



Presidential Commission
for the Study of Bioethical Issues

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45

TRANSCRIPT
Historical Investigation -- Ethics Standards and Practices

Meeting 6, Session 2
August 29, 2011
Washington, DC

1 DR. GUTMANN: So that's a good segue, right?

2 We are going to talk now in this session addressing
3 directly the ethical standards of the day and, in
4 particular, here are the questions we want to address.

5 Did the researchers try to keep the
6 experiments secret? What standards did the researchers
7 employ to protect human subjects in an earlier
8 experiment conducted in Terre Haute, Indiana, in a
9 federal or state penitentiary there? I think it was a
10 state penitentiary, I think, state. What about in
11 Guatemala, how did the protections of human subjects in
12 Terre Haute compare to the protections in Guatemala?
13 And what standards were available at the time for the
14 protection of human subjects?

15 And I've asked Anita Allen to begin by a

1 summary of what the answers to those questions are and
2 then we will open it up again for discussion and again
3 if there are any members of the public who have -- we
4 didn't receive any questions in the last session but if
5 there are any questions that you want to jot down on
6 cards and deliver it up here, we welcome that.

7 Anita Allen, can you begin our discussion,
8 please?

9 DR. ALLEN: Thank you, Dr. Gutmann. The first
10 question you raised was whether the researchers tried
11 to keep the experiments secret and that question raises
12 another question which is why do we care?

13 Well, we care because secrecy sometimes
14 signifies mindfulness of wrong-doing and a desire, a
15 selfish one, to avoid ethical accountability.

16 Yes, Dr. Cutler and others did try to keep
17 complete information about the research protocols
18 involved in the experiments out of the hands of agency
19 officials, agency oversight officials, scientific
20 peers, the general public, and the research subjects
21 themselves and on this count, the researcher's own
22 words tell the story and I think some would say condemn

1 them.

2 In a letter in 1947 to his colleague, Dr.
3 Mahoney, Dr. Cutler confided that it would be advisable
4 to not have too many people concerned with this work in
5 order to keep down talk and premature writing and Dr.
6 Arnold expressed concern in 1947 that "some goody
7 organization might get wind of the work and raise a lot
8 of smoke." So people involved were definitely very
9 aware of their own efforts at concealment.

10 In 1955, looking back on the experiments, Dr.
11 Cutler admitted that efforts had been made during the
12 Guatemala years to confine knowledge to as few people
13 as possible. I quote him directly. "It was deemed
14 advisable to work so that as few people as possible
15 know the experimental procedure."

16 As the principal investigator, he clearly
17 wanted to avoid ethical criticism, to avoid
18 interference, and any political barriers to his work.
19 He even at one point said he wanted the research to be
20 "guarded and subterranean."

21 So to maintain Dr. Cutler's secrecy, he and
22 Dr. Mahoney worked hard at keeping reports away from

1 those who would normally get them. They adopted a set
2 of procedures that involved bypassing the normal
3 oversight officers in the agency and instead Dr. Cutler
4 would send everything to Dr. Mahoney who had promised
5 to keep things secret and when there was a requirement
6 to post a summary or report, Dr. Cutler offered what he
7 termed "barest summaries of our progress."

8 It's already been noted that Dr. Cutler's
9 final reports and results of the STD experiments were
10 never directly published. He himself, Dr. Cutler
11 himself sometimes seemed to insert little references to
12 his own research in some of his papers but they were in
13 a highly-disguised form, again trying to keep things
14 secret. So, yes, there was a lot of effort to keep
15 this stuff secret.

16 But in a way, we got to this point a little
17 bit earlier, the research was not secret. Framed as an
18 STD prevention and treatment research project, the
19 research was funded by the U.S. Public Health Service's
20 Venereal Disease Division and its Venereal Disease
21 Research Laboratory which is now part of the Centers
22 for Disease Control and Prevention.

1 The research was conducted pursuant to open
2 agreements executed between the nation of Guatemala and
3 the United States. Many public officials,
4 institutional directors, physicians, researchers, were
5 aware of the broad outlines and research protocols.
6 Evidence shows that Guatemalan officials, including the
7 Ministry of Public Health, were aware of and supported
8 the research. The research staff for the experiments
9 included the National Psychiatric Hospital in
10 Guatemala, National Orphanage, Chief Army Medical
11 Department, as well as the Director and Assistant
12 Director of the Venereal Disease Research Unit, and
13 numerous other medical and scientific staff from that
14 office.

15 So while secret in one respect, in another
16 respect this was by no means a secret matter.

17 Indication of lack of secrecy, and an odd one, is that Dr.
18 Cutler did choose to keep his records. He didn't burn
19 them. He kept them and then in 1990 he donated them to
20 the University of Pittsburgh Archive where they sat and
21 others might review them which, indeed, happened in the
22 case of Dr. Susan Reverby who brought those records to

1 light very recently.

2 The second question was about whether what
3 standards were applied or employed in the protection of
4 human subjects in the Terre Haute Prison Experiments in
5 1943 and '44, an important question because what the
6 Terre Haute project shows is that some of the same
7 researchers, Drs. Mahoney and Cutler and others,
8 involved in STD research just a year or two earlier
9 than Guatemala did in fact show some regard for human
10 subject research values.

11 So just prior to Guatemala, research was
12 conducted by the Public Health Service at the Federal
13 Prison, Terre Haute Prison, and this was research that
14 was done in collaboration with and in cooperation with
15 the U.S. Bureau of Prisons.

16 The purpose of the research was to identify
17 chemical prophylaxis against gonorrhoea, so as to
18 protect men in the Armed Forces from the disease in
19 order to protect military readiness at the time. It
20 was believed that something like seven million man
21 hours were lost every year due to gonorrhoea at a cost
22 of about \$34 million for treatment.

1 So there were 241 prisoners who participated
2 in the experiments in Terre Haute and these men were
3 inoculated with strain concentrations of gonorrhea
4 where the bacteria was deposited into the end of their
5 penises, as described earlier by my colleague.

6 The experiments were discontinued, however,
7 only 10 months after they began due to the inability to
8 reliably infect the men in spite of different strains
9 of gonorrhea and different modification methods of
10 inoculation.

11 So by the end of this particular experiment,
12 the researchers sadly concluded they had learned very
13 little and that they still didn't even know whether the
14 35-year-old silver protenate that they'd been using was
15 actually effective in preventing gonorrhea.

16 As for what standards were used, there were
17 two main standards that were employed to protect those
18 241 U.S. prisoners: risk minimization and informed
19 autonomous consent. Risk minimization measures
20 included situating the research at what at the time was
21 the very best federal prison in the nation, the one
22 with the best medical facilities I might say, and here

1 you have a captive population, but people were able to
2 get good medical treatment.

3 When it came to informed consent, in this
4 instance the prisoners were actually volunteers and
5 they were given a written informed consent document to
6 use to waive their rights and the document did make an
7 effort to explain to them the costs and benefits and
8 nature of the research.

9 The project, they were told, would study the
10 effectiveness of two types of prophylaxis against
11 gonorrhoea and that with that information in hand, the
12 men could perhaps make a better decision about whether
13 or not to participate and they weren't over-induced.
14 The men were paid but they weren't paid so much that
15 they would do it as if they were sort of compelled to do it
16 to get the money and while they were offered a
17 certificate of merit at the end of the research and a
18 commendation to the Parole Board, they weren't promised
19 early release from prison as a condition of
20 participation.

21 So risk minimization and informed consent or
22 autonomy were respected in the Terre Haute U.S.-based

1 experiments, even though we see in Guatemala those same
2 values and norms were not respected.

3 In Guatemala, the same researchers did not
4 offer their subjects informed consent and did not make
5 a serious attempt, I would argue, to minimize risk and
6 the subjects included some of the most vulnerable
7 people one could imagine: soldiers in active duty,
8 prisoners in prisons and jails, sex workers, some as
9 young as 18, children, people with leprosy, people with
10 epilepsy, people with mental illnesses, indigenous
11 Guatemalans, so-called Indians, poor people, uneducated
12 Latinos. This is the population of people that the
13 United States Public Health doctors went to Guatemala
14 to use as subjects for their research and they offered
15 them none of the same protections that were offered to
16 the U.S.-based research subjects in Terre Haute.

17 Why Guatemala? I think I've pretty much just
18 said it. Because the population was available and
19 vulnerable, powerless, but there were other reasons, as
20 well. There was a Dr. Juan Funes who was a Guatemalan
21 physician who had worked for one year as a fellow with
22 Drs. Mahoney, Arnold, and Cutler at the Venereal

1 Disease Research Center in Staten Island in 1945 and he
2 suggested the United States doctors go down to
3 Guatemala. He had a clinic there that he worked in and
4 that was made attractive by the fact that there was
5 already a preexisting relationship between the U.S. and
6 Guatemala to provide medical services and to develop
7 public health facilities down in that part of the
8 world.

9 The U.S. went to Guatemala bearing gifts of
10 medical infrastructure and some medications that were
11 scarce and expensive. The U.S. researchers felt they
12 would be able to employ some protocols they would not
13 be able to do in the United States. It wouldn't pass
14 muster with the U.S. ethical standards and also I
15 should note that in Guatemala, the use of prostitutes
16 was less troublesome because there it was both legal
17 and there was a provision of routine public health
18 examinations of the sex workers.

19 So in Guatemala, no informed autonomous
20 consent. The subjects were not told about the goals of
21 the study, the purposes of the study, the methods, the
22 risks, or the social benefits that might be involved.

1 The subjects included people who were well under 21
2 years of age, children, schoolchildren, and orphans,
3 and their parents were not offered informed consent and
4 the children were not offered informed consent either.

5 The subjects included prisoners, mental
6 patients, and others with lack of cognitive
7 competencies. The subjects included people who were
8 actively ill, people who were sick with chronic and
9 acute diseases. They were nonetheless included as
10 research subjects.

11 Superiors could force inferiors to participate
12 using deception about the purposes, about the risks
13 involved, and, of course, we had here very, very
14 disenfranchised people in general, people who just
15 didn't have the same education, knowledge of science,
16 medicine, and so forth that the public health doctors
17 had.

18 Very, very few risk minimization measures were
19 put into place. I think it even violates our sense of
20 human rights, what went on in Guatemala, not just the
21 lack of informed consent, not just a lack of research
22 minimization of risk, not just lack of privacy and

1 autonomy, but actually cruel and inhumane conduct took
2 place, abrading, scarifying, exposing to bacteria, to
3 meningitis, to neuro-syphilis. These are very, very
4 grave human rights violations and I think we'd have to
5 all agree.

6 So there was not the same level of protection
7 in Guatemala that was offered to subjects in the United
8 States.

9 What were the available standards at the time?
10 What ethical standards might the researchers have
11 relied upon?

12 Well, to start off with, they could have
13 relied upon ordinary morality and conscience. Those
14 were available. But such standards that we all learn at
15 our grandparents' knees were not followed. Why weren't
16 they followed? It's really impossible to say, but it
17 seems as though, seems to me personally as though the
18 researchers put their own medical, scientific and
19 personal advancement first and human decency and
20 respect for others a far, far second.

21 These experiments could not be approved under
22 contemporary regulations for human subjects research.

1 Informed consent today is key. Risk minimization is
2 key. Respect for vulnerable groups is key. But these
3 ideas were not unheard of in the 1940s. They were in
4 circulation and the researchers could have turned to
5 them. We know they knew about them because they
6 employed them in Terre Haute, Indiana, just a year or
7 two earlier.

8 We also know that it was the time of the
9 highly-publicized Nuremberg trials in the 1940s, 1946,
10 the American research community was highly mindful of
11 the fact that 23 doctors and bureaucrats were being
12 accused of involvement in very cruel concentration camp
13 experiments in the Nazi Third Reich, and coming out of
14 the international attention shined on the Nazi doctors
15 and their collaborators were principles of informed
16 consent and respect for vulnerable people that were,
17 indeed, published in the Journal of The American
18 Medical Association in 1947 and these principles
19 included a principle that there must be consent of a
20 human subject in all cases.

21 Everyone has to consent. Coercion is not
22 authorized or not appropriate.

1 And, finally, there was a need to be concerned
2 about the avoidance of unnecessary physical and mental
3 suffering, according to the Journal of The American
4 Medical Association principles and these experiments in
5 Guatemala involved a lot of needless and cruel
6 suffering, both physical and mental. A lot of
7 people who were experimented on were terrified, were
8 avoidant but were nonetheless coerced, both emotionally
9 and physically coerced to participate.

10 So we have the Terre Haute background
11 providing us values. We have the post-Nuremberg
12 principles that were promulgated in major journals
13 providing some guidance. We have common sense and
14 ordinary morality providing guidance and we also have a
15 sense at the time that the media was promulgating and
16 reflecting current values. So there's a newspaper
17 article from the New York Times in 1947 that our
18 preliminary report, our draft report cites, a
19 journalist called Walter Canford, who reported on STD
20 research involving animals, and he said that it, of
21 course, would be ethically impossible to shoot living
22 syphilis germs into human bodies. It would be

1 ethically impossible.

2 Well, little did he know that down the road,
3 this exact thing was happening with human beings but
4 it's inconceivable to this major media journalist that
5 such a thing could be done. Why did he think that? I
6 think probably because most people thought that at the
7 time.

8 So, you know, in conclusion, there was
9 definitely not the same level of federal public law
10 that there is today to guide scientists. There wasn't
11 the same level of formal professional documents laying
12 out printables. There was no detailed ethical code for
13 doctors and researchers as there are today, many of
14 them today. We had no Belmont principles yet and so
15 forth, but we did have, I think, enough ethics in the
16 air and in society that would have instructed the
17 Guatemalan researchers to do differently than they did
18 and I'll stop it there.

19 DR. GUTMANN: Thank you very much. There's an
20 important distinction in ethics between whether
21 something is morally wrong on the one hand and on the
22 other hand whether the people who conducted what was

1 morally wrong are morally blameworthy and we as a
2 commission need to address both those questions.

3 It's in retrospect but it is to actually come
4 to terms with our history and to honor the people who
5 were subjected to what was clearly in our minds as a
6 commission morally wrong.

7 I would ask any members of the Commission, if
8 you would, to say something not only about the moral
9 wrongs in this case but about how one assesses -- and
10 this is not for the sake of legal judgment. We are not
11 sitting -- we're sitting as a bioethics commission.
12 This is -- but as a matter of intelligence, ethical
13 assessment, to what extent was there moral
14 blameworthiness in this case?

15 And let me start with John Arras.

16 DR. ARRAS: Thank you, Amy. I spent a lot of
17 time pondering this very question. As my fellow
18 commissioners know during our e-mail conversations,
19 I've been fretting about this distinction between blame
20 and wrong-doing for quite some time and in large part
21 this stems from my own teaching and research where, you
22 know, I canvass the history of the Nazi experiments

1 and, you know, experiments done in the U.S. without
2 consent and I'm acutely aware of the rather dramatic
3 shift in values and perspective that was beginning to
4 take place around that time.

5 So I think that it would be a case of what my
6 colleagues in history call presentism, in other words,
7 imposing the views of the present on the past, to view
8 these physicians in exactly the same light that we
9 would view people today who did these things, and I
10 think that this is especially true with regard to
11 informed consent.

12 Even though Andrew Ivey at the Nuremberg
13 trials said that informed consent was an absolute
14 bedrock of medical experimentation, in this country I
15 think that he was exaggerating by a long shot. This
16 was a time, this was the heyday of physician discretion
17 in medical ethics and medical research, and the debate
18 over the moral necessity of informed consent lasted
19 well into the 1960s and '70s. So there were people on
20 both sides of that debate.

21 So I, for one, have been extremely reluctant
22 to bring the moral hammer down, you know, with full

1 force on the question of blame.

2 However, the issue of informed consent is not
3 the only question and even on the issue of informed
4 consent, we're not simply talking about failure to
5 inform. We're talking about active deception, right?

6 But apart from informed consent, we have all
7 these issues about not subjecting people to needless
8 suffering, not imposing risks upon them that can't be
9 justified by the scientific study, and once we add all
10 of those issues into the account, I really do believe
11 that a very vigorous judgment of moral blame can be
12 lodged against some of these people.

13 For me, the most powerful argument that can be
14 made here is to repeat a story that's in our report and
15 this is the case profile of a patient named Berta.
16 This is given on Page 117 of our report.

17 So Berta was a patient in a psychiatric ward.
18 She was injected with syphilis and not given penicillin
19 until three months after her infection, but here's the
20 interesting part, and I'm just reading here from the
21 profile. Soon after, on August 23rd, Cutler wrote that
22 Berta appeared as if she was going to die but he did

1 not specify why. That same day, he put gonorrhoeal pus
2 from another male patient into both of Berta's eyes as
3 well as in her urethra and rectum. He also reinfected
4 her with syphilis. Several days later, her eyes were
5 filled with pus from the gonorrhoea and she was bleeding
6 from her urethra. Six months later, she died.

7 I would submit that this kind of case cannot
8 be waved away by even the most acute awareness of
9 fluctuation in medical ethics standards of the time.

10 DR. GUTMANN: That's why I think we stand by
11 the view I earlier articulated, that if Berta was
12 considered treated like a human being, nobody, not
13 a -- and most especially not a doctor could have
14 treated her like that.

15 DR. ARRAS: The only thing I would add to that
16 is that -- and a comment that was made at the time of
17 the Nazi trials was that if they had only treated the
18 subjects of those studies as well as they treated
19 animals in their studies, there would have been no
20 scandal, and I think we can say the same thing of this
21 study.

22 DR. GUTMANN: That's why I earlier said things

1 rather than other animals. We are higher, you know,
2 but sometimes lower.

3 I would just add -- could I just make one
4 comment because it is our -- this is on
5 the -- Christine Grady earlier said, you know, some of
6 the science was not useless and I will defer it to
7 that. That may be true, as it was true of some of the
8 Nazi science. There is something worse than doing
9 useless science.

10 DR. FARAHANY: So, first, Anita, thank you for
11 that again very sobering account of the ethics of the
12 research.

13 To your question, Amy, about blameworthiness
14 versus wrong-doing, I likewise struggled with this
15 quite a bit because one of the difficulties in
16 retrospective judgments of ethical conduct is, first,
17 that it is retrospective, but, second, understanding
18 what the researchers knew and understood at the time.

19 But we don't really have that problem here in
20 a way that we do often in retrospective judgments and
21 so I teach both law and philosophy and I in fact teach
22 a comparative class on the difference between

1 responsibility, liability and blameworthiness, and
2 whether it's in law or in philosophy, one of the
3 hallmarks of thinking about blameworthiness of
4 individuals is knowledge of wrong-doing and acting with
5 knowledge of wrong-doing.

6 We don't -- because we can't directly ask or
7 find out what the knowledge was at the time, we use
8 objective evidence to infer what the subjective intents
9 were at the time and we have a lot of that from the
10 Terre Haute studies that Anita recounts and the
11 knowledge that they were acting under from the
12 contemporaneous documentation, the desire to keep
13 things secret, the back and forth letters that were
14 exchanged suggesting a need to avoid the political
15 consequences of the study.

16 All this was done with knowledge and
17 understanding of the ethical limitations and so the
18 only thing that for me was something I wanted to ponder
19 as a potential mitigating circumstance was is there
20 something different about international research
21 standards at the time than there was about domestic
22 research standards because obviously they understood

1 what the domestic context was, having Terre Haute, but
2 is there something different about a partnership with
3 another country where, for example, we know that
4 commercial sex workers were not outside of the norm
5 there, weren't considered to be, you know, an ethically
6 impermissible use, and so I think there are some things
7 that we can say that we wouldn't have done here but
8 within the context there would have been permissible
9 but very few things in this study that we can say.

10 We can say the use of commercial sex workers
11 perhaps with everyone's full knowledge and informed
12 consent would have been permissible but to
13 intentionally infect people, to do so with deception,
14 to do so with bad science, to do so in secrecy, to do
15 so without actually publishing the reports, all this to
16 me suggests very clear objective evidence of subjective
17 knowledge of wrong-doing which is sufficient for a case
18 of moral blameworthiness.

19 DR. GUTMANN: Raju.

20 DR. KUCHERLAPATI: You know, I'm trained as a
21 scientist and I'm a practicing scientist and I'm not an
22 ethicist. So it was very important for me to

1 understand and however, you know, I find it difficult
2 to be able to put myself in the shoes of those people
3 and trying to judge them based upon contemporary
4 today's standards.

5 We understand what today's standards are, but
6 the argument that's most persuasive for me of all of
7 the different piece of evidence that was presented is
8 the Terre Haute experiments. I think that the Terre
9 Haute experiments were contemporary for that time. The
10 people were specifically involved in those experiments.
11 They knew that, you know, that it is necessary to be
12 able to obtain consent from patients and they also knew
13 that these Guatemalan experiments could not be
14 conducted in Terre Haute and the same individuals made
15 that statement said that these experiments just cannot
16 be conducted in our country. We have to go out to be
17 able to do these experiments.

18 So of all of the different sorts of things,
19 the three different sets of arguments that we make, the
20 one that's most persuasive for me is the ones
21 that -- because they have direct knowledge. It's the
22 other types of things, you know, great moral principles

1 and, you know, those are in the background that you may
2 not be directly be, you know, thinking about them every
3 day, but these are very clear.

4 And the other thing that's also persuasive is
5 the fact that the New York Times reporter writes about
6 these experiments and that there are no circumstance in
7 which these types of experiments can be done. He is
8 not talking about Guatemala experiments. He's just
9 talking about experiments of the nature that were
10 conducted in Guatemala. And so those things, you know,
11 make a persuasive case that, you know, clearly that the
12 people should have known and most likely have known
13 that these are unethical experiments but they conducted
14 them anyway and that is what is reprehensible.

15 DR. GUTMANN: Barbara.

16 DR. ATKINSON: Maybe I should introduce
17 myself. I think I haven't the last couple times.

18 I'm Barbara Atkinson. I'm the Executive Vice
19 Chancellor at the University of Kansas Medical Center,
20 and to me the blameworthiness relates mostly to the
21 vulnerable populations and it just seemed like they
22 went from not so vulnerable to the most vulnerable,

1 getting more egregious every time.

2 So at Terre Haute, it was prisoners and it was
3 really done pretty well but then they went to
4 Guatemala. The Army people got mostly gonorrhoea,
5 pretty straightforward gonorrhoea studies, but then they
6 went to the prisoners there and they started the penile
7 abrasions and scarifications in order to get to them
8 and then they complained about the blood draws and
9 these they called the indigenous Indians and they
10 complained about the blood draws and the pain and then
11 they went to the psychiatric patients and started doing
12 things like cisternal injections and what you just
13 heard in John's study.

14 So that progression to me seems as if they
15 really must have recognized that they were
16 getting -- had to get to people that were so vulnerable
17 that they really couldn't complain in order to do the
18 very worst of the things they wanted to do and I just
19 can't forgive that or not see a recognition of blame in
20 that.

21 DR. GUTMANN: Lonnie Ali.

22 MS. ALI: Thank you, Amy. And, John, thank

1 you for your comments. That one patient profile was
2 something that really got to me, too.

3 I wanted to ask Nelson something because I was
4 going to ask a question, Anita went before me, and it
5 was the same idea of them being cognizant of what went
6 on in Terre Haute and then going to Guatemala and the
7 standards perhaps being different there.

8 Do you have any knowledge if that is true, and
9 how much work was being done outside of the United
10 States with regards to using human research subjects?

11 DR. GUTMANN: Nelson, could I just ask you to
12 preface your answer by saying a little bit about the
13 research just so people know that Nelson does research
14 outside of the United States? So I think that's
15 relevant.

16 DR. MICHAEL: Yes. Yes, and most of the
17 research that my organization does is done outside the
18 United States in East Africa and West Africa, South
19 Africa and in Thailand. We've been doing those kinds of
20 studies in HIV since the middle 1980s.

21 So because of the fact that the work that we
22 do is represented, is funded through and represents an

1 agency of the U.S. Government, we really feel like
2 there's no difference between the level of ethics that
3 would apply to U.S. soldiers as research participants
4 or American citizens or citizens of any country and
5 that we have extensive review of those kinds of
6 research proposals that includes oversight by normative
7 bodies, like the World Health Organization, extensive
8 involvement of community groups, to include NGOs, and
9 representatives of the community in which research is
10 done, and that's something I'll probably talk about a
11 lot more tomorrow when Christine and I talk about the
12 International Research Panel deliberations.

13 But I don't think that in this case you really
14 have much that's different in that sense. The Public
15 Health Service is an arm of the U.S. Government. There
16 were research standards in the United States that the
17 researchers clearly felt like were going to represent a
18 challenge to do the kind of work they wanted to do and
19 they went elsewhere to do it.

20 My own view is I don't think that's ever
21 defensible. I think that if a research is done in the
22 world community, it needs to be done in the world

1 community, and there's no difference between borders.

2 So from a personal standpoint, I don't think
3 it's defensible to say that you do research elsewhere
4 because it addresses an expediency, and I think that,
5 going back to Anita's very careful dissection of
6 blameworthiness, these individuals, I think, had a
7 pretty clear idea of what they were doing and why they
8 were doing it and they were driven by expediency.

9 So at that time, if what you're asking me is,
10 you know, what was the prevalence of research
11 standards or ethics that were codified, I'll tell you
12 I'm not aware of any set of standards that would have
13 said it's okay to go offshore and do this kind of
14 research. I think they did it because they found a
15 doorway that they found darkened and went through it
16 and they ended up, I think, for the longest period of
17 time getting away with it.

18 MS. ALI: Can I ask you one more question,
19 please, Nelson? In the Terre Haute experiment, one of
20 the things that James Bennett was very concerned about,
21 he was the Director of Prisons at that time, was not
22 giving incentive to the prisoners to participate in the

1 study and it wasn't so much because he thought it was
2 coercion, he was really more concerned about the rest
3 of the population who did not have an opportunity to be
4 a part of the experiment.

5 Would that be appropriate today? Would that
6 be considered coercion to offer money and perhaps some
7 type of recommendation to a parole board, a good word
8 per se, to participate in a study? Would that -- you
9 know, we had a little discussion about this beforehand,
10 about what is coercion. Would that be acceptable
11 today?

12 DR. MICHAEL: Well, I think that, I'm looking
13 over at my colleague Christine, we've been spending a
14 lot of time together, we're both on the IRP, but I
15 think that when you work in vulnerable populations, you
16 are entering into a realm of very great ethical concern
17 and I think that to me the bottom line is it matters
18 less that you are completely compliant with regulations
19 to do what you do with research volunteers of any type,
20 but especially in vulnerable populations, I think you
21 need to ensure that the broadest possible transparent
22 dialogue occurs, so that if all agree that research

1 goes forward, that it really does involve a series of
2 checks and balances that advocates for the research
3 subjects themselves are adequately represented and I
4 think that you have to ask yourself, and we were having
5 this discussion at lunch about some of the work that we
6 have done in Thailand, is what defines an adequate
7 review of that kind of work? What defines an adequate
8 engagement with the community? Who says what's good
9 enough?

10 So I think that when you're involving
11 individuals that, by dint of their circumstance, have
12 less intrinsic ability to speak for themselves, I think
13 that you really have a moral obligation to do the best
14 that you can possibly do but don't rely on simply your
15 own judgment or judgment of regulators or boards that
16 oversee that process and ensure that they have a voice
17 and a powerful voice that comes from the community and
18 the volunteers themselves and doing that, I think, in
19 those populations is very challenges.

20 DR. GUTMANN: Christine, do you want to say
21 something about standards of undue inducement and --

22 DR. GRADY: Yes, I do.

1 DR. GUTMANN: -- from what we know is at the
2 time?

3 DR. GRADY: Yeah. Well, I don't know about
4 the time. I think in response to Lonnie's question, I
5 think two really important things to point out and that
6 is, we have come to understand in a way that we didn't
7 in the '40s and '50s and '60s that prisoners are
8 vulnerable for lots of reasons, partially what Nelson
9 just said, that they are in a position where it might
10 be difficult for them to protect their own interests
11 and to say no in the context of research and therefore
12 the current rules limit the kinds of research that can
13 be done in prisons to a great degree.

14 The second question, though, is about
15 incentives and what's acceptable and what's not. This
16 is a very controversial area of research and very
17 controversial in general.

18 I think it is true that many people who are
19 participants in research receive an incentive of one
20 sort or another. Sometimes it's money, sometimes it's
21 food or soap, sometimes it's medicine that they want
22 for something that they are struggling with. So there

1 are incentives that are provided in research all the
2 time.

3 The debate that continues to ensue is at what
4 point do any of those incentives become unduly
5 influential to the point where it might distort an
6 individual's ability to make a good judgment, to look
7 at the risks and benefits and decide for him or herself
8 whether or not to join a study and that's really an
9 ongoing discussion.

10 DR. GUTMANN: Steve, you might -- we should
11 circle back a little bit to the experiments. You might
12 want to say, if I could ask you, on some of the
13 experiments on the prisoners, what the nature of those
14 experiments were because I think that helps illuminate
15 some of the ethical problems here.

16 DR. HAUSER: The details of the inoculation --

17 DR. GUTMANN: Yes.

18 DR. HAUSER: The details of the inoculation
19 experiments? Well, to put more detail on a broader
20 discussion earlier, these experiments in many cases
21 involved two types of experiments. One they called
22 natural infection which was intercourse or other sexual

1 activity with prostitutes, with commercial sex workers,
2 inoculated or infected deliberately and instructed to
3 have multiple encounters without washing. They
4 involved inoculation by variously-stringent mechanisms
5 to try to directly infect prisoners with these diseases
6 and, as was said earlier, some of these methods
7 actually did cause at least localized infections but
8 not the model that they were searching for.

9 Was that the type of --

10 DR. GUTMANN: Yeah.

11 DR. HAUSER: -- detail that you were --

12 DR. GUTMANN: Part of -- some of the facts
13 that have come out in the historical study indicate,
14 and this is why Lonnie's question, I think, is so
15 important, indicate that, despite the fact that there
16 were something -- there was something offered to the
17 prisoners, which is not uncommon, the prisoners
18 were -- expressed, indeed, at some points were so
19 unhappy with the way they were being treated that the
20 doctors were fearful of a revolt and did as much as
21 they could to continue the experiments, despite the
22 fact that the prisoners who were not asked for consent,

1 who were given some inducement, whether it was -- it
2 was not large. It was a \$100, I believe. They still
3 were a vulnerable population which is known and was
4 known at the time to be more willing to undergo
5 experiments. They were extremely unhappy with the way
6 they were being treated.

7 So there was again something, to go back to
8 Lonnie Ali's question and Nelson's answer, there was a
9 sense that these very experimenters, researchers, as
10 Nita Farahany has said, knew they couldn't do this in
11 the United States.

12 Steve.

13 DR. HAUSER: Just a comment, two comments, one
14 partially a question, and again I come to this, as my
15 colleague Raju also said, that we are not bioethicists.
16 We are scientists.

17 So I think the first point that I wanted to
18 touch on was Amy's question about individual guilt that
19 a number of my colleagues have spoken about and it's
20 difficult to infer motivation, especially for those of
21 us who never met the principals in this trial.

22 There is a documentary called The Deadly

1 Deception that is available online about a different
2 study that Dr. Cutler was involved in, the Tuskegee
3 study, and the belated closure of the Tuskegee study
4 after people were followed without treatment when
5 therapy for syphilis was available and there's an
6 interview with Dr. Cutler for the 1993 documentary, an
7 old man at this time, and he says that he was furious
8 that the study was stopped. He continued to argue that
9 the study was too important to stop.

10 It's difficult to infer what someone's
11 motivation was 40 years earlier or 35 years earlier,
12 but it's hard not to come away with the conclusion that
13 this was a person who believed that the ends, that the
14 importance of the study was paramount, and I think we
15 have to take that into account when we think of the
16 issue of individual guilt.

17 The other issue, question that I wanted to
18 raise was that we began this afternoon with a
19 discussion of the science before the ethics, so that we
20 could understand the science before the ethics, and a
21 question was the science good science or were elements
22 of the science good science?

1 In my field, neuroscience, we have experience
2 with human experimentation done by the Nazis that led
3 to potentially useful information about how our nervous
4 system is organized anatomically but we do not use that
5 information because it was obtained illegitimately.

6 So my question to the group relates in part to
7 that. The ethical underpinnings of a scientific
8 experiment are so paramount that is it perhaps even
9 more effective to think of that before we even weigh
10 the value of the science?

11 DR. GUTMANN: So, Steve, I'm going to call on
12 Nita in a moment, but I would answer that an
13 unequivocal yes. I don't think that science can be
14 understood as good science without an ethical
15 underpinning to it and I think everybody around this
16 table who is a scientist and a doctor does that and
17 understands that as a given. And when we are confronted,
18 as you so eloquently said, with somebody who sees
19 science as divorced from the way human subjects or any
20 animate beings are treated, divorced from that, it is
21 shocking in a different way than the shock of somebody
22 who is what we call in -- it's a technical as well as a

1 colloquial term, a hypocrite, somebody who knows that
2 he's doing wrong and does it anyway.

3 The first is even more shocking. We are more
4 used to dealing with people who are hypocrites, who
5 know that they're doing something wrong and for
6 self-interested reasons do it than we are used to
7 dealing with somebody who is doing something that, by
8 all ordinary, correct ordinary standards is wrong but
9 doesn't accept it because he thinks that what -- the
10 purpose he is serving in science is so paramount that
11 it trumps the basic ethical considerations.

12 So I think what you brought out is very
13 important for us to understand and it is and it ought
14 to, it ought to intellectually as well as emotionally
15 shock us.

16 Nita.

17 DR. FARAHANY: Thank you, Amy. I agree very
18 much with your perspective on it and also with yours in
19 that I think there's a difference between thinking that
20 he was doing something unethical and recognizing that
21 he was doing something wrongful.

22 So I think he knew he was doing something at

1 odds with social norms and he knew that he was doing
2 something that was at odds with what the prevailing
3 norms of the treatment of human research subjects were
4 and he nevertheless thought that his values were more
5 important than social values and social norms at the
6 time and by ordinary standards of blameworthiness, it
7 is appropriate for us to both weigh his value, right?
8 I mean, there are defenses we have and mitigating
9 circumstances we consider all the time, like is this
10 such a mitigating circumstance, does it outweigh the
11 existing prevailing norm, and I think we've done that
12 in this report.

13 I think we've looked to see what are the
14 mitigating circumstances which are his claims. Of
15 course, they're vastly undercut by how poor the science
16 itself was and by the methods that he used, but we can
17 simply say he knew he was doing something wrongful,
18 even if he believed that the ends justified the means,
19 and that makes it a blameworthy action by deviating
20 from what the norms were at the time which he
21 recognized and intentionally flouted.

22 DR. GUTMANN: I just -- and then I'll call on

1 Anita and go around. I saw almost everybody's hand up.

2 We have limited time.

3 But let -- I think it's important to recognize
4 here that when we talk about moral blameworthiness and
5 wrong, we're not only -- and the report will make this
6 clear -- talking about Dr. Cutler. There were, alas,
7 other doctors and scientists who knew and approved of
8 this experiment and they're named in the report. We're
9 not trying to put fine gradations of blame here because
10 there's no practical reason there.

11 I think John Arras said it very well in that
12 we want to avoid the assumption that everybody
13 practicing at the time should have practiced at the
14 highest standards that we now expect, not just
15 recognize but expect today. Nonetheless, there were
16 other doctors, including, I'll just name one so there's
17 another name out there, Dr. Mahoney, who knew and
18 approved of these experiments.

19 Anita.

20 DR. ALLEN: Well, I think Nita said everything
21 so beautifully, I hardly have anything left to say, but I
22 did want to make this point maybe to sort of follow up

1 on Nita's point.

2 I don't think that there's any mitigation or
3 defense in the notion here that Dr. Cutler or his
4 colleagues were well-intended or they were acting in
5 accordance with what they felt was right, knowing they
6 were going contrary to social norms, and that's because
7 we also recognize as a moral failing arrogance and
8 hubris and it is arrogant to the max to put your own
9 values in front of social norms, especially when that
10 involves a massive display of disrespect for 5,000
11 other human beings whom you're inflicting with pain and
12 suffering and diseases.

13 So for that reason, I don't see any mitigation
14 or any relief at all from the brand of immorality or
15 unethical conduct or unethical character for these
16 doctors.

17