found low testosterone levels and congenital abnormalities among the boys (aged ten to nineteen) who had been exposed to endosulfan.¹⁴⁵ The scientists urged further study with a larger sample size over a longer time period.¹⁴⁶

Although the only source of information found on this study is an article written by the researchers themselves, the study as represented in the article bears the signs of ethical practice. The researchers showed knowledge of the preexisting studies in the field;¹⁴⁷ they designed the study to answer a scientific question not yet solved;¹⁴⁸ and they attempted to do so with as large a sample as possible¹⁴⁹ given that only 43% of the study subjects agreed to undergo the physical examination necessary to establish their sexual maturity.¹⁵⁰ The researchers appeared to understand the various vectors of exposure to endosulfan,¹⁵¹ and attempted to minimize the socioeconomic and other differences between the study group and the control group.¹⁵² There does not appear to be a danger that test subjects’ families would alter their pesticide exposure in response to the study or

140. *Id.* at 1958.

141. *Id.*

142. *Id.* at 1959.

143. *Id.*

144. *Id.*

145. *Id.* at 1958.

146. *Id.* at 1962.

147. *Id.* at 1958 (the article begins with an analysis of prior research on the subject).

148. *Id.*

149. *Id.*

150. *Id.* at 1959.

151. *Id.* at 1958.

152. *Id.*

compensation from the study. There does not appear to be a conflict of interest between the researchers and pesticide manufacturers or other interested parties.

The ethical question that remains is:

(1) Were the consent forms used in this study ethical? Acquiring the informed consent of parents or guardians of children is not equivalent to the informed consent of the test subject children themselves. And yet children cannot give informed consent because they are either too young to understand or are too subject to the influence of their parents or guardians.¹⁵³ Therefore is it even possible to acquire informed consent for non-therapeutic research conducted on children?

IV. The Laws and Regulations that Govern Pesticides

A. FIFRA, FFDCA, and FOQA

In order for a pesticide to be manufactured, imported, or sold in the U.S. it needs to be registered by the EPA.¹⁵⁴ The EPA will only register those pesticides it considers “safe,” as defined by the Federal Insecticide, Fungicide, and Rodenticide Act (“FIFRA”), the Federal Food, Drug, and Cosmetic Act (“FFDCA”), and the Food Quality Protection Act (“FQPA”).¹⁵⁵

In determining what is considered “safe,” FIFRA demands that the pesticide perform its intended function without causing any “unreasonable adverse effects on the environment,”¹⁵⁶ defined as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”¹⁵⁷ The FFDCA allows the sale of food only if its pesticide residue is less than the “safe” residue tolerance determined by the EPA.¹⁵⁸ Lastly, FQPA sets a

153. The question of whether parents can provide informed consent on behalf of their children for non-therapeutic treatment and/or testing is beyond the scope of this article. It is a highly complex and controversial subject, worthy of a literature review and a deeper exploration than is possible in these pages.

154. Marshall Lee Miller, *Pesticides*, ENVTL. LAW HANDBOOK, § 3.0 at 693 (9th ed., 2007).

155. Br. for Pet. at 8, NRDC v. EPA, No. 06-0820 (2d Cir. Oct. 4, 2006), available at <http://www.beyondpesticides.org/documents/OpeningBr%2010%204%2006%20FINAL.pdf>.

156. 7 U.S.C. § 136a(c)(5)(C).

157. 7 U.S.C. § 136(bb); see also Br. for Pet., *supra* note 155, at 8; Miller, *supra* note 154, at 694.

158. 21 U.S.C. §§ 331(a), 341(a)(2)(B), 346(a)(1) & (2), 346a(b)(2)(A)(i); see also Br. for Pet., *supra* note 155, at 8.

precautionary standard¹⁵⁹ to protect children from pesticide residues in food.¹⁶⁰ It requires EPA address the special risks to infants and children when setting pesticide tolerances, by demanding EPA apply an extra ten-fold safety factor for children (bringing the animal:human safety factor to 1000:1), with limited exceptions.¹⁶¹

The FQPA has had an interesting effect on the pesticide industry. In 1999 the EPA announced its first FQPA review of two pesticides, azinphos methyl and methyl parathion.¹⁶² Soon after the review was announced - but before the review began - two manufacturers of these pesticides agreed to more stringent use limitations.¹⁶³ The manufacturers thereby avoided review of their pesticides' effect on children, along with any EPA-mandated restrictions that might follow.¹⁶⁴

The *Chemical Market Reporter* wrote "[i]nterest in human testing has increased since enactment of the Food Quality Protection of [sic] Act of 1996, which requires consideration of an extra tenfold safety factor to protect infants and children in the absence of adequate data."¹⁶⁵ *Science* magazine reported that the FQPA "reduced the market for some pesticides by 90% - and had the unintended effect of increasing the incentives for pesticide companies to test on humans, including children, in an effort to demonstrate pesticide safety."¹⁶⁶ In 2001, the EPA stated that it was

159. Alexandra B. Klass, *Pesticides, Children's Health Policy, and Common Law Tort Claims*, 7 MINN. J. L. SCI. & TECH. 529, 89, 96 (2006).

160. *Id.*; 21 U.S.C. § 346a(b)(C)(ii)(II). When President Clinton signed FQPA into law on Aug. 3, 1996, he declared: "This act puts the safety of our children first. It sets a standard high; if a pesticide poses a danger to our children, it won't be in our food, period." NATIONAL ARCHIVES AND RECORDS ADMINISTRATION, PUBLIC PAPERS OF THE PRESIDENTS OF THE UNITED STATES, ADMINISTRATION OF WILLIAM J. CLINTON 1251 (1996). The policies of the Clinton and Bush administrations on human pesticide experiments are outside the scope of this paper. They are described in CONGRESSIONAL REPORT, *supra* note 91, at 2 - 7.

161. 21 U.S.C. § 346a(b)(C)(ii)(II).

162. EPA *Begins Study of Pesticides' Effects on Children's Health*, WALL ST. J., Aug. 3, 1999, at A6.

163. *Id.*

164. *Id.*

165. *Human Testing Considered Necessary to Establish Pesticide Exposure Levels*, 8 CHEM. MARKET REP. 263, 10 (2003).

166. Jocelyn Kaiser, *Testing pesticides on humans given qualified endorsement; Ethics*, SCIENCE, Feb. 27, 2004, at 1272 ("[p]esticide makers funded human exposure studies in response to children protection rules in a 1996 law: It

“concerned about the possibility of increased human testing as a way to potentially avoid some of the protections that the Food Quality Protection Act establishes.”¹⁶⁷

In the ten years before the Food Quality Protection Act was passed, the EPA received “a handful of human tests.”¹⁶⁸ In the three years that followed, the agency received [fourteen] new, unsolicited human subject studies on [ten] pesticides.”¹⁶⁹

Pesticides are now subject to nine federal laws, but this piece focuses on the three laws described above, and the regulations interpreting them, as they have the greatest bearing on the subjects addressed.¹⁷⁰

requires EPA to consider lowering the official safe level of pesticide exposure on the theory that children are especially vulnerable”).

167. See NRDC Report, *supra* note 116. According to the Los Angeles Times, in 2005 “[r]esults of two dozen human experiments involving pesticides [were] being reviewed by the EPA – most of them conducted outside of the U.S.. Marla Cone, *The Nation*; EPA Criticized for Pesticide Testing Rules; A Proposed policy on experiments on human volunteers in inadequate and could lead to abuse by industry, California lawmakers charge, L.A. TIMES, June 28, 2005, at A12.

168. Elizabeth Shogren, U.S. Will Use Once-Banned Human Tests; Pesticides: EPA Says It Will Accept Industry Data Gathered By Giving Paid Subjects Chemical Doses, L.A. TIMES, Nov. 27, 2001, at A1.

169. *Id.*

170. Three of the nine laws that that govern registration and use of pesticides in the U.S., but have no known bearing on the subject of this article, are the Safe Drinking Water Act [42 U.S.C. § 300g-1(b)(3)(C)(i), (b)(4)(B)], the Comprehensive Environmental Response [42 U.S.C. §§ 9604, 9606], Compensation and Liability Act, and the Resource Conservation and Recovery Act [42 U.S.C. §§ 6922 – 6924]; see Br. for Pet., *supra* note 155. The other three laws are the Clean Air Act, the Clean Water Act, and the Occupational Safety and Health Act. The National Research Council describes the legal standard for each:

“ ‘[T]o protect public health’ (Clean Air Act; 42 U.S.C. § 7412(f) [2003]), ‘assure protection of public health’ (Clean Water Act; 33 U.S.C. § 1312(a) [2003]), and [to] ‘adequately assure[]’, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity’ (Occupational Safety and Health Act; 29 USC § 655(b) [2003]).”

NATIONAL RESEARCH COUNCIL, COMMITTEE ON TOXICITY TESTING AND ASSESSMENT OF ENVIRONMENTAL AGENTS, TOXICITY TESTING FOR ASSESSMENT OF ENVTL. AGENTS: INTERIM REP. 16 (2006).

B. Human Health Risk Assessments

Federal agencies like the EPA interpret and apply the laws that govern pesticides in the U.S. by promulgating regulations that set acceptable pesticide exposure levels¹⁷¹ and corresponding safe levels of use. These regulations are built on human health risk assessments. Human health risk assessments are primarily established through toxicity testing on animals.¹⁷² Although there may be a welcome shift towards non-animal chemical toxicity tests¹⁷³ that are quick,¹⁷⁴ cost effective¹⁷⁵ and humane, animal testing is currently the mainstay of toxicity testing.¹⁷⁶ Animal testing is used to establish a symptom threshold: the level of exposure to the pesticide where no statistically significant adverse reaction is observed.¹⁷⁷ This threshold is usually called the “no observed effect level” (“NOEL”).¹⁷⁸

Once the NOEL is established for a pesticide, the EPA divides it by ten to account for the interspecies variations between non-human animals and humans (10:1).¹⁷⁹ The resulting number is then divided by ten again, to account for variation between individual humans (because some humans

171. NATIONAL RESEARCH COUNCIL, *supra* note 170.

172. CHRISTOPHER L. BELL ET AL., ENVTL. LAW HANDBOOK 738 (19th ed. 2007). In terms of linguistics, “toxicity testing on animals” could include testing on humans, since humans are animals. In fact, there is a mere 3% gene difference between many of “the higher apes” and us. JANE GOODALL & MARC BEKOFF, *THE TEN TRUSTS* 3 (2002). Nonetheless animals in this piece will only mean “non-human animals,” as per common parlance.

173. ENVIRONMENTAL PROTECTION AGENCY, EPA AWARDS CONTRACTS TO U.S. COMPANIES TO SCREEN CHEMICALS FOR HUMAN HEALTH IMPACTS (Aug. 4, 2011).

In 2002 the Toxicology Working Group of the British Parliament’s Select Committee on Animals in Scientific Procedures found that “the effectiveness and reliability of animal tests is unproven.” SELECT COMMITTEE ON ANIMALS IN SCIENTIFIC PROCEDURES, REPORT, 2001-02, H.L. 150. The Working Group recommended that “the reliability and relevance of all existing animal tests should be reviewed as a matter of urgency.” *Id.*; see also NIALL SHANKS ET AL., ARE ANIMAL MODELS PREDICTIVE FOR HUMANS?, PHILOS., ETHICS, AND HUMANIT. IN MED. 4:1 (2009), available at <http://www.peh-med.com/content/4/1/2>.

174. NRDC Report, *supra* note 116.

175. *Id.*

176. BELL ET AL., *supra* note 172, at 738.

177. Oleskey et al., *supra* note 114, at 915.

178. *Id.*

179. *Id.*

are more sensitive than others).¹⁸⁰ As a result, the overall NOEL from the animal tests is divided by 100 to establish a “reference dose” for humans (100:1).¹⁸¹ In other words, if animals can be exposed to 1 milligram of a pesticide without showing any negative effects, then it is extrapolated that humans can be exposed to .01 milligram of that pesticide without showing any negative effects. The safe exposure level for humans is set at that level.

The FOQA demands that the animal:human reference dose ratio be divided by 100 a third time in order to protect children, who are more sensitive than adults to pesticides.¹⁸² This brings the animal to human reference dose ratio to 1000:1.¹⁸³

180. *Id.*

181. *Id.*

182. The National Pesticide Information Center addresses children’s increased sensitivity to pesticides:

Infants and children are more sensitive to the toxic effects of pesticides than adults. An infant’s brain, nervous system, and organs are still developing after birth. When exposed, a baby’s immature liver and kidneys cannot remove pesticides from the body as well as an adult’s liver and kidneys. Infants may also be exposed to more pesticide [sic.] than adults because they take more breaths per minute and have more skin surface relative to their body weight. Children often spend more time closer to the ground, touching baseboards and lawns where pesticides may have been applied. Children often eat and drink more relative to their body weight than adults, which can lead to a higher dose of pesticide residue per pound of body weight.

NATIONAL PESTICIDE INFORMATION CENTER, PESTICIDES AND CHILDREN, <http://npic.orst.edu/health/child.html> (last visited Oct. 16, 2012). The National Pesticide Information Center describes itself (in a standing paragraph at the bottom of every webpage on its website) as the result of “a cooperative agreement between Oregon State University and the U.S. Environmental Protection Agency” that “provides objective, science-based information about pesticides and pesticide-related topics to enable people to make informed decisions.” *Id.* The same paragraph ends by saying that “[t]he information in this publication does not in any way replace or supersede the restrictions, precautions, directions, or other information on the pesticide label or any other regulatory requirements, nor does it necessarily reflect the position of the U.S. EPA.” *Id.*

Note also that there is a narrow exception to the 1000:1 human reference dose ratio, where “reliable data show that a different factor will be safe.” Oleskey et al., *supra* note 114, at 915.

183. *Id.*

C. Incentives to Test Pesticides on People

The first division of the reference dose (10:1) is intended to make up for the biological differences between animals and humans. However, if the pesticide is tested directly on people, that first division by ten is no longer necessary.¹⁸⁴ As a result, testing pesticides on human subjects makes a lower safety factor possible, which “often leads to a higher permitted exposure level[.]”¹⁸⁵ According to the trade publication *Chemical Week*, “[i]ndustry believes human testing data could disprove some of the harmful risks associated with pesticides.”¹⁸⁶ The chemical industry argues that human tests “provide more accurate results, allowing pesticides to be applied to crops in larger quantities and closer to delivery to supermarkets.”¹⁸⁷

According to a trade industry newspaper, the EPA increased the accepted level of exposure to the pesticide aldicarb “after Rhone-Poulenc submitted human studies conducted in Scotland,”¹⁸⁸ and dichlorvos in response to “human studies submitted by Amvac Chemical.”¹⁸⁹

In January of 2004, an EPA official wrote a memo regarding a test on humans of methyl isothiocyanate, a pesticide and wood preservative.¹⁹⁰ In the test, methyl isothiocyanate was sprayed into the eyes of volunteers.¹⁹¹ The EPA official wrote that the study showed “little concern for the safety or welfare of the research subjects.” “Nonetheless,” he wrote, “I am aware of no barrier in current law or agency policy to your giving this study full consideration in your risk assessment.”¹⁹²

Even if law, regulation, and agency policies have improved sufficiently since 2004 to prevent unethical pesticide tests on people (an untested

184. Steve Milloy, *Commentary; A Matter of Ethics*, CHI. SUN-TIMES, June 12, 2000, at 50.

185. *Id.*

186. Neil Franz, *Report Sets Stage for Human Testing Debate*, CHEM. WEEK, Aug. 2, 2000, at 37.

187. Elizabeth Shogren, *U.S. Will Use Once-Banned Human Tests; Pesticides: EPA Says It Will Accept Industry Data Gathered By Giving Paid Subjects Chemical Doses*, L.A. TIMES, Nov. 27, 2001, at A1.

188. Andrea Foster, *Report on Human Toxic Testing Raises EPA Concern*, CHEM. WEEK, Aug. 5, 1998 at 15.

189. *Id.*

190. Juliet Eilperin, *EPA Proposal Would Allow Human Tests of Pesticides; Draft Rule Omits Some Recommended Safeguards*, WASH. POST, June 28, 2005, at A13.

191. *Id.*

192. *Id.*

hypothesis that welcomes analysis) they are at the mercy of the political climate. And the political climate is unpredictable when unobserved. Currently, few know enough about the issue of pesticide testing on people to follow it in public affairs.

V. Conclusion

As long as we choose to use pesticides, we owe it to ourselves and to future generations to find out if they are safe, and that their safety has been established through the best possible science, acquired through ethical means.

This article aims to reveal the past forty-five years of pesticide tests on people in order to bring this largely unknown industry (as well as its scientific and ethical shortcomings) into the light of day. As the public desire for pesticide safety increases, so does the industry's motivation to conduct such tests. Knowing the history of pesticide tests on people, expanding the public discourse on the subject, and exploring its ethical quandaries is our best protection against unethical pesticide experiments on humans in the future.