

# **Comment Submissions - Proposed Adoption of Exposures to Listed Chemicals in Coffee Posing No Significant Risk**

Published Name:

CERT's Submission No. 7 regarding the Opinions of Dr. Peter F. Infante Regarding the Cancer Epidemiology of Acrylamide.

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Post date:

08/15/2018 - 3:43pm

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August 15, 2018

*Via electronic submission to  
<https://oehha.ca.gov/comments>*

Monet Vela  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010  
Sacramento, California 95812-4010

Re: Proposed Adoption of New Section Under Article 7: No Significant Risk Levels  
Section 25704: Exposures to Listed Chemicals in Coffee Posing No Significant Risk

## **CERT'S SUBMISSION NO. 7**

Dear Ms. Vela:

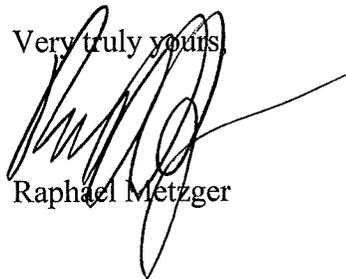
Enclosed herewith are the following documents that are being submitted on behalf of our client, the Council for Education and Research on Toxics (CERT) regarding the Opinions of Dr. Peter F. Infante Regarding the Cancer Epidemiology of Acrylamide.

1. Exhibit A - Opinions of Dr. Peter F. Infante Regarding the Cancer Epidemiology of Acrylamide (2014).
2. Exhibit B - Conclusions of Dr. Peter F. Infante Regarding the Cancer Epidemiology of Acrylamide (2014).
3. Exhibit C - Testimony of Dr. Peter Infante in *CERT v. Starbucks* trial, October 20, 2014 a.m.
4. Exhibit D - Testimony of Dr. Peter Infante in *CERT v. Starbucks* trial, October 20, 2014 p.m.
5. Exhibit E - Testimony of Dr. Peter Infante in *CERT v. Starbucks* trial, October 21, 2014 a.m.

6, Exhibit F - Curriculum Vitae of Dr. Peter Infante.

Kindly include these materials of Dr. Peter F. Infante in the record for this rulemaking proceeding.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Raphael Metzger', with a long horizontal line extending to the right.

Raphael Metzger

RM:ip  
encls: as specified

**EXHIBIT “A”**

## **Opinions of Dr. Peter F. Infante Regarding the Cancer Epidemiology of Acrylamide**

[These opinions were prepared by Dr. Infante in 2014 for the Phase 1 Trial in *CERT v. Starbucks* that concerned the coffee industry's No Significant Risk Level defense for acrylamide in coffee]

### **Occupational Cohort Epidemiology Studies of Acrylamide and Cancer**

1. Occupational epidemiological cohort studies demonstrate an excess of pancreatic cancer among acrylamide (ACM) exposed workers. (Collins 1989, Marsh 1999, Marsh 2007, Swaen 2007)
2. A monotonic dose-response relationship between exposure to ACM and risk of pancreatic cancer has been demonstrated for duration of employment and duration of exposure (Marsh 1999 [with Schulz 2001 reanalysis], Cal-EPA 2005, Marsh 2007 [with Schulz 2001 adjustment]), notwithstanding an exposure classification scheme that would appear to bias results toward the null hypothesis of no association.
3. Elevation in risk of other cancer sites is difficult to determine in terms of dose response because of potential for exposure misclassification.
4. The studies of ACM workers are not sufficiently powerful to detect the low risks predicted by low-dose extrapolation modeling of animal data. (Erdreich 2003)

### **Dietary Epidemiology Studies of Acrylamide and Cancer**

5. Dietary epidemiological studies of ACM lack adequate statistical power to detect increased risks of cancer at dietary exposure levels. (Hagmar 2003, Dybing 2003, JIFSAN 2004, Mucci 2005, WHO/FAO 2005, WHO/FAO 2006, Carere 2006, Besaratinia 2007, WHO 2011)
6. Notwithstanding their lack of statistical power, several dietary epidemiology studies of ACM have reported significant increased risks of cancers. Hogervorst 2007 (ovarian and endometrial cancer), Olesen 2008 (estrogen receptor positive breast cancer based on acrylamide-hemoglobin adduct levels), Hogervorst 2008 (renal cell cancer), Schouten 2009 (oral cancer), Wilson 2010 (endometrial and serous ovarian cancer), Lin 2010 (esophageal cancers), Hirvonen 2010 (lung cancer in male smokers), Burley 2010 (premenopausal breast cancer), Bongers 2012 (follicular lymphoma and multiple myeloma in men), Hogervorst 2014 (colorectal cancer with *k-ras* mutations in men); Lujan-Barroso 2014 (esophageal cancer).
7. A number of these studies demonstrate a dose-response relationship. Hogervorst 2007 (ovarian and endometrial cancer), Hogervorst 2008 (renal cell cancer), Wilson 2010 (ovarian serous and endometrial cancer), Hirvonen 2010 (lung cancer in male smokers), Burley 2010 (premenopausal breast cancer), Hogervorst 2014 (colorectal cancer with *k-ras* mutations in men)

8. Several studies report significantly increased cancer risks among non-smoking populations. Hogervorst 2007 (endometrial and ovarian cancer among never-smokers), Schouten 2009 (oral cancer in female nonsmokers), Lin 2010 (squamous cell esophageal cancer in nonsmokers), Bongers 2012 (multiple myeloma in male never-smokers), Hogervorst 2014 (colorectal cancer with *k-ras* mutations in male non-smokers). This is important because cigarette smoke exposure is a substantial source of confounding both because of the carcinogenicity of cigarette smoke and because of its ACM content.

9. The studies of dietary ACM intake also suffer from inadequate estimation of the amount of ACM from ingestion of foods known to contain ACM. For example, fried potatoes or chips contain widely varying amounts of ACM depending upon storage and treatment during cooking and there is no indication that such variation was taken into account during ACM intake estimation. The authors of some of the research papers also indicate that some ACM containing foods may not have been included during the dietary interview. If one does not account for such variability, or food source of ACM during estimation of ACM intake, misclassification occurs, which results in a bias toward the null, particularly in dose-response analyses.

10. Dietary studies of ACM also did not take into consideration dietary factors that reduce cancer risk such as fruits and vegetables. Lack of such information does not allow for one to make adjustments for factors that modify dose response.

### **Dietary Epidemiology Studies of Potato Consumption and Cancer**

11. Numerous epidemiologic studies report significantly increased risks of cancer from consumption of potatoes. Phillips 1975 (breast and colon cancer), Hu 1988 (stomach cancer), Steineck 1990 (urothelial cancer), Franceschi 1991 (thyroid cancer), Franceschi 1997 (colorectal cancer), Bosetti 2002 (laryngeal cancer), Hu 2002 (lung cancer), Lee 2003 (breast cancer), De Stefani 2004 (gastric cancer in women), Bunin 2005 (medulloblastoma in children from maternal consumption), Chan 2005 (pancreatic cancer), Rodasavljevic 2005 (bladder cancer), Iso 2007 (colon cancer), Marchioni 2007 (oral cancer), Lucenteforte 2008 (stomach cancer), Nashar 2008 (colorectal cancer), Williams 2009 (rectal cancer), Lazarevic 2010 (gastric cancer), Polesel 2010 (pancreatic cancer), Arafa 2011 (colorectal cancer), Bravi 2013 (oral and pharyngeal cancer), Shamsi 2013 (breast cancer), Stott-Miller 2013 (prostate cancer).

12. Several of these studies reported a greater than doubling of the risk of cancer that was statistically significant. Phillips 1975 (breast cancer: OR 2.4,  $p \leq 0.05$ ; colon cancer OR 2.7,  $p \leq 0.05$ ); Rodasavljevic 2005 (bladder cancer: OR 6.31, 95% CI 2.91 - 13.70), Bunin 2005 (childhood medulloblastoma: OR 2.4, 95% CI 1.2 - 4.9), Lucenteforte 2008 (stomach cancer: OR 2.04, 95% CI 1.05 - 3.98); Williams 2009 (rectal cancer: OR 2.55, 95% CI 1.74 - 3.73); Lazarevic 2010 (gastric cancer: OR 4.79, 95% CI 1.44 - 5.94), Marchioni 2007 (oral cancer: OR 2.22, 95% CI 1.53 - 3.25); Lucenteforte 2008 (stomach cancer: OR 2.04, 95% CI 1.05 - 3.98); Lazarevic 2010 (gastric cancer: OR 4.75, 95% CI 1.44 - 5.94).

13. Importantly, a number of these studies reported a statistically significant dose response relationship. Franceschi 1997, Bosetti 2002, Iso 2007, Marchioni 2007, Lucenteforte 2008, Bravi 2009, Williams (in whites) 2009, Polesel 2010, Bravi 2013, Stott-Miller 2013.

14. According to my research, ACM is the major recognized carcinogen in cooked potatoes. The abundance of epidemiologic studies showing increased risks of various cancers from potato consumption, with many of the studies demonstrating dose-response relationships, also provides some evidence of ACM carcinogenicity in humans.

### **Acrylamide Clastogenicity**

15. Acrylamide induces chromosomal aberrations in germ cells of rodents, in somatic cells of rodents in vivo, and in cultured cells in vitro. (IARC 1994)

16. Acrylamide induces cell transformation in rodent cell lines. (IARC 1994)

17. Acrylamide has been shown to inhibit Topoisomerase II in vitro. (Sciandrello 2010).

### **Epidemiology Studies of Chromosome Aberrations and Human Cancer**

18. Epidemiologic studies demonstrate that chromosomal breakage (micronuclei, chromosome breaks, and translocations) is associated with increased cancer risk. (Brogger 1990, Hagmar 1994, Bonassi 1995, Hagmar 1998, Bonassi 2000, Bonassi 2001, Hagmar 2001, Bonassi 2002, Bonassi 2004, Hagmar 2004, Rossner 2005, Norppa 2006, Bonassi 2007, Boffetta 2007, Bonassi 2008, Bonassi 2011). These studies show that these specific types of chromosomal damage in people are predictive of future human cancer risk. The ability of ACM to induce chromosome aberrations adds to the evidence that it likely causes human cancer.

### **Authoritative Body Determinations Regarding Acrylamide Carcinogenicity**

19. Based upon experimental animal studies showing the induction of multiple tumors in multiple species and other experimental and mechanistic studies, the International Agency for Research on Cancer has concluded that ACM is probably carcinogenic to humans. (IARC 1994)

20. The National Toxicology Program has concluded that ACM is reasonably anticipated to be a human carcinogen. (NTP 12<sup>th</sup> RoC 2010)

21. The California Environmental Protection Agency has listed ACM as a chemical known to the state of California to cause cancer. (Cal-EPA 2005).

# **EXHIBIT “B”**

## **Conclusions of Dr. Peter F. Infante Regarding the Cancer Epidemiology of Acrylamide**

1. Occupational epidemiological cohort studies conducted to date consistently demonstrate an excess of pancreatic cancer among acrylamide (ACM) exposed workers.
2. Some analyses related to #1 above also demonstrate a dose-response relationship between exposure to ACM and risk of pancreatic cancer even in the presence of an exposure classification scheme that would appear to bias results toward the null hypothesis of no association.
3. Elevation in risk of other cancer sites is difficult to determine in terms of dose response because of potential for exposure misclassification.
4. Dietary studies of ACM intake show little evidence of elevated risk of specific cancers, however, these studies have insufficient statistical power to detect an elevated risk if in fact one were present.
5. The studies of dietary ACM intake also suffer from inadequate estimation of the amount of ACM one may have ingested from foods known to contain ACM. For example, fried potatoes or chips contain widely varying amounts of ACM depending upon storage and treatment during cooking and there is no indication that such variation was taken into account during ACM intake estimation. The authors of some of the research papers also indicate that some ACM containing foods may not have been included during the dietary interview. If one does not account for such variability, or food source of ACM during estimation of ACM intake, misclassification occurs, which results in a bias toward the null.
6. Dietary studies of ACM also did not take into consideration dietary factors that reduce cancer risk such as fruits and vegetables. Lack of such information does not allow for one to make adjustments for factors that modify dose response. Nevertheless, a recent study demonstrates a significant dose-response for dietary ACM exposure and renal cell carcinoma.
7. Epidemiological studies have demonstrated significantly elevated risks of multiple cancers in relation to fried potato consumption. To my knowledge, ACM is the only chemical found in fried potatoes to any significant degree that is considered a carcinogenic substance.
8. ACM is known to be clastogenic in experimental animals. Several epidemiological studies indicate that chromosomal breakage in humans is associated with elevated cancer risk.

9. Based upon experimental animal studies showing the induction of multiple tumors, IARC has concluded that ACM is probably carcinogenic to humans.

10. In my opinion, the epidemiological data provide some evidence of elevated cancer risk among workers exposed to ACM and among those who consume fried potatoes. Evidence of ACM's ability to cause cancer in humans is supported by experimental data indicating the induction of multiple types of tumors in experimental animals and IARC's conclusion that ACM is probably carcinogenic to humans. Further evidence to support ACM as a probable human carcinogen is provided by data indicating that ACM causes chromosomal breakage.

# **EXHIBIT “C”**

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

DEPARTMENT NO. 323

HON. ELIHU M. BERLE, JUDGE

COUNCIL FOR EDUCATION AND )  
RESEARCH ON TOXICS, )

PLAINTIFF, )

VS. )

NO. BC435759

STARBUCKS CORPORATION, )  
ET AL., )

DEFENDANTS. )

AND CONSOLIDATED ACTION. )

REPORTER'S TRANSCRIPT OF TRIAL PROCEEDINGS

MONDAY, OCTOBER 20, 2014

MORNING SESSION

APPEARANCES:

FOR THE PLAINTIFF:

METZGER LAW GROUP  
BY: RAPHAEL METZGER  
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MICHAEL CABRAL  
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FOR DEFENDANTS:

MORRISON & FOERSTER  
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(415) 268-7124

CCROLA JOB  
NO. 114673

DANA L. SHELLEY, RPR, CSR #10177  
OFFICIAL REPORTER PRO TEM

INDEX FOR OCTOBER 20, 2014  
MORNING SESSION

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INFANTE, PETER FRANCIS

DIRECT EXAMINATION BY MR. METZGER 7

DEFENDANTS '  
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(NONE.)

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MORNING SESSION

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	<u>I.D.</u>	<u>EVIDENCE</u>	<u>DRAWN</u>
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1 CASE NUMBER: BC435759  
2 CASE NAME: CERT VS. STARBUCKS  
3 DEPARTMENT: 323 HON. ELIHU M. BERLE  
4 REPORTER: DANA SHELLEY, RPR, CSR #10177  
5 LOS ANGELES, CALIFORNIA MONDAY, OCTOBER 20, 2014  
6 TIME: 9:40 A.M.  
7 APPEARANCES: (AS HERETOFORE NOTED.)  
8

9 THE COURT: GOOD MORNING, AGAIN, ON THE CERT VS.  
10 STARBUCKS CASE. WE'RE BACK ON THE RECORD. ALL COUNSEL  
11 ARE PRESENT, AND WE'RE READY FOR THE NEXT WITNESS.

12 BEFORE WE DO THAT, LET ME DISCUSS --  
13 HAVE A SEAT. MAKE YOURSELVES COMFORTABLE.  
14 LET ME DISCUSS A COUPLE OF OTHER MATTERS.  
15 WE HAVE PLAINTIFF'S REQUEST FOR A JUDICIAL  
16 NOTICE OF PORTIONS OF WHAT'S CALLED A BRIEFING BINDER  
17 AND ACCOMPANYING PUBLICATIONS FROM THE U.S. EPA.

18 ANYONE WISH TO BE HEARD ON THAT?

19 MR. METZGER: YES, YOUR HONOR.

20 SO IN PARTICULAR, WE'RE SEEKING JUDICIAL  
21 NOTICE OF A FEW DOCUMENTS, GOVERNMENT DOCUMENTS. AND  
22 THE BASIS FOR THE LISTING OF ACRYLAMIDE AS KNOWN TO THE  
23 STATE TO CAUSE CANCER, IT'S BECOME ESPECIALLY RELEVANT  
24 IN THIS CASE.

25 BECAUSE YOU MAY RECALL THAT THE REGULATIONS  
26 INDICATE THAT IF ONE IS GOING TO DO A RISK ASSESSMENT  
27 THAT'S NOT BASED ON A -- A QUANTITATIVE RISK ASSESSMENT,  
28 AS PROVIDED IN THE REGULATIONS, SUCH AN ASSESSMENT HAS

1 TO BE BASED ON EVIDENCE AND STANDARDS OF COMPARABLE  
2 SCIENTIFIC VALIDITY TO THOSE EVIDENCE AND STANDARDS  
3 WHICH FORM THE BASIS OF THE LISTING.

4 SO WE NEED TO KNOW WHAT THE BASIS OF THE  
5 LISTING WAS -- THE COURT NEEDS TO KNOW THAT, IN  
6 EVALUATING THE CASE. SO THAT'S WHY WE'RE REQUESTING  
7 JUDICIAL NOTICE.

8 THE COURT: WELL, I DIDN'T HEAR A REASON WHY --  
9 BUT WHAT'S THE STORY ABOUT THIS BRIEFING BINDER? WHAT  
10 KIND OF DOCUMENT IS THAT?

11 MR. METZGER: WELL, THIS IS JUST A BINDER THAT THE  
12 OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT PUT  
13 TOGETHER WHEN THEY WERE DOING AN EVALUATION OF  
14 ACRYLAMIDE IN 2003.

15 AND IT'S NOT SO MUCH THE BINDER THAT WE'RE  
16 SEEKING JUDICIAL NOTICE OF. IT'S REALLY THE MEMORANDUM,  
17 WHICH WAS PART OF IT. IF YOU LOOK, THERE'S A MEMORANDUM  
18 DATED FEBRUARY 27, 1990.

19 THE COURT: RIGHT. I MEAN, SO WHAT'S THE DIGNITY  
20 WE HAVE TO GIVE TO A MEMORANDUM?

21 MR. METZGER: WELL, THIS IS A MEMORANDUM PREPARED  
22 BY THE -- IS IT THE "DEPUTY"; IT'S HARD TO READ -- THE  
23 DEPUTY HEAD OF THE DEPARTMENT OF HEALTH SERVICES OF THE  
24 STATE OF CALIFORNIA, WHICH SETS FORTH THE BASIS FOR THE  
25 LISTING.

26 THE COURT: I'LL HEAR FROM THE DEFENDANT --

27 MR. METZGER: IF YOU SEE, IT SAYS THAT -- IN THE  
28 MEMORANDUM:

1 "THE ENVIRONMENTAL PROTECTION AGENCY HAS  
2 PUBLISHED CANCER POTENCY EVALUATIONS FOR  
3 SEVERAL CHEMICALS LISTED AS CARCINOGENS UNDER  
4 THE ACT."

5 SO WE HAVE THIS, WHICH SHOWS THAT AND WHEN  
6 THAT OCCURRED.

7 THE COURT: WELL --

8 MR. METZGER: AND THEN, IN PARTICULAR, THERE'S THE  
9 REFERENCES LISTED, WHICH INCLUDES THE INTEGRATED RISK  
10 INFORMATION SYSTEM, REFERENCE NO. 1 OF THE EPA. AND  
11 THAT IS THEN ATTACHED. AND THAT SHOWS THE BASIS FOR THE  
12 LISTING.

13 THE COURT: ALL RIGHT. THANK YOU.

14 DEFENDANTS?

15 MS. CORASH: YES. GOOD MORNING, YOUR HONOR.

16 YOUR HONOR, THIS MEMORANDUM WHICH PLAINTIFF  
17 SEEKS TO HAVE JUDICIALLY NOTICED IS A MEMORANDUM WRITTEN  
18 NOT BY THE DEPUTY SECRETARY AT ALL BUT BY SOMEONE WHO  
19 DESCRIBES HIMSELF AS "SCIENCE ADVISOR TO THE SECRETARY."  
20 IT REFLECTS THE VIEWS OF A SINGLE STAFF MEMBER. IT'S  
21 NOTHING BUT HEARSAY.

22 ACRYLAMIDE -- THE LISTING OF ACRYLAMIDE IS A  
23 REGULATORY ACT. AND IF MR. METZGER WANTS TO TALK ABOUT  
24 THE BASIS FOR LISTING ACRYLAMIDE AND REFER THE COURT TO  
25 THE BASIS FOR THAT LISTING, THOSE MATERIALS ARE  
26 AVAILABLE AS PART OF THE RECORD FOR LISTING ACRYLAMIDE.

27 THESE MATERIALS WERE ASSEMBLED BY OEHH  
28 STAFF IN CONNECTION WITH A PROPOSED RULE-MAKING. THE

1 RULE-MAKING PROPOSED WAS WITHDRAWN, ALONG WITH THE  
2 MATERIALS THAT WERE PREPARED IN SUPPORT OF IT.

3 SO THESE MATERIALS ARE NOT AN OFFICIAL ACT,  
4 WHICH IS A REQUIREMENT FOR JUDICIAL NOTICE. THEY ARE  
5 SIMPLY THE VIEWS OF A SINGLE STAFFER. NONE OF US COULD  
6 RELY ON THEM, WHETHER IT'S PROSECUTORS OR WHETHER IT'S  
7 DEFENDANTS.

8 NONE OF US WOULD BE ENTITLED TO RELY ON  
9 THESE MATERIALS BECAUSE THEY ARE NOT THE ACT OF THE  
10 AGENCY OR OF ANY OTHER PART OF GOVERNMENT.

11 THE COURT: THE COURT IS GOING TO SUSTAIN THE  
12 OBJECTION TO THE REQUEST FOR JUDICIAL NOTICE. IT DOES  
13 NOT APPEAR THAT THESE MATERIALS, THIS BRIEFING BINDER  
14 AND ACCOMPANYING MEMORANDUM, ARE OFFICIAL GOVERNMENT  
15 PUBLICATIONS; AND THEREFORE, THEY'RE NOT OFFICIAL ACTS,  
16 UNDER EVIDENCE CODE SECTION 452.

17 MR. METZGER: YOUR HONOR --

18 THE COURT: THE NEXT ITEM IS A REQUEST FOR  
19 JUDICIAL NOTICE OF U.S. EPA GUIDELINES.

20 MR. METZGER: YOUR HONOR, COULD I JUST REQUEST  
21 THAT THAT RULING BE WITHOUT PREJUDICE TO US BRINGING A  
22 REQUEST FOR JUDICIAL NOTICE JUST OF THE IRIS DOCUMENT,  
23 THE EPA DOCUMENT --

24 THE COURT: YES.

25 MR. METZGER: -- WHICH IS ATTACHED?

26 THE COURT: YES.

27 MR. METZGER: THANK YOU.

28 THE COURT: AND IT'S WITHOUT PREJUDICE.

1 AND THEN THE NEXT REQUEST IS FOR JUDICIAL  
2 NOTICE OF U.S. EPA GUIDELINES.

3 ANYONE WISH TO BE HEARD ON THAT?

4 MR. METZGER: YES, YOUR HONOR.

5 THIS IS -- THE COURT HAS ALREADY GRANTED  
6 JUDICIAL NOTICE OF OTHER EPA GUIDELINES FOR RISK  
7 ASSESSMENT. IN PARTICULAR, THIS ONE ON PAGE 5, STATES  
8 THAT, REGARDING TRANSPLACENTAL CARCINOGENESIS, THAT IT  
9 IS CONSIDERED APPROPRIATE TO USE THE GUIDELINES FOR  
10 CARCINOGEN RISK ASSESSMENT FOR ASSESSING THAT RISK.

11 AND THE COURT HAS ALREADY JUDICIALLY NOTICED  
12 THOSE GUIDELINES FOR CARCINOGEN RISK ASSESSMENT. WE'RE  
13 SEEKING JUDICIAL NOTICE OF THIS DOCUMENT, IN PARTICULAR,  
14 BECAUSE THIS EXPRESSES THE VIEW OF THE EPA, THE U.S.  
15 EPA, THAT FOR TRANSPLACENTAL CARCINOGENESIS RISK  
16 ASSESSMENT, ONE SHOULD USE THE GUIDELINES FOR CARCINOGEN  
17 RISK ASSESSMENT.

18 THE COURT: ALL RIGHT. THANK YOU.

19 DEFENDANTS?

20 MS. CORASH: YES.

21 YOUR HONOR, IT IS CERTAINLY THE CASE THAT  
22 THERE ARE INSTANCES IN WHICH IT IS APPROPRIATE TO LOOK,  
23 IN INTERPRETING PROP 65, TO HOW OTHER HEALTH REGULATORY  
24 AGENCIES OR TO HOW INTERNATIONAL AGENCIES DEAL WITH A  
25 SUBJECT WHICH IS DESCRIBED IN SUBJECTIVE TERMS.

26 HERE, PLAINTIFF SEEKS JUDICIAL NOTICE OF  
27 THESE EPA GUIDELINES AND ASSERTS, AS THE RELEVANCE OF  
28 THOSE GUIDELINES, THAT THEY'RE RELEVANT TO INTERPRETING

1 HOW TRANSPLACENTAL CARCINOGENICITY IS DEALT WITH UNDER  
2 PROPOSITION 65.

3 IN THIS INSTANCE, THAT ISSUE HAS BEEN  
4 DIRECTLY AND EXPLICITLY ADDRESSED BY OEHHA BY THE FINAL  
5 STATEMENT OF REASONS UNDERLYING THE REGULATIONS AND BY  
6 THE SCIENCE PANEL'S OWN GUIDELINES.

7 THERE IS NO AMBIGUITY HERE. IT IS PERFECTLY  
8 CLEAR HOW PROPOSITION 65 DEALS WITH TRANSPLACENTAL  
9 CARCINOGENICITY. AND IN THOSE CIRCUMSTANCES, THE FACT  
10 THAT EPA OR ANYONE ELSE HAS A DIFFERENT VIEW IS  
11 IRRELEVANT TO THE ISSUE BEFORE THIS COURT.

12 AND ONE THING THE PARTIES DO AGREE ON IS  
13 THAT JUDICIAL NOTICE IS APPROPRIATE AND CAN BE GIVEN  
14 ONLY AS TO RELEVANT MATERIALS. THESE MATERIALS ARE NOT  
15 RELEVANT TO THE ISSUE OF TRANSPLACENTAL CARCINOGENICITY.

16 THE COURT: THANK YOU.

17 THE COURT IS GOING TO GRANT JUDICIAL NOTICE  
18 OF THESE DOCUMENTS, WHICH ARE U.S. EPA'S GUIDELINES,  
19 UNDER EVIDENCE CODE SECTION 452, AS BEING OFFICIAL  
20 PUBLICATIONS AND THEREFORE ACTS OF GOVERNMENTAL  
21 AUTHORITY.

22 HOWEVER, IT'S WITHOUT PREJUDICE TO  
23 DEFENDANTS ARGUING THAT THEY'RE NOT RELEVANT AND NOT  
24 CONCLUSIVE ON THIS COURT AND NOT -- WITHOUT PREJUDICE TO  
25 ARGUING WHAT WEIGHT, IF ANY, SHOULD BE GIVEN TO THOSE  
26 DOCUMENTS.

27 MS. CORASH: THANK YOU, YOUR HONOR.

28 THE COURT: ALL RIGHT. MR. METZGER, ARE YOU GOING

1 TO CALL YOUR NEXT WITNESS?

2 MR. METZGER: YES. THE PLAINTIFFS WOULD CALL DR.  
3 PETER INFANTE, WHO IS ON THE STAND.

4 THE COURT: GOOD MORNING.

5 THE CLERK: SIR, WILL YOU PLEASE STAND AND RAISE  
6 YOUR RIGHT HAND.

7

8 PETER FRANCIS INFANTE,  
9 CALLED AS A WITNESS BY THE PLAINTIFF, WAS SWORN AND  
10 TESTIFIED AS FOLLOWS:

11 THE CLERK: THANK YOU. PLEASE BE SEATED.

12 WILL YOU STATE AND SPELL YOUR NAME FOR THE  
13 RECORD.

14 THE WITNESS: YES. PETER FRANCIS INFANTE: I-N-F,  
15 AS IN FRANK, -A-N-T-E.

16 THE COURT: GOOD MORNING, DR. INFANTE.

17 THE WITNESS: GOOD MORNING, YOUR HONOR.

18 THE COURT: COUNSEL, MR. METZGER, YOU MAY PROCEED.

19 MR. METZGER: THANK YOU, YOUR HONOR.

20

21 DIRECT EXAMINATION

22 BY MR. METZGER:

23 Q GOOD MORNING, DR. INFANTE.

24 A GOOD MORNING.

25 Q YOU'RE AN EPIDEMIOLOGIST?

26 A YES.

27 Q I'D LIKE TO SHOW YOU WHAT'S BEEN MARKED AS  
28 EXHIBIT 214. AND WOULD YOU CONFIRM THAT THIS IS YOUR

1 CURRICULUM VITAE.

2 A YES, IT IS. I'M JUST CHECKING TO SEE IF YOU  
3 HAVE THE MOST UPDATED VERSION.

4 Q THAT'S OKAY.

5 AND DOES THIS CURRICULUM VITAE LIST YOUR  
6 QUALIFICATIONS, YOUR EDUCATIONAL BACKGROUND, THE  
7 POSITIONS THAT YOU'VE HELD, AND YOUR PUBLICATIONS?

8 A YES.

9 MR. METZGER: ALL RIGHT. YOUR HONOR, I WOULD  
10 OFFER EXHIBIT 214 IN EVIDENCE.

11 THE COURT: ANY OBJECTION?

12 MR. SCHURZ: NO OBJECTION, YOUR HONOR.

13 THE COURT: EXHIBIT 214 IS ADMITTED INTO EVIDENCE.

14 (EXHIBIT 214 MARKED FOR IDENTIFICATION  
15 AND RECEIVED IN EVIDENCE.)

16 Q BY MR. METZGER: DR. INFANTE, I'M GOING TO  
17 SHOW YOU SOME DOCUMENTS SO THAT WE CAN HAVE THEM BE  
18 IDENTIFIED.

19 FIRST I'M GOING TO SHOW YOU WHAT'S BEEN  
20 MARKED AS EXHIBIT 215. AND WOULD YOU CONFIRM FOR THE  
21 COURT THAT THIS IS A LIST OF WRITTEN OPINIONS THAT YOU  
22 FORMED FOR THIS CASE THAT WAS PRODUCED AT YOUR  
23 DEPOSITION.

24 A (REVIEWS DOCUMENT.)

25 YES.

26 Q OKAY.

27 A YES, IT IS.

28 (EXHIBIT 215 MARKED FOR IDENTIFICATION.)

1 Q BY MR. METZGER: I'M GOING TO SHOW YOU  
2 WHAT'S BEEN MARKED AS EXHIBIT 222. AND WOULD YOU  
3 CONFIRM FOR THE COURT THAT THIS IS A -- THAT THESE ARE  
4 NOTES SETTING FORTH DATA REGARDING EPIDEMIOLOGIC STUDIES  
5 OF MATERNAL COFFEE CONSUMPTION AND CHILDHOOD LEUKEMIA  
6 THAT YOU PREPARED FOR THIS CASE.

7 A (REVIEWS DOCUMENT.)

8 Q ACTUALLY, LET ME REPHRASE THAT. THIS  
9 ACTUALLY CONTAINS SEVERAL MATERIALS.

10 DO THE FIRST -- ARE THESE NOTES REGARDING  
11 VARIOUS EPIDEMIOLOGIC STUDIES THAT YOU PREPARED FOR THIS  
12 CASE?

13 A YES. I PREPARED THIS -- THESE LISTS.

14 (EXHIBIT 222 MARKED FOR IDENTIFICATION.)

15 Q BY MR. METZGER: OKAY. RIGHT. AND IF WE  
16 JUST TAKE A LOOK AT -- THE FIRST TWO PAGES ARE  
17 CONCERNING MATERNAL CONSUMPTION OF COFFEE DURING  
18 PREGNANCY, AND CHILDHOOD LEUKEMIA; IS THAT CORRECT?

19 A YES.

20 Q I SEE AT THE BOTTOM OF THE SECOND PAGE YOU  
21 HAVE SOME NOTES REGARDING CENTRAL NERVOUS SYSTEM TUMORS  
22 FROM MATERNAL CONSUMPTION OF COFFEE; IS THAT CORRECT?

23 A YES.

24 Q ALL RIGHT. AND THEN THE THIRD PAGE IS --  
25 THIRD, FOURTH, AND FIFTH PAGE AND SIXTH PAGE CONCERN  
26 EPIDEMIOLOGIC STUDIES OF COFFEE CONSUMPTION AND BLADDER  
27 CANCER; IS THAT CORRECT?

28 A YES. THOSE ARE THE RESULTS OF THOSE

1 STUDIES.

2 Q RIGHT. THIS IS ALSO IMPORTANT DATA THAT YOU  
3 EXTRACTED FROM THE STUDIES?

4 A CORRECT.

5 Q AND THEN THE LAST PAGES ARE CONCERNING THE  
6 EPIDEMIOLOGIC STUDIES OF COFFEE CONSUMPTION AND  
7 PANCREATIC CANCER; IS THAT CORRECT?

8 A YES.

9 Q VERY GOOD.

10 I'LL SHOW YOU WHAT'S BEEN MARKED AS EXHIBIT  
11 223. WOULD YOU CONFIRM FOR THE COURT THAT THESE ARE  
12 LIKEWISE NOTES THAT YOU MADE OF DATA FROM THE  
13 EPIDEMIOLOGIC STUDIES REGARDING COFFEE CONSUMPTION AND  
14 LUNG CANCER.

15 A YES, THEY ARE.

16 (EXHIBIT 223 MARKED FOR IDENTIFICATION.)

17 Q BY MR. METZGER: ALL RIGHT. AND WOULD YOU  
18 CONFIRM FOR THE COURT THAT EXHIBIT 224 ARE NOTES THAT  
19 YOU PREPARED REGARDING META-ANALYSES OF COFFEE  
20 CONSUMPTION AND VARIOUS CANCERS?

21 A (REVIEWS DOCUMENT.)

22 YES, I PREPARED THIS LIST.

23 (EXHIBIT 224 MARKED FOR IDENTIFICATION.)

24 Q BY MR. METZGER: OKAY. WOULD YOU ALSO  
25 CONFIRM FOR THE COURT THAT EXHIBIT 225 IS A SINGLE PAGE  
26 OF YOUR NOTES REGARDING COFFEE CONSUMPTION STUDIES AND  
27 BLADDER CANCER, REGARDING THOSE STUDIES CONCERNING  
28 DOSE-RESPONSE RELATIONSHIPS?

1 A (REVIEWS DOCUMENT.)

2 YES, I PREPARED THIS LIST.

3 Q AND IS THAT WHAT IT IS?

4 A YES.

5 (EXHIBIT 225 MARKED FOR IDENTIFICATION.)

6 Q BY MR. METZGER: ALL RIGHT. AND WOULD YOU  
7 CONFIRM FOR COURT THAT EXHIBIT 226 IS A LIST OF STUDIES  
8 THAT YOU PREPARED CONCERNING COFFEE CONSUMPTION AND  
9 PANCREATIC CANCER, STUDIES SHOWING A POSITIVE DOSE  
10 RESPONSE?

11 A YES, THAT'S WHAT IT IS. AND I PREPARED THE  
12 LIST.

13 (EXHIBIT 226 MARKED FOR IDENTIFICATION.)

14 Q BY MR. METZGER: OKAY. WOULD YOU CONFIRM  
15 FOR THE COURT ALSO THAT EXHIBIT 227 ARE NOTES THAT YOU  
16 PREPARED REGARDING THE DATA FROM THE EPIDEMIOLOGIC  
17 STUDIES OF COFFEE CONSUMPTION AND PANCREATIC CANCER.

18 A (REVIEWS DOCUMENT.)

19 YES, AND SEPARATED BY THE VARIOUS TYPES OF  
20 ANALYSES THAT WERE DONE.

21 MR. METZGER: YES. ALL RIGHT.

22 (EXHIBIT 227 MARKED FOR IDENTIFICATION.)

23 Q BY MR. METZGER: AND WOULD YOU ALSO TAKE A  
24 LOOK AT EXHIBIT 228 AND CONFIRM THAT THESE ARE NOTES  
25 THAT YOU PREPARED REGARDING YOUR REVIEW OF EPIDEMIOLOGIC  
26 STUDIES CONCERNING ACRYLAMIDE AND CANCER.

27 A (REVIEWS DOCUMENT.)

28 Q REGARDING POTATO CONSUMPTION AND CANCER, I

1 SHOULD SAY.

2 A YES, REGARDING POTATO CONSUMPTION AND  
3 CANCER. THIS IS MY LIST.

4 (EXHIBIT 228 MARKED FOR IDENTIFICATION.)

5 Q BY MR. METZGER: ALL RIGHT. AND LASTLY,  
6 WOULD YOU CONFIRM FOR THE COURT THAT EXHIBIT 229 ARE  
7 YOUR NOTES REGARDING STUDIES -- EPIDEMIOLOGIC STUDIES OF  
8 DIETARY EXPOSURE TO ACRYLAMIDE AND CANCER.

9 A YES, THIS IS MY LIST RELATED TO THE DIETARY  
10 EPIDEMIOLOGY, MINUS THE POTATO STUDIES. THE PREVIOUS  
11 ONE INCLUDED THE POTATO STUDIES.

12 (EXHIBIT 229 MARKED FOR IDENTIFICATION.)

13 Q BY MR. METZGER: AND DID YOU PRODUCE ALL OF  
14 THESE NOTES, EXHIBITS 222 THROUGH 229, AT YOUR  
15 DEPOSITION IN THIS CASE?

16 A YES, I DID.

17 Q AND WERE THEY MARKED AS EXHIBITS TO YOUR  
18 DEPOSITION?

19 A YES.

20 Q ALL RIGHT. HAVE YOU PREPARED A POWERPOINT  
21 PRESENTATION TO ELUCIDATE YOUR TESTIMONY FOR THIS CASE?

22 A YES.

23 Q DOES THAT POWERPOINT PRESENTATION TAKE THE  
24 DATA THAT YOU HAVE IN THESE NOTES AND PUT IT IN THAT  
25 POWERPOINT SO THAT WE CAN ALL SEE THE DATA AS WE'RE  
26 GOING THROUGH YOUR TESTIMONY?

27 A YES.

28 Q ALL RIGHT.

1                   AND WHAT IS THE EXHIBIT FOR THE POWERPOINT?  
2 EXHIBIT -- HERE WE GO.

3                   WOULD YOU CONFIRM THAT EXHIBIT 253 IS THE  
4 POWERPOINT PRESENTATION THAT YOU PREPARED.

5           A        YES, IT IS.

6                   (EXHIBIT 253 MARKED FOR IDENTIFICATION.)

7           Q        BY MR. METZGER: ALL RIGHT. WE'LL TALK  
8 FIRST ABOUT SOME OF YOUR QUALIFICATIONS AND EXPERIENCE.

9                   DR. INFANTE, WOULD YOU TELL US --

10          A        EXCUSE ME. HOW DO I GET THIS ON?

11          Q        I DON'T KNOW. IT SHOULD TURN ON.

12                   (DISCUSSION HELD OFF THE RECORD.)

13          Q        BY MR. METZGER: CAN YOU LOOK AT THE SCREEN  
14 OVER THERE?

15          A        YES.

16                  MR. METZGER: PERHAPS WE COULD MOVE THE SCREEN  
17 BACK A LITTLE BIT.

18                   (DISCUSSION HELD OFF THE RECORD.)

19          Q        BY MR. METZGER: IS THAT A LITTLE BIT MORE  
20 VISIBLE?

21          A        YES, I CAN SEE.

22          Q        OKAY. ALL RIGHT. WOULD YOU TELL THE COURT  
23 BRIEFLY ABOUT YOUR EDUCATIONAL BACKGROUND, DR. INFANTE.

24          A        YES. I DON'T KNOW HOW FAR BACK YOU WANT ME  
25 TO START, BUT --

26          Q        WELL, JUST YOUR PROFESSIONAL -- YOUR COLLEGE  
27 AND BEYOND THAT.

28          A        YES. WELL, I GUESS I COULD GO BACKWARDS.

1 I HAVE A DOCTORATE IN PUBLIC HEALTH FROM THE  
2 DEPARTMENT OF EPIDEMIOLOGY, THE UNIVERSITY OF MICHIGAN.  
3 THEN ALSO, OF COURSE, A MASTER'S OF PUBLIC HEALTH I  
4 RECEIVED BEFORE THE DOCTORAL DEGREE.

5 THEN FROM OHIO STATE UNIVERSITY,  
6 GRADUATED --

7 THE COURT: ANY IRRECONCILABLE CONFLICT ON  
8 MICHIGAN AND OHIO STATE?

9 THE WITNESS: WELL, ONE TIME A YEAR, I HAVE TO  
10 DECIDE WHO TO ROOT FOR.

11 THE COURT: OKAY. COUNSEL.

12 Q BY MR. METZGER: SO DR. INFANTE, YOUR  
13 GRADUATE WORK WAS IN PUBLIC HEALTH AND EPIDEMIOLOGY?

14 A YES, THAT'S CORRECT.

15 Q ALL RIGHT. AND BEFORE THAT, DID YOU HAVE  
16 SOME OTHER EDUCATION IN THE MEDICAL FIELD?

17 A YES, I DID.

18 Q TELL US ABOUT THAT.

19 A WELL, I GRADUATED FROM OHIO STATE  
20 UNIVERSITY, COLLEGE OF DENTISTRY, IN '66. AND THEN I  
21 DID A TWO-YEAR INTERNSHIP AT THE CHILDRENS HOSPITAL OF  
22 THE UNIVERSITY, FOR TWO YEARS, WHERE I TOOK CARE OF  
23 CHILDREN FOR TWO YEARS.

24 AND I ALSO DID GENERAL ANESTHESIA AND WHAT  
25 WAS CALLED AT THE TIME A HANDICAP CLINIC, WHERE HALF OF  
26 A DAY EVERY DAY OF THE WEEK I TOOK CARE OF CHILDREN WHO  
27 HAD VARIOUS TYPES OF HANDICAPPING CONDITIONS LIKE  
28 LEUKEMIA, MENTAL RETARDATION, DOWN'S SYNDROME --

1 Q OKAY.

2 A -- EPILEPSY. HYDROCEPHALUS, AT THE TIME,  
3 BECAUSE THERE WASN'T A WAY TO TREAT CHILDREN THAT HAD  
4 BLOCKAGE OF FLUID IN THEIR BRAIN AT THAT TIME.

5 SO CHILDREN THAT HAD JUST ABOUT ANY TYPE OF  
6 HANDICAPPING CONDITION, I TOOK CARE OF THEM IN THE  
7 DENTAL CLINIC FIVE HALF-DAYS A WEEK.

8 Q AND EARLY IN YOUR CAREER, DID YOU PROVIDE  
9 PUBLIC SERVICE TO CHILDREN FOR DENTAL ISSUES? DID YOU  
10 DO SOME RESEARCH IN THAT AREA?

11 A YES. I DID RESEARCH IN CHILD GROWTH AND  
12 DEVELOPMENT. I WAS PART OF THE NATIONAL PRESCHOOL  
13 NUTRITIONAL SURVEY FROM 1968 TO 1970, WHERE I WENT ALL  
14 OVER THE UNITED STATES EXAMINING PRESCHOOL CHILDREN.

15 AND I WAS LOOKING AT THEIR DENTAL  
16 DEVELOPMENT AND DENTAL ISSUES IN RELATION TO THEIR  
17 HEIGHT, WEIGHT, HEAD CIRCUMFERENCE, AND DIETARY INTAKE.  
18 I WAS PART OF A TEAM THAT DID THAT.

19 Q OKAY. NOW, YOU SPENT MOST OF YOUR CAREER  
20 PROVIDING GOVERNMENT -- FEDERAL GOVERNMENT SERVICE; IS  
21 THAT CORRECT?

22 A STATE AND FEDERAL GOVERNMENT, YES.

23 Q OKAY.

24 A MOSTLY FEDERAL GOVERNMENT.

25 Q ALL RIGHT. WOULD YOU TELL US WHAT YOUR  
26 FIRST POSITION WAS WITH THE FEDERAL GOVERNMENT AND WHAT  
27 YOU DID.

28 A YES. BEGINNING IN 1975 TO 1978, I WORKED

1 FOR THE NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND  
2 HEALTH.

3 AND I WAS AN EPIDEMIOLOGIST IN THE BIOMETRY  
4 SECTION, WHICH IS A SECTION THAT DOES STUDIES OF WORKERS  
5 EXPOSED TO VARIOUS SUBSTANCES AND CHEMICALS IN THE  
6 WORKPLACE, TO DETERMINE WHETHER THEIR RISK IS OF VARIOUS  
7 TYPES OF DISEASES; MOSTLY CANCER, HEART DISEASE.

8 AND THEN ALSO LOOKING AT REPRODUCTIVE  
9 HAZARDS, AS WELL, IS ANOTHER AREA I SPECIALIZED IN  
10 BECAUSE OF MY TRAINING IN CHILD GROWTH AND DEVELOPMENT  
11 AND MY INTEREST IN THAT FIELD.

12 Q OKAY. AND WHAT WAS YOUR NEXT POSITION IN  
13 THE FEDERAL GOVERNMENT?

14 A WELL, AFTER WORKING AT MY NIOSH FOR THREE  
15 YEARS -- AND ONE OF THOSE YEARS, I WAS ACTING CHIEF OF  
16 THE BIOMETRY SECTION, RESPONSIBLE FOR ALL OF THE  
17 EPIDEMIOLOGICAL STUDIES THAT NIOSH WAS CARRYING OUT  
18 THROUGHOUT THE COUNTRY -- THE INDUSTRYWIDE STUDIES  
19 BRANCH WAS.

20 AND THEN SUBSEQUENT TO THAT, THEN I WAS  
21 OFFERED A JOB AT OSHA, THE OCCUPATIONAL SAFETY AND  
22 HEALTH ADMINISTRATION. SO I WENT TO OSHA. AND MY FIRST  
23 JOB THERE WAS, I WAS DIRECTOR OF THE OFFICE OF  
24 CARCINOGEN IDENTIFICATION AND CLASSIFICATION.

25 Q AND WHAT DID THAT INVOLVE?

26 A WELL, THAT, JUST AS THE DESCRIPTION OF THE  
27 OFFICE IMPLIES, IS THE OFFICE THAT WOULD IDENTIFY AND  
28 CLASSIFY SUBSTANCES FOUND IN THE OCCUPATIONAL SETTING AS

1 TO THEIR DEGREE OF CARCINOGENICITY; AND THEN MAKE  
2 RECOMMENDATIONS TO THE SECRETARY OF LABOR, WHICH WAS  
3 RECOMMENDED THAT SHOULD -- IN TERMS OF WHAT SHOULD BE  
4 THE PRIORITY FOR REGULATING THEM.

5 Q AND DID YOU HAVE SUBSEQUENT POSITIONS WITH  
6 OSHA?

7 A YES. THEN SUBSEQUENT TO THAT -- I THINK,  
8 FOR THE NEXT 19 YEARS -- I WAS DIRECTOR OF THE OFFICE OF  
9 STANDARDS REVIEW, IN THE HEALTH STANDARDS PROGRAM.

10 AND AS PART OF THAT -- WELL, THE JOB OF THAT  
11 OFFICE WAS TO EVALUATE DATA FOR SUBSTANCES AND TO  
12 DETERMINE RISK AND THEN TO SET STANDARDS FOR EXPOSURE TO  
13 THOSE SUBSTANCES IN THE WORKPLACE BASED ON  
14 EPIDEMIOLOGICAL DATA, INDUSTRIAL HYGIENE DATA, RISK  
15 ASSESSMENTS.

16 AND SO I WAS INVOLVED IN ALL OF THOSE  
17 ISSUES, EVALUATING STUDIES AS TO THE RISK OF CANCER,  
18 MOSTLY. AND I WOULD QUANTIFY THAT RISK AND MAKE  
19 RECOMMENDATIONS TO THE SECRETARY.

20 AND THEN I WOULD FOLLOW THROUGH ON THAT AND  
21 WORK ON THE DEVELOPMENT OF STANDARDS IN TERMS OF  
22 ANALYSES, THAT WOULD BE PRESENTED IN THE PREAMBLE TO THE  
23 STANDARD, THAT WOULD JUSTIFY THE ACTION THAT WAS BEING  
24 TAKEN BY THE SECRETARY OF LABOR.

25 Q OKAY. DID YOU RETIRE FROM GOVERNMENT  
26 SERVICE IN 2002?

27 A YES, I DID.

28 Q AND THEN DID YOU BECOME A PROFESSOR?

1 A YES.

2 Q AT WHAT INSTITUTION?

3 A AT GEORGETOWN -- OR AT GEORGE WASHINGTON  
4 UNIVERSITY, IN WASHINGTON, D.C. I WAS ADJUNCT PROFESSOR  
5 THERE. AND ALSO, I WAS INVOLVED IN CONSULTING IN  
6 OCCUPATIONAL AND ENVIRONMENTAL HEALTH.

7 Q YOU WERE A PROFESSOR OF ENVIRONMENTAL AND  
8 OCCUPATIONAL HEALTH?

9 A YES.

10 Q OKAY. BRIEFLY, WOULD YOU TELL THE COURT  
11 ABOUT SOME OF THE AWARDS THAT YOU'VE RECEIVED OVER YOUR  
12 CAREER -- VERY BRIEFLY.

13 A WELL, I RECEIVED A SPECIAL COMMENDATION FROM  
14 THE PUBLIC HEALTH SERVICE CENTER FOR DISEASE CONTROL FOR  
15 MY CONTRIBUTIONS TOWARD THE UNDERSTANDING OF THE  
16 TOXICITY OF BENZENE AND BERYLLIUM TO HUMANS.

17 I RECEIVED A -- WELL, I RECEIVED A  
18 SPECIAL -- I WAS AWARDED TRAINEESHIP TO STUDY PUBLIC  
19 HEALTH AT THE UNIVERSITY OF MICHIGAN.

20 AND THEN I RECEIVED OTHER -- LIKE THE  
21 SECRETARY'S EXCEPTIONAL ACHIEVEMENT AWARD, IN '93, AND  
22 SPECIAL ACHIEVEMENT AWARD.

23 Q ALL RIGHT. AND HAVE YOU PROVIDED  
24 CONSULTATION TO SUCH ORGANIZATIONS AS THE AMERICAN  
25 PUBLIC HEALTH ASSOCIATION, THE NATIONAL RESEARCH  
26 COUNCIL, NATIONAL ACADEMY OF SCIENCES, THE INTERNATIONAL  
27 AGENCY FOR RESEARCH ON CANCER, AND VARIOUS OTHER FEDERAL  
28 AGENCIES -- AND THE WORLD HEALTH ORGANIZATION?

1 A YES, I HAVE.

2 Q AND DO YOU HAVE MORE THAN A HUNDRED  
3 PEER-REVIEWED PUBLICATIONS TO YOUR NAME?

4 A YES.

5 Q ALL RIGHT. AND HAVE YOU PUBLISHED REGARDING  
6 THE AGENCIES THAT EVALUATE CARCINOGENIC RISKS TO HUMANS?

7 A YOU MEAN "AGENTS"?

8 Q HAVE YOU PUBLISHED ARTICLES THAT ARE ABOUT  
9 THAT?

10 A YES.

11 Q OKAY. AND HAVE YOU PUBLISHED ARTICLES  
12 REGARDING CARCINOGENICITY TESTING?

13 A YES.

14 Q AND REGARDING CARCINOGENICITY?

15 A YES.

16 Q AND MUTAGENICITY?

17 A YES.

18 Q EXPOSURE ASSESSMENT?

19 A YES.

20 Q RISK ASSESSMENT?

21 A YEAH. AND DOSE-RESPONSE ANALYSES IS PART OF  
22 THAT.

23 Q AND ETHICS AND BIAS IN PUBLICATION?

24 A DO I HAVE ONE IN THERE ON THAT?

25 Q WELL, GO AHEAD TO THE LAST ONE. SLIDE 14.

26 APPARENTLY, YOU DON'T RECALL YOUR

27 PUBLICATIONS.

28 SO I SEE IN 1993 AN ARTICLE --

1           A       OH, YES.  YES.

2           Q       "MEDICAL AND ETHICAL ISSUES RELATED TO  
3 CHRONIC BERYLLIUM DISEASE," "OSHA'S VIEW OF GENETIC  
4 SCREENING," AND TWO OTHER ARTICLES REGARDING ETHICS AND  
5 BIAS?

6           A       YES.

7           Q       OKAY.  SO NOW LET'S TALK ABOUT YOUR SUBJECT  
8 OF EXPERTISE, EPIDEMIOLOGY.  WILL YOU TELL US, FIRST:  
9 WHAT IS EPIDEMIOLOGY?

10          A       YES.  WELL, I PUT A SLIDE IN HERE ON THE  
11 DERIVATION OF THE NAME:  "EPI," MEANING "AMONG"; AND  
12 "DEMOS," "PEOPLE"; AND "OLOGY" IS "THE STUDY."  SO  
13 EPIDEMIOLOGY IS THE STUDY OF PEOPLE.

14                   AND THE WAY IT'S PRACTICED TODAY, IT'S THE  
15 STUDY OF DISEASES OR THE DETERMINANTS OF DISEASES, LIKE  
16 IN THE HUMAN POPULATIONS.

17          Q       OKAY.  ARE THERE -- DO EPIDEMIOLOGISTS NEED  
18 TO KNOW SOMETHING ABOUT VARIOUS ASPECTS OF MEDICAL  
19 SCIENCE?

20          A       YES.  IT CERTAINLY HELPS IN INTERPRETING  
21 YOUR DATA.

22          Q       AND WHAT TYPES OF MEDICAL SCIENCE DATA DO  
23 EPIDEMIOLOGISTS NEED TO KNOW SOMETHING ABOUT?

24          A       WELL, YOU HAVE TO KNOW SOMETHING ABOUT  
25 MEDICINE.  AND I LEARNED THAT FROM -- DURING MY  
26 INTERNSHIP AND RESIDENCY AT CHILDRENS HOSPITAL.  I WAS  
27 ALSO IN GRADUATE SCHOOL FOR A SUMMER AT -- MEDICAL  
28 SCHOOL, AT OHIO STATE UNIVERSITY.

1                   AND IT HELPS TO KNOW ABOUT -- WELL,  
2                   CERTAINLY, YOU HAVE TO KNOW ABOUT STATISTICS. AND YOU  
3                   HAVE TO KNOW -- WELL, MORE SPECIFICALLY NOW, TODAY, IT'S  
4                   HOW TO DO DOSE-RESPONSE ANALYSIS. SO IT'S IMPORTANT TO  
5                   KNOW HOW TO EVALUATE EXPOSURE DATA.

6                   BECAUSE WHEN YOU'RE DOING DOSE-RESPONSE  
7                   ANALYSIS, THE DOSE IS THE EXPOSURE, AND THE RESPONSE IS  
8                   THE RELATIVE RISK. SO YOU HAVE TO KNOW SOMETHING ABOUT  
9                   STATISTICS, CERTAINLY.

10                  Q           OKAY. LET'S TALK ABOUT EPIDEMIOLOGIC  
11                  STUDIES. ARE THERE A FEW TYPES OF -- BASIC TYPES OF  
12                  EPIDEMIOLOGIC STUDIES THAT YOU CAN INFORM THE COURT OF?

13                  A           YES.

14                  Q           SO TELL US ABOUT THOSE.

15                  A           WELL, THERE ARE CASE-CONTROL STUDIES, COHORT  
16                  STUDIES, AND INTERVENTION STUDIES, ARE THE MAIN THREE  
17                  THAT ARE MOSTLY LINKED TO TRYING TO DETERMINE CAUSALITY.

18                  Q           OKAY.

19                  A           I MEAN, THERE ARE OTHER MORE DESCRIPTIVE  
20                  STUDIES, BUT THEY'RE USUALLY -- THE PURPOSE IS TO THEN  
21                  FOLLOW THOSE UP WITH MORE DETAILED STUDIES, LIKE A  
22                  CASE-CONTROL STUDY.

23                  Q           ALL RIGHT. AND CAN YOU EXPLAIN TO THE COURT  
24                  WHAT A CASE-CONTROL STUDY IS.

25                  A           YES. A CASE -- I THINK I HAVE SOME -- WELL,  
26                  YEAH. A CASE-CONTROL STUDY IS THE TYPE OF STUDY WHERE  
27                  YOU'RE IDENTIFYING INDIVIDUALS WHO HAVE THE DISEASE.  
28                  THEY'RE THE CASES. THEN YOU'RE LOOKING AT THE EXPOSURE

1 THAT YOU'RE INTERESTED IN AMONG THE CASES.

2 Q OKAY.

3 A AND THEN FOR THE CASES, YOU PICK CONTROLS  
4 THAT DO NOT HAVE THE DISEASE, THAT ARE MATCHED AS  
5 CLOSELY AS YOU CAN TO THE CASES IN TERMS OF SEX, RACE,  
6 SOCIOECONOMIC STATUS; TRYING MATCH THEM TO THE CASE AS  
7 CLOSELY AS YOU CAN.

8 AND THEN YOU LOOK TO SEE THERE WHAT THEIR  
9 EXPOSURE IS, OF THE EXPOSURES OF INTEREST. AND THEN YOU  
10 LOOK AT THE RATIO OF THOSE EXPOSURES IN THE CASES VERSUS  
11 THOSE IN THE CONTROLS. AND THAT ENDS UP BEING AN ODDS  
12 RATIO.

13 SO IT'S THE ODDS OF EXPOSURE TO THE CASES  
14 VERSUS THE ODDS OF EXPOSURE TO THE SUBSTANCES OR  
15 SUBSTANCE YOU'RE INTERESTED IN IN THE CONTROLS.

16 Q ALL RIGHT.

17 A AND THEN THAT ODDS RATIO IS A SURROGATE FOR  
18 WHAT'S CALLED THE RELATIVE RISK OF THE DISEASE.

19 Q OKAY. AND WILL YOU TELL THE COURT BRIEFLY  
20 WHAT A COHORT STUDY IS.

21 A YES. WELL, I HAVE SOME SLIDES HERE THAT --

22 Q WE'LL GET TO IT, THEN.

23 A OKAY. A COHORT STUDY IS WHERE YOU IDENTIFY  
24 A GROUP OF PEOPLE -- I THINK THE WORD COMES FROM LIKE  
25 THE ROMAN DAYS, OF ROMAN COHORTS AND LEGIONS.

26 AND THEN YOU IDENTIFY THEM AT A CERTAIN  
27 PERIOD OF TIME. AND THEN YOU CAN DO IT RETROSPECTIVELY  
28 OR PROSPECTIVELY.

1                   MEANING AS IF LIKE, SAY, TODAY I WANTED TO  
2 DO A STUDY, A COHORT STUDY OF CANCER, I WOULD HAVE TO GO  
3 BACK IN TIME FAR ENOUGH TO ALLOW THAT CANCER TO BECOME  
4 MANIFEST, SO THERE'S AN ADEQUATE LATENCY PERIOD, AND  
5 THEN IDENTIFY INDIVIDUALS EXPOSED TO THAT SUBSTANCE.

6                   LIKE, FOR EXAMPLE, WHICH I'VE DONE MY WHOLE  
7 LIFE IN OCCUPATIONAL EPIDEMIOLOGY AND OCCUPATIONAL  
8 COHORT STUDY. LET'S SAY IF YOU WERE INTERESTED IN  
9 WORKERS EXPOSED TO BENZENE AND WHAT THEIR RISK WAS FROM,  
10 SAY, LEUKEMIA OR OTHER CANCERS, YOU WOULD TRY TO  
11 IDENTIFY A GROUP OF WORKERS EXPOSED TO BENZENE, GOING  
12 BACK AS FAR AS YOU CAN -- SAY, IN THE '40S OR '50S, IF  
13 YOU COULD FIND THEM BACK THAT FAR; AND THE '60S.

14                   YOU IDENTIFY THEM FROM EMPLOYMENT RECORDS  
15 FROM THE COMPANY, OR YOU USED TO BE ABLE TO USE SOCIAL  
16 SECURITY RECORDS. THEN YOU IDENTIFY THAT GROUP, AND  
17 THEN YOU FOLLOW THAT GROUP FORWARD.

18                   AND YOU SAY, "OKAY. NOW I'M GOING TO LOOK  
19 AND SEE WHAT KIND OF -- WHAT DISEASES -- WHAT CANCERS  
20 ARE THEY DYING FROM?"

21                   AND LET'S SAY YOU'RE FOLLOWING A COHORT, AND  
22 YOU HAVE TEN CASES OF LEUKEMIA. YOU MIGHT SAY, ALL  
23 RIGHT; BUT NOW, IF YOU COMPARE THEM TO, LET'S SAY, AN  
24 UNEXPOSED POPULATION -- WHICH QUITE OFTEN IS THE GENERAL  
25 POPULATION.

26                   OR BETTER YET, WOULD BE OTHER WORKERS NOT  
27 EXPOSED TO THE SUBSTANCE YOU'RE INTERESTED IN. AND IT'S  
28 BETTER IF YOU CAN FIND THEM, BECAUSE THEY'RE MORE

1 MATCHED SOCIOECONOMICALLY TO THE EXPOSURE GROUP YOU'RE  
2 INTERESTED IN.

3 SO YOU LOOK AT THE RATE OF DEATH IN THE  
4 EXPOSED GROUP, AND YOU COMPARE THAT TO THE RATE OF DEATH  
5 IN THE UNEXPOSED GROUP.

6 AND IF IT'S A MORTALITY STUDY, THAT'S CALLED  
7 A STANDARDIZED MORALITY RATIO, OR SMR; OR YOU COULD CALL  
8 IT A RELATIVE RISK, IF YOU WANT. IT'S ALL  
9 INTERCHANGEABLE.

10 SO AN ODDS RATIO FROM A CASE-CONTROL STUDY  
11 AND AN SMR, OR RELATIVE RISK, FROM A COHORT STUDY --  
12 THOSE ESSENTIALLY ARE THE SAME MEASURE OF RISK.

13 Q OKAY.

14 A SO YOU CAN EQUATE -- SAY, AN ODDS RATIO OF 2  
15 WOULD BE A RELATIVE RISK OF 2 OR AN SMR OF 2.

16 Q ALL RIGHT. NOW, OVER YOUR CAREER, WHAT TYPE  
17 OF EPIDEMIOLOGIC STUDY HAVE YOU DONE MORE OF THAN  
18 OTHERS?

19 A COHORT STUDIES.

20 Q OKAY. NOW, ALTHOUGH MOST OF THE  
21 EPIDEMIOLOGIC STUDIES THAT YOU HAVE DONE OVER YOUR  
22 CAREER ARE COHORT STUDIES, DO YOU STILL CONSIDER  
23 CASE-CONTROL STUDIES IN ASSESSING RISK AND CAUSALITY?

24 A YES. NOT ONLY DO I DO IT, BUT ANYONE. IT  
25 DEPENDS ON WHAT THE QUESTION IS YOU'RE ASKING. OF  
26 COURSE, YOU WOULD USE COHORT STUDIES. AND YOU WOULD USE  
27 CASE-CONTROL STUDIES.

28 AND I SUPPOSE IF YOU WERE AT FOOD AND DRUG

1 ADMINISTRATION, YOU WOULD -- THEY'RE THE STANDARD -- THE  
2 BEST STANDARD -- THE GOLD STANDARD WOULD BE INTERVENTION  
3 STUDIES.

4 Q OKAY. WHAT IS AN INTERVENTION STUDY?

5 A AN INTERVENTION STUDY IS A STUDY WHERE YOU  
6 ARE GOING TO, SAY, DISPENSE THE AGENT YOU'RE CONCERNED  
7 ABOUT -- THE VITAMIN OR WHATEVER IT IS THAT YOU'RE  
8 CONCERNED ABOUT -- TO A GROUP YOU'VE IDENTIFIED. AND  
9 THEN YOU'RE GOING TO IDENTIFY ANOTHER GROUP THAT YOU'RE  
10 NOT GOING TO GIVE THAT AGENT TO.

11 AND THEN YOU'RE GOING TO FOLLOW THEM OVER  
12 TIME AND SEE WHAT PARTICULAR DISEASE ARE YOU INTERESTED  
13 IN STUDYING, TO SEE IF THERE'S A PROTECTIVE EFFECT FROM  
14 THAT CHEMICAL.

15 LIKE, FOR EXAMPLE, I MEAN, I THINK ONE OF  
16 THE FAMOUS EXAMPLES IS LIKE BETA CAROTENE AND LUNG  
17 CANCER. THERE WERE THOSE COHORT AND CASE-CONTROL  
18 STUDIES WHICH SHOWED BENEFITS FROM DIETARY CAROTENE  
19 SUPPLEMENTS OR PEOPLE WITH HIGH BETA CAROTENE DIETS, AND  
20 THE RISK OF LUNG CANCER WAS SUPPOSEDLY REDUCED.

21 SO PEOPLE WERE PROMOTING BETA CAROTENE AND  
22 VITAMIN A FOR PEOPLE TO TAKE, TO REDUCE RISK OF LUNG  
23 CANCER, BECAUSE THAT'S WHAT THE COHORT AND CASE-CONTROL  
24 STUDIES SHOWED.

25 THEN WHEN THEY DID AN INTERVENTION STUDY, IN  
26 FACT, THEY FOUND JUST THE OPPOSITE: THAT IN THE GROUP  
27 THEY WERE STUDYING, THOSE THAT WERE ADMINISTERED THE  
28 BETA CAROTENE VERSUS THOSE THAT WERE NOT, THEY FOUND, IN

1 FACT, IT WAS PRODUCING MORE LUNG CANCER.

2 Q OKAY.

3 A THE BETA CAROTENE, WHICH WAS SUPPOSED TO BE  
4 PROTECTIVE IN THE OTHER STUDIES, IN THE INTERVENTION  
5 STUDIES, IT SHOWED HARMFUL EFFECTS. SO I DIDN'T WORK AT  
6 FDA, BUT I'M SAYING, IF I WAS AT THE FDA, THAT WOULD BE  
7 THE GOLD STANDARD.

8 Q ALL RIGHT. NOW, ARE EPIDEMIOLOGIC STUDIES  
9 SOMETIMES CLASSIFIED AS BEING EITHER RETROSPECTIVE OR  
10 PROSPECTIVE?

11 A YES, THEY CAN BE EITHER.

12 Q OKAY.

13 A I MEAN, MOST ARE RETROSPECTIVE; BUT THERE  
14 ARE SOME ALSO THAT ARE ONGOING, THAT ARE PROSPECTIVE.

15 Q SLIDE 25.

16 AND WOULD YOU EXPLAIN TO THE COURT WHAT THIS  
17 SLIDE 25 IS SHOWING.

18 A CASE CONTROL -- YES. IF YOU LOOK OVER ON  
19 THE RIGHT-HAND COLUMN, YOU SEE WHERE IT SAYS "STUDY  
20 POPULATION." SO THIS IS A CASE-CONTROL STUDY, LIKE I  
21 SPOKE OF BEFORE.

22 AND ON THE TOP, YOU SEE CASES OF DISEASE.  
23 YOU SEE CONTROLS, NO DISEASE. SO WHEN YOU IDENTIFY THE  
24 CASES AND THE CONTROLS, THEN YOU EVALUATE THOSE  
25 INDIVIDUALS TO SEE WHAT THE DIFFERENCES IN THEIR  
26 EXPOSURE IS, TO THE EXPOSURE OF INTEREST THAT YOU WANT  
27 TO STUDY, OR THE EXPOSURES OF INTEREST.

28 Q AND THAT'S THE FACTOR PRESENT OR ABSENT HERE

1 ON THIS?

2 A YES; RIGHT.

3 Q ALL RIGHT.

4 A AND SO THE RATIO OF THAT, THEN, WOULD BE --  
5 THE RATIO OF THE EXPOSURE IN THE CASES TO THE EXPOSURE  
6 IN THE CONTROLS WOULD BE CALLED AN ODDS RATIO. IT'S THE  
7 ODDS OF EXPOSURE FOR A CASE VERSUS THE CONTROL.

8 Q AND ON --

9 A WHICH IS THE SAME -- IT GENERATES THE SAME  
10 STATISTIC, ESSENTIALLY, AS A SURROGATE FOR THE RELATIVE  
11 RISK OF THE DISEASE.

12 Q ARE CASE-CONTROL STUDIES RETROSPECTIVE  
13 STUDIES?

14 A WELL, YES, THEY WOULD HAVE TO BE BY NATURE,  
15 BECAUSE YOU'RE IDENTIFYING INDIVIDUALS THAT ALREADY HAVE  
16 THE DISEASE OR THE CANCER OR WHATEVER YOU'RE STUDYING.

17 Q ARE THERE CERTAIN ADVANTAGES OF CASE-CONTROL  
18 STUDIES?

19 A YES.

20 Q WHAT ARE SOME OF THEM?

21 A WELL, SOME OF THE ADVANTAGES OF THE  
22 CASE-CONTROL STUDIES ARE THAT THEY DON'T TAKE AS LONG TO  
23 DO AS A COHORT STUDY, SO THEY'RE CHEAPER TO DO.

24 THEY CAN HAVE A LOT MORE STATISTICAL POWER,  
25 IF THERE ARE SPECIFIC CANCERS THAT YOU'RE INTERESTED IN,  
26 OR YOU DON'T HAVE TO WAIT FOR A LATENCY PERIOD LIKE YOU  
27 WOULD IN A -- CERTAINLY, IN A PROSPECTIVE COHORT STUDY.  
28 SO YOU CAN IDENTIFY THE CASES MUCH MORE QUICKLY FROM A

1 CANCER REGISTRY OR FROM OTHER SOURCES.

2 SO THEY'RE LESS EXPENSIVE, AND THEY HAVE  
3 MORE STATISTICAL POWER IN TERMS LOOKING AT PARTICULAR  
4 CANCERS BECAUSE YOU CAN IDENTIFY A LARGE NUMBER OF THE  
5 CANCERS.

6 IN PARTICULAR, WHEN YOU'RE TALKING ABOUT  
7 CANCER, A LOT OF CANCERS ARE RARE DISEASES. SO IF YOU  
8 WERE TO FOLLOW A COHORT, YOU MIGHT HAVE TO HAVE A VERY  
9 LARGE COHORT WHICH YOU'D HAVE TO ENROLL AND THEN FOLLOW  
10 OVER TIME. AND YOU'RE NOT GOING TO FIND NEARLY AS MANY  
11 RARE CANCERS IN A COHORT STUDY.

12 Q OKAY. AND ARE THERE CERTAIN LIMITATIONS OF  
13 CASE-CONTROL STUDIES?

14 A YES, THERE ARE LIMITATIONS. I THINK I -- I  
15 HAVE A SLIDE. HERE IT IS, YES.

16 SO IF YOU LOOK AT THE BOTTOM BULLET THERE.  
17 SO THEY'RE DIFFICULT FOR STUDYING UNCOMMON EXPOSURES  
18 BECAUSE YOUR CASES MIGHT NOT HAVE ANY OF THE EXPOSURE  
19 THAT YOU WANT TO EVALUATE. SO IT'S DIFFICULT TO DO FOR  
20 UNCOMMON EXPOSURES.

21 AND THERE'S -- YOU WOULD HAVE TO BE  
22 CONCERNED, ALSO, ABOUT THE MISCLASSIFICATION OF THE  
23 EXPOSURE BECAUSE THESE ARE RETROSPECTIVE EXPOSURE  
24 DETERMINATIONS. SO YOU MAY BE ASKING SOMEBODY ABOUT  
25 WHAT THEY WERE EXPOSED TO 5, 10, 15, 20 YEARS AGO. AND  
26 SOME MAY RECALL, AND SOME RECALL BETTER THAN OTHERS.

27 SO YOU HAVE SOME DIFFICULTIES IN EXPOSURE  
28 MISCLASSIFICATION, AND YOU CAN ALSO HAVE RECALL BIAS.

1 Q OKAY. LET'S TALK ABOUT COHORT STUDIES.  
2 GO TO SLIDE 30, PLEASE.

3 AND WOULD YOU TELL THE COURT ABOUT SOME OF  
4 THE ADVANTAGES OF COHORT STUDIES.

5 A WELL, I HAVE DIFFERENT NUMBERED SLIDES THAN  
6 YOU DO.

7 THE ADVANTAGES OF COHORT STUDIES IS, YOU CAN  
8 LOOK AT MULTIPLE DISEASES AT ONE TIME, WHEREAS IN A  
9 CASE-CONTROL STUDY, YOU'RE LOOKING AT A SINGLE DISEASE,  
10 LOOKING AT THE ODDS OF THE EXPOSURE. IN A COHORT STUDY,  
11 YOU CAN STUDY SEVERAL DISEASES AT ONE TIME.

12 Q WHAT ARE SOME OF THE LIMITATIONS OF COHORT  
13 STUDIES?

14 A WELL, IN COHORT STUDIES SOMETIMES, BECAUSE  
15 OF -- MANY OF THESE ARE MORTALITY STUDIES, AND THE CAUSE  
16 OF DEATH MAY NOT BE CORRECTLY LISTED ON THE DEATH  
17 CERTIFICATE; WHEREAS IN A CASE-CONTROL STUDY, USUALLY  
18 YOU'RE GETTING THAT KNOWLEDGE FROM THE CANCER REGISTRY.  
19 SO THE PERSON HAS BEEN TREATED FOR THEIR CANCER, SO  
20 YOU'RE GOING TO HAVE PRETTY GOOD INFORMATION ON THE TYPE  
21 OF CANCER THAT THEY HAVE.

22 SO IT'S A DISADVANTAGE.

23 THE OTHER THING ABOUT COHORT STUDIES, AS I  
24 MENTIONED BEFORE, YOU HAVE TO FOLLOW THEM FOR A LONG  
25 ENOUGH PERIOD OF TIME TO ALLOW THE CANCER TO BECOME  
26 MANIFEST. AND SOME CANCERS MAY TAKE 30, 40 YEARS --  
27 SAY, 20 TO 40 YEARS TO MANIFEST THEMSELVES CLINICALLY.

28 SO IF YOU DON'T FOLLOW THE COHORT LONG

1 ENOUGH, YOU'RE NOT GOING TO BE ABLE TO OBSERVE WHETHER  
2 OR NOT THAT COHORT IS, IN FACT, DEVELOPING THOSE  
3 CANCERS. SO THAT'S ONE OF THEM.

4 AND THEY HAVE LOW STATISTICAL POWER IN TERMS  
5 OF THE INDIVIDUAL CANCERS BECAUSE YOU MAY NOT HAVE  
6 ENOUGH CANCERS TO GIVE YOU ENOUGH STATISTICAL POWER TO  
7 IDENTIFY, SAY, A CANCER RISK IF, IN FACT, IT'S PRESENT.

8 Q SO ALTHOUGH A COHORT STUDY MAY HAVE SEVERAL  
9 HUNDRED THOUSAND PEOPLE AS PARTICIPANTS, ONLY A SMALL  
10 NUMBER OF THOSE WILL GET CANCERS, AND THEN YOU'RE  
11 EVALUATING THAT SMALL NUMBER. IS THAT HOW THAT WORKS?

12 MR. SCHURZ: OBJECTION; LEADING.

13 THE COURT: OVERRULED.

14 THE WITNESS: AS YOU'RE FOLLOWING THEM, YES. YES.  
15 AND THE RARER THE CANCER, THE FEWER YOU WILL HAVE.

16 Q BY MR. METZGER: OKAY. ARE COHORT STUDIES  
17 PRACTICABLE OR FEASIBLE TO DO FOR RARE CANCERS?

18 A IT'S VERY DIFFICULT FOR RARE CANCERS BECAUSE  
19 YOU JUST SIMPLY WOULDN'T HAVE ENOUGH -- YOU WOULDN'T  
20 HAVE ENOUGH STATISTICAL POWER. YOU WOULDN'T IDENTIFY  
21 ENOUGH OF THEM.

22 Q CAN YOU GIVE US AN EXAMPLE.

23 A YEAH, SURE. LIKE IF YOU WERE, SAY, STUDYING  
24 ANGIOSARCOMA OF THE LIVER IN A COHORT STUDY. I THINK  
25 THERE ARE ONLY ABOUT 50 CASES A YEAR IN THE UNITED  
26 STATES. AND SO IF YOUR -- 50 CASES IN THE ENTIRE UNITED  
27 STATES, WHICH IS OVER, WHAT, 200 MILLION PEOPLE.

28 SO IF YOU'RE DOING A COHORT STUDY OF 3,000

1 PEOPLE, LET'S SAY -- 5,000 PEOPLE, 10,000 PEOPLE -- AND  
2 YOU'RE FOLLOWING IT FOR 30 YEARS, YOU WOULD PROBABLY  
3 EXPECT LESS THAN ONE TO DEVELOP.

4 Q OKAY.

5 A AND EVEN IF YOU FOUND ONE, I MEAN, WHAT ARE  
6 YOU GOING TO SAY BASED ON ONE CANCER? YOU'RE GOING TO  
7 SAY, "THIS IS WHAT THE RISK IS FOR ANGIOSARCOMA"? SO IN  
8 THAT SITUATION, YOU WOULD NEED TO IDENTIFY CASES OF  
9 ANGIOSARCOMA.

10 Q WHAT ARE --

11 A THE EXCEPTION BEING -- LET ME JUST EXPLAIN  
12 IT. BECAUSE, IN FACT, VINYL CHLORIDE EXPOSED WORKERS  
13 BEING STUDIED DID DEMONSTRATE AN ELEVATED RISK OF LIVER  
14 CANCER, FOR WHICH ANGIOSARCOMA WAS THE MAIN LIVER CANCER  
15 EARLY ON, BUT THAT'S BECAUSE THE EXPOSURES WERE SO HIGH  
16 AMONG THOSE WORKERS.

17 THAT'S HOW -- IT WAS SUCH A RARE CANCER. IT  
18 WAS LATER CONFIRMED IN AN EPIDEMIOLOGICAL STUDY. BUT IT  
19 WAS FIRST IDENTIFIED BY A PATHOLOGIST, WHO SAID, "HEY,  
20 I'VE SEEN THREE OF THESE RARE LIVER CANCERS IN MY  
21 PRACTICE HERE COMING FROM THIS ONE PLANT, AND THERE ARE  
22 ONLY LIKE MAYBE 50 IN THE ENTIRE UNITED STATES A YEAR.  
23 MAYBE SOMETHING -- THIS IS RARE. SOMETHING MUST BE  
24 GOING ON."

25 SO IT WAS SO RARE AND IT WAS SO OUTSTANDING  
26 AT THE COMPANY THAT IT WAS IDENTIFIED BY, REALLY, A  
27 PATHOLOGIST. AND THEN IT WAS CONFIRMED BY ANIMAL  
28 STUDIES THAT SHOWED THAT ADMINISTERING VINYL CHLORIDE TO

1 ANIMALS, THEY DEVELOPED ANGIOSARCOMA.

2 Q OKAY.

3 A BASED ON THAT, IN FACT, OSHA SET AN  
4 EMERGENCY STANDARD.

5 Q ALL RIGHT. WHAT ABOUT FOR A CANCER LIKE  
6 CHILDHOOD LEUKEMIA, THAT'S NOT QUITE AS RARE AS  
7 ANGIOSARCOMA OF THE LIVER. ARE COHORT STUDIES FEASIBLE  
8 TO EVALUATE THAT?

9 A I THINK YOU WOULD HAVE TO DO CASE-CONTROL  
10 STUDIES BECAUSE IT'S SO RARE. LIKE CHILDHOOD LEUKEMIAS  
11 UNDER THE AGE OF 19 IS ABOUT 4 PER 100,000 DEATHS A  
12 YEAR; 4, 4.5 PER 100,000 DEATHS. SO YOU WOULD HAVE TO  
13 FOLLOW -- IF YOU WANTED TO FOLLOW -- BECAUSE YOU WANT TO  
14 FOLLOW CHILDHOOD LEUKEMIA AND MOTHERS. IS THAT WHAT  
15 YOU'RE SPEAKING ABOUT?

16 Q YES, FROM A -- YEAH.

17 A YOU WOULD NEED AN IMPOSSIBLY LARGE COHORT TO  
18 DO A COHORT STUDY OF THAT. IN FACT, I DID A  
19 CALCULATION.

20 Q LET'S TAKE A LOOK AT THAT. CAN YOU EXPLAIN  
21 THE CALCULATION.

22 A EXCUSE ME. AN EXAMPLE.

23 HERE WE GO. THAT SLIDE IS A LITTLE CROOKED.  
24 I CAN'T READ THE READING ON IT.

25 Q LET ME SEE IF I CAN MOVE THIS JUST A LITTLE  
26 TO TRY TO GET IT --

27 (DISCUSSION HELD OFF THE RECORD.)

28 Q BY MR. METZGER: MAYBE THAT'S GOOD. LET'S

1 LEAVE IT THERE. I THINK YOU CAN SEE IT.

2 A SO I WAS SAYING, WELL, THIS IS A CASE THAT  
3 IF YOU WANTED TO ENROLL MOTHERS IN A COHORT STUDY AND  
4 SAY, "OKAY. NOW I WANT TO STUDY CHILDHOOD LEUKEMIA IN  
5 THEIR OFFSPRING," HOW MANY WOULD YOU NEED?

6 SO IF YOU LOOK AT -- THERE'S A DECIMAL POINT  
7 OFF IN THAT FIRST LINE THERE, IN THE U.S. BIRTH RATE.  
8 IT'S REALLY 14.1 PER 100,000.

9 THE BIRTH RATE IN THE UNITED STATES -- THIS  
10 IS FOR ALL WOMEN -- IS 14.1 PER 100,000 WOMEN PER YEAR.  
11 AND THE INCIDENCE OF LEUKEMIA IS 4.5 PER 100,000. SO IT  
12 WOULD TAKE 1,000 WOMEN TO GIVE YOU 14.1 CHILDREN.

13 AND IF THE LEUKEMIA INCIDENCE IS 4.5 PER  
14 100,000, IT WOULD TAKE ESSENTIALLY A MILLION -- OVER  
15 1,500,000 WOMEN TO PRODUCE ONE LEUKEMIA CASE.

16 Q SO IF YOU WANTED TO DO A STUDY OF MATERNAL  
17 CONSUMPTION OF COFFEE AND CHILDHOOD LEUKEMIA, AND YOU  
18 WANTED TO HAVE, SAY, 500 CASES, HOW MANY -- WHAT SIZE  
19 COHORT WOULD YOU NEED? OR JUST A HUNDRED CASES. LET'S  
20 MAKE IT EASY.

21 A WELL, YOU WOULD NEED TO DO A CASE-CONTROL  
22 STUDY. YOU WOULD NEVER BE ABLE TO GENERATE A HUNDRED  
23 CASES BY LOOKING AT A COHORT OF WOMEN WHO, SAY, DRANK  
24 COFFEE VERSUS A COHORT WHO DIDN'T.

25 Q ALL RIGHT. NOW, LET'S MOVE ON TO SLIDE 34.  
26 AND I THINK HERE YOU HAVE A -- YOU DEPICT AN  
27 INTERVENTION STUDY. CAN YOU BRIEFLY EXPLAIN THAT TO THE  
28 COURT.

1           A           WELL, AN INTERVENTION STUDY -- AND THESE ARE  
2 THE ONES LIKE FDA REQUIRES IF YOU'RE, SAY, LOOKING AT  
3 VITAMINS OR DRUGS OR NUTRITIONAL SUPPLEMENTS. IF YOU  
4 WANT TO PUT A CLAIM THAT THERE'S A BENEFIT TO THIS -- TO  
5 TAKING OF THIS WHATEVER IT IS, YOU WOULD HAVE TO DO AN  
6 INTERVENTION STUDY.

7                       AND BY DOING THAT, WHAT YOU WOULD DO IS, YOU  
8 WOULD IDENTIFY -- WITH A CLINICAL TRIAL, YOU WOULD  
9 IDENTIFY INDIVIDUALS THAT YOU WOULD GIVE THAT AGENT TO.  
10 AND YOU WOULD LOOK AT THE OUTCOME OF THEM, LOOK AT THE  
11 RATE OF WHATEVER YOU'RE EVALUATING IN THEM. AND THEN  
12 YOU WOULD HAVE A CONTROL GROUP THAT YOU WOULD NOT GIVE  
13 THAT DRUG TO.

14                      AND THEN YOU WOULD FOLLOW THEM OVER TIME AND  
15 SAY, "OKAY. WHAT IS THE DIFFERENCE IN" -- IF YOU'RE  
16 INTERESTED IN HEART DISEASE, "WHAT'S THE DIFFERENCE IN  
17 THE RATE OF HEART DISEASE? IS THERE A BENEFIT, OR IS  
18 THERE A HARM TO TAKING -- IN THIS CASE, LIKE THE BETA  
19 CAROTENE?"

20           Q           OKAY. HAVE ANY INTERVENTION STUDIES BEEN  
21 DONE TO ASSESS COFFEE AND CANCER?

22           A           NOT TO MY KNOWLEDGE, NO.

23           Q           OKAY. ALL RIGHT.

24                      LET'S MOVE ON TO MEASURES OF ASSOCIATION.

25           A           I JUST WANTED TO MAKE ONE POINT.

26           Q           GO AHEAD.

27           A           I HAVE IT ON MAYBE SLIDE 35, WHILE WE'RE ON  
28 THE INTERVENTION STUDIES.

1 JUST THAT THE ADVANTAGES, THAT YOU'RE  
2 AVOIDING MISCLASSIFICATION OF EXPOSURE BECAUSE YOU'RE  
3 GIVING THE EXPOSURE TO THE GROUP, TO THE EXPOSED GROUP.

4 Q RIGHT.

5 A AND YOU'RE NOT GIVING IT TO THE CONTROL  
6 GROUP. SO, IN FACT, YOU KNOW THAT THE CONTROL GROUP  
7 ISN'T GETTING IT.

8 AND SO THEN YOU DON'T HAVE TO DEAL WITH  
9 RECALL BIAS BECAUSE YOU'RE ADMINISTERING WHATEVER IT IS  
10 TO THE TWO GROUPS.

11 AND YOU'RE AVOIDING ANY SELECTION BIAS  
12 BECAUSE YOU'RE SELECTING THEM AHEAD OF TIME, BEFORE YOU  
13 ADMINISTER THE AGENT TO THE GROUP THAT GETS IT VERSUS  
14 THE CONTROLS THAT DON'T GET IT.

15 SO IT -- BUT IT'S VERY EXPENSIVE AND TIME  
16 CONSUMING.

17 Q OKAY. THANK YOU.

18 LET'S GO ON TO MEASURES OF ASSOCIATION,  
19 SLIDE 40. COULD YOU TELL THE COURT WHAT MEASURES OF  
20 ASSOCIATION ARE.

21 A YES. THESE ARE MEASURES OF ASSOCIATION.  
22 THEY'RE MEASURING LIKE RISK OR RELATIVE RISK IN GROUPS  
23 THAT YOU'RE STUDYING.

24 SO IN A CASE-CONTROL STUDY, YOU WOULD  
25 MEASURE THE ODDS RATIO, WOULD BE THE ESTIMATE OF  
26 RELATIVE RISK. IN, SAY, AN OCCUPATIONAL STUDY, WHERE  
27 YOU'RE LOOKING AT THE DISEASE INCIDENCE IN THE  
28 OCCUPATIONALLY EXPOSED TO THAT AGENT VERSUS, LET'S SAY,

1 OTHER WORKERS WHO WEREN'T EXPOSED TO IT, THERE YOU WOULD  
2 GENERATE A RELATIVE RISK.

3 IF YOU WERE DOING A MORTALITY STUDY, YOU  
4 WOULD CALL THE SAME ESTIMATE A STANDARDIZED -- I'M  
5 SORRY. IT WOULD BE A STANDARDIZED MORTALITY RATIO,  
6 WHICH IS THE SECOND BULLET FROM THE BOTTOM.

7 IF YOU'RE LOOKING AT THE INCIDENCE OF  
8 DISEASE, IT WOULD BE A STANDARDIZED INCIDENCE RATIO.  
9 AND THEN WE HAVE SOME THINGS THAT ARE CALLED  
10 PROPORTIONATE MORTALITY RATIOS, WHERE ONLY LOOKING AT  
11 DEATHS IN THE TWO GROUPS.

12 THEY'RE ALL MEASURES OF ASSOCIATION, AND  
13 THEY CAN ALL BE USED INTERCHANGEABLY AS ESTIMATES OF  
14 RELATIVE RISK.

15 Q OKAY. LET'S TALK ABOUT HOW ONE CALCULATES  
16 AN ODDS RATIO. CAN YOU GO TO SLIDE 42 AND EXPLAIN THIS  
17 TO THE COURT.

18 A NOW, THIS IS A SIMPLE TWO BY TWO. IN OTHER  
19 WORDS, YOU'RE LOOKING AT THE ODDS OF EXPOSED OVER THE  
20 ODDS OF THE -- I'M SORRY, THE ODDS OF EXPOSURE TO THOSE  
21 WITH THE DISEASE VERSUS THE ODDS OF EXPOSURE TO THOSE  
22 WITHOUT THE DISEASE.

23 SO, FOR EXAMPLE, IF YOU LOOK UNDER  
24 "EXPOSURE," THE FIRST BLUE BOX SAYS "PRESENT," AND THE  
25 OUTCOME IS "PRESENT." SO THAT'S A.

26 SO -- AND THEN, OF COURSE, THE OPPOSITE  
27 EXTREME IS, IF THERE'S THE ABSENCE OF EXPOSURE, THERE'S  
28 ABSENCE OF THE DISEASE. THAT'S IN BOX D. WHAT YOU DO

1 IS, YOU MULTIPLY A TIMES D, AND YOU DIVIDE THAT BY B  
2 TIMES C, AND THAT BECOMES THE ODDS RATIO.

3 Q OKAY. AND HOW DOES ONE INTERPRET THE NUMBER  
4 THAT ONE GETS IN DOING THAT CALCULATION?

5 A WELL, YOU LOOK AND SEE, WELL, IS THERE AN  
6 INCREASE IN THE ODDS OF EXPOSURE AMONG THOSE WITH THE  
7 DISEASE, OR IS THERE A DECREASE IN EXPOSURE THAT YOU'RE  
8 INTERESTED IN AMONG THOSE WITH THE DISEASE? IT CAN GO  
9 EITHER WAY.

10 OR THERE COULD BE -- THE ODDS RATIO COULD BE  
11 1, WHICH MEANS THERE'S NO ASSOCIATION AT ALL, EITHER  
12 WAY.

13 Q SO IF THE ODDS RATIO IS ABOVE 1, THE RISK IS  
14 INCREASED. AND IF IT'S BELOW 1, IT'S DECREASED. IS  
15 THAT THE ESSENCE OF IT?

16 A RIGHT.

17 Q OKAY. ALL RIGHT. I DON'T WANT TO GO  
18 THROUGH ALL OF THESE. BUT LET'S GO TO SLIDE 48, IF WE  
19 COULD, WHICH YOU'VE INDICATED HERE HOW RISK IS  
20 EXPRESSED. AND COULD YOU EXPLAIN THAT TO THE COURT.

21 A YES. WELL, IN THE ODDS RATIO -- YOU MIGHT  
22 SAY LIKE, FOR EXAMPLE, THE ODDS RATIO IS 2, WHICH MEANS  
23 THE CASES HAVE TWICE AS MUCH EXPOSURE AS THE NON-CASES.  
24 AND THEN YOU CALCULATE A CONFIDENCE INTERVAL AROUND THAT  
25 ESTIMATE, SO FOR -- A 95 PERCENT CONFIDENCE INTERVAL.

26 WHICH MEANS THAT WHEN YOU GENERATE THE ODDS  
27 RATIO -- LET'S SAY IN THIS CASE IT'S 2. THEN YOU WANT  
28 TO SAY, OKAY, IT'S 2. BUT THEN -- AND ALSO, YOU'RE --

1 FROM THE DATA ANALYSIS, THAT YOU'RE 95 PERCENT SURE THAT  
2 THE RANGE WOULD BE SOMEWHERE BETWEEN 1.5 AND 2.5.

3 WHICH MEANS THAT 95 TIMES OUT OF 100, THAT  
4 THAT ODDS RATIO WOULD BE SOMEWHERE BETWEEN 1.5 AND 2.5,  
5 SINCE IT'S THE 95 PERCENT CONFIDENCE INTERVAL.

6 Q OKAY. AND WHERE YOU HAVE UP THERE, FOR  
7 EXAMPLE, "ODDS RATIO EQUALS 2.0, 95 PERCENT CONFIDENCE  
8 INTERVAL, 1.5 TO 2.5," WOULD YOU EXPLAIN TO THE COURT  
9 WHAT THAT MEANS.

10 A WELL, WHAT THAT INDICATES IS THAT THE RESULT  
11 IS STATISTICALLY SIGNIFICANT, IF THE LOWER BOUND OF THE  
12 CONFIDENCE INTERVAL IS ABOVE 1.0.

13 Q OKAY.

14 A AND THEN THE RESULT WOULD BE STATISTICALLY  
15 SIGNIFICANT IF YOU'RE USING A 95 PERCENT CONFIDENCE  
16 INTERVAL, WITH THE 95 PERCENT LEVEL OF CONFIDENCE.

17 I MEAN, SOMETIMES YOU'LL SEE RESULTS THAT  
18 ARE 1.0, AND YOU'RE NOT QUITE SURE, IS THAT  
19 STATISTICALLY SIGNIFICANT? IS IT ROUNDING OFF? BECAUSE  
20 1.0 -- 1.04 WOULD BE ROUNDED OFF TO 1.0.

21 Q OKAY.

22 A SOMETIMES AUTHORS WILL GIVE YOU MORE  
23 DECIMALS IN THE ODDS RATIO SO YOU CAN SEE WHETHER OR NOT  
24 IT'S SIGNIFICANT IF THE LOWER BOUND IS CLOSE TO 1.

25 Q ALL RIGHT. SO IN LOOKING AT EPIDEMIOLOGIC  
26 STUDIES AND THESE ODDS RATIOS, OR RELATIVE RISKS, ONE  
27 WANTS TO LOOK AT WHETHER THE RATIO -- WHETHER THE RISK  
28 IS INCREASED OR DECREASED AND WHETHER IT IS

1 SIGNIFICANTLY INCREASED OR DECREASED; IS THAT CORRECT?

2 A CORRECT. AND THEN THE ODDS -- THE  
3 CONFIDENCE INTERVAL CAN TELL YOU THAT.

4 Q OKAY. WOULD YOU GO TO SLIDE 52.

5 AND WOULD THE TELL THE COURT ABOUT SOME  
6 OTHER THINGS OR FACTORS THAT EPIDEMIOLOGISTS LOOK FOR IN  
7 EVALUATING EPIDEMIOLOGIC STUDIES.

8 A YES. I HAVE THIS LIST HERE.

9 YOU LOOK, FIRST OF ALL, ON THE -- YEAH,  
10 QUALITY OF THE EXPOSURE ASSESSMENT. SO IN OTHER WORDS,  
11 ARE THOSE THAT YOU'RE STUDYING THAT ARE SUPPOSED TO BE  
12 EXPOSED, ARE THEY ACTUALLY EXPOSED.

13 THEN IF YOU'RE MEASURING THE EXPOSURE, DID  
14 YOU ACTUALLY -- DOES THE STUDY REALLY INDICATE THAT  
15 YOU'RE GETTING THE EXPOSURE CORRECT OR NOT; OR ARE YOU  
16 BASING THE EXPOSURE ON, SAY, FOR CERTAIN PERIODS WHEN  
17 YOU DON'T HAVE ANY EXPOSURE DATA, WHICH QUITE OFTEN  
18 HAPPENS, AND YOU'RE ESTIMATING IT FROM TIME PERIODS  
19 LATER ON WHERE YOU DO HAVE EXPOSURE?

20 SO YOU'RE DOING RETROSPECTIVE EXPOSURE  
21 ESTIMATION. SO YOU MAY NOT HAVE DATA FOR SOME OF YOUR  
22 COHORT MEMBERS THAT, SAY, BEGAN IN THE '50S AND '60S, OR  
23 EVEN '70S, SO YOU HAVE TO ESTIMATE THAT. SO YOU HAVE TO  
24 LOOK AT WHAT THE ESTIMATION PROCEDURES ARE, TO SEE IF  
25 THAT'S BEEN PROPERLY DONE.

26 OR SOMETIMES THE INVESTIGATORS DO THEM AS  
27 BEST AS THEY CAN DO, BUT -- IT MAY BE GOOD; OR IN OTHER  
28 CASES, IT JUST MAY NOT BE GOOD ENOUGH, BUT THEY DID THE

1 BEST THEY COULD DO.

2 SO YOU HAVE TO EVALUATE THE QUALITY OF THE  
3 EXPOSURE ASSESSMENT, PARTICULARLY IN STUDIES WHERE  
4 YOU'RE TRYING TO DETERMINE A DOSE-RESPONSE RELATIONSHIP.

5 IF YOU'RE DOING A STUDY WHERE YOU'RE JUST  
6 SAYING, "EXPOSED; WHAT'S THE RISK?" VERSUS A COMPARISON  
7 GROUP, THEN IT'S NOT AS IMPORTANT TO KNOW WHAT THE --  
8 THE EXPOSURE ASSESSMENT DOESN'T HAVE TO BE QUITE AS  
9 GOOD, IF YOU KNOW THEY WERE EXPOSED.

10 YOU MAY NOT KNOW HOW MUCH THEY WERE EXPOSED  
11 TO, BUT YOU KNOW THEY WERE EXPOSED OVER SOME THRESHOLD  
12 OF AT LEAST A DAY OR A WEEK OR A YEAR, BUT YOU DON'T  
13 KNOW HOW MUCH.

14 THAT'S A QUALITATIVE EXPOSURE ESTIMATE, AND  
15 YOU'RE LOOKING AT THE RISK OF DISEASE.

16 IN THE STUDY I PUBLISHED IN 1977 ON BENZENE  
17 AND LEUKEMIA, THE INITIAL STUDY, I KNEW THEY WERE -- THE  
18 WORKERS WERE EXPOSED, BUT I DIDN'T KNOW EXACTLY HOW MUCH  
19 BENZENE EXPOSURE THEY HAD.

20 BUT I KNEW THEY WORKED IN THIS PROCESS WHERE  
21 THEY WERE ALL EXPOSED TO BENZENE. AND I FOLLOWED THEM  
22 AND FOUND THAT THEY HAD A FIVE- TO TEN-FOLD RISK OF  
23 LEUKEMIA.

24 AND FOR THE TIME THAT IT WAS DONE, IN 1977,  
25 THAT WAS ADEQUATE. THEN SUBSEQUENT TO THAT, IF YOU WANT  
26 TO DETERMINE, WELL, HOW MUCH BENZENE EXPOSURE CAUSES HOW  
27 MUCH RISK OF LEUKEMIA, NOW IT BECOMES IMPORTANT TO KNOW  
28 HOW MUCH BENZENE EXPOSURE THEY HAD AND HOW THAT WAS

1 DETERMINED.

2 Q OKAY.

3 A SO IT DEPENDS ON WHAT THE ANALYSIS IS THAT  
4 YOU'RE DOING. BUT YOU HAVE TO LOOK AT THE QUALITY OF  
5 THE EXPOSURE ASSESSMENT.

6 Q WHAT ELSE DO YOU HAVE TO LOOK FOR, AS AN  
7 EPIDEMIOLOGIST?

8 A PARDON ME?

9 Q WHAT ELSE DO YOU HAVE TO LOOK FOR, AS AN  
10 EPIDEMIOLOGIST?

11 A WELL, YOU WANT TO LOOK AT THE -- AS WE  
12 MENTIONED EARLIER, IS THE LATENCY PERIOD ADEQUATE? IN  
13 OTHER WORDS, HAS THE GROUP BEEN FOLLOWED LONG ENOUGH TO  
14 ALLOW CANCERS -- PARTICULARLY THOSE WITH LONG LATENCY  
15 PERIODS -- TO BECOME CLINICALLY MANIFEST.

16 THEN THE OTHER THING YOU LOOK AT IS THE  
17 STRENGTH OF THE ASSOCIATION.

18 Q WHAT DOES THAT MEAN?

19 A THAT'S WHAT I WAS TALKING ABOUT BEFORE:  
20 WHAT IS THE RELATIVE RISK OF THE GROUP? IS IT  
21 SIGNIFICANTLY ELEVATED, OR ISN'T IT? IS IT CLOSE?

22 AND THEN THE NEXT ONE IS CONSISTENCY OF THE  
23 RESULTS. ARE THERE OTHER STUDIES THAT SHOW SIMILAR  
24 OBSERVATIONS, OR IS THIS THE ONLY STUDY?

25 Q OKAY.

26 A THEN DOSE-RESPONSE RELATIONSHIPS, THAT'S  
27 IMPORTANT. BECAUSE IF YOU CAN IDENTIFY DOSE RESPONSE IN  
28 AN EPIDEMIOLOGICAL STUDY, IT'S A PRETTY POWERFUL TOOL IN

1 TERMS OF CAUSALITY.

2 BECAUSE MOST OF YOUR ERRORS IN EXPOSURE  
3 ASSESSMENT ARE GOING TO BIAS YOU TOWARDS NOT FINDING A  
4 DOSE RESPONSE. SO YOU'VE GOT TO -- SO IF YOU'RE  
5 DOING -- SO IF YOU CAN, IF THE DATA ARE ADEQUATE TO DO A  
6 DOSE-RESPONSE ANALYSIS, THAT HELPS IN THE INTERPRETATION  
7 OF DATA.

8 Q OKAY.

9 A ON THE OTHER HAND, YOU COULD STILL DO A  
10 DOSE-RESPONSE ANALYSIS AND DON'T HAVE VERY GOOD DATA.

11 AND YOU MIGHT BE STUDYING A POPULATION THAT,  
12 IN FACT, YOU KNOW SUBSTANCE A CAUSES DISEASE B, AND YOU  
13 FIND IT OVERALL, BUT YOU DON'T FIND IT IN YOUR  
14 DOSE-RESPONSE ANALYSIS. AND YOU WONDER, WELL, WHY IS  
15 THAT?

16 WELL, ONE THING, IT COULD BE A REFLECTION OF  
17 A POOR DOSE ESTIMATION, BECAUSE YOUR ERRORS IN YOUR  
18 EXPOSURE ESTIMATION WILL FLATTEN THE DOSE RESPONSE.

19 Q OKAY. AND WHAT ELSE, AS AN EPIDEMIOLOGIST,  
20 DO YOU LOOK FOR IN EVALUATING EPIDEMIOLOGIC STUDIES?

21 A WELL, YOU WOULD SEE IF THE STUDY ACCOUNTED  
22 FOR KNOWN CONFOUNDERS RELATED TO THE DISEASE.

23 Q OKAY.

24 A BUT THEN, ON THE OTHER HAND, THAT'S WHY DOSE  
25 RESPONSE IS IMPORTANT, BECAUSE A LOT OF STUDIES, THEY'RE  
26 ABLE TO MAYBE ADJUST -- STATISTICALLY ADJUST FOR  
27 CONFOUNDERS, AND THEY HAVE VARYING DEGREES OF QUALITY OF  
28 THE DATA RELATED TO CONFOUNDERS.

1 SO THAT'S WHY, WHEN YOU HAVE A DOSE-RESPONSE  
2 ANALYSIS, IT OVERCOMES A LOT OF THAT.

3 Q WHAT ELSE DO YOU CONSIDER?

4 A WELL, IS THERE ADEQUATE STATISTICAL POWER?  
5 LIKE FOR THE -- SAY, IF YOU'RE DOING A STUDY FOR THE  
6 RISK YOU MIGHT EXPECT FROM THIS EXPOSURE, DO YOU HAVE  
7 ENOUGH PEOPLE ENROLLED IN YOUR STUDY TO BE ABLE TO  
8 IDENTIFY A 30 PERCENT INCREASE, A 50 PERCENT INCREASE, A  
9 100 PERCENT INCREASE? THAT HAS TO DO WITH STATISTICAL  
10 POWER.

11 AND WHEN YOU LOOK AT STATISTICAL POWER, IT  
12 HAS TO DO WITH BETA ERROR. YOU HAVE ALPHA ERROR, AND  
13 ALPHA ERROR HAS TO DO WITH LIKE STRENGTH OF THE  
14 ASSOCIATION: IS THE RESULT STATISTICALLY SIGNIFICANT?

15 BUT WHEN YOU DO A STUDY AND YOU DON'T FIND  
16 ANY INCREASE IN RISK, THEN THE QUESTION YOU WANT TO ASK:  
17 WELL, WHAT'S THE BETA ERROR? WHAT WAS THE STRENGTH OF  
18 THE STUDY? WHAT WAS THE STATISTICAL POWER THAT WAS  
19 PROVIDED BY THE STUDY TO BE ABLE TO EVALUATE VARIOUS  
20 ESTIMATES OF RELATIVE RISK IN THE STUDY?

21 Q OKAY. ANYTHING ELSE THAT YOU CONSIDER, AS  
22 AN EPIDEMIOLOGIST, IN EVALUATING EPIDEMIOLOGIC STUDIES?

23 A WELL, THE FINAL THING IS -- AND I THINK  
24 THIS -- ACTUALLY, THE LAST BULLET REALLY HAS TO DO WITH  
25 INTERPRETATION IN EVALUATING THE STUDIES.

26 SO THE BIOLOGICAL PLAUSIBILITY REALLY HAS  
27 MORE TO DO WITH YOUR INTERPRETATION OF THE  
28 EPIDEMIOLOGICAL STUDY RESULTS. DOES IT MAKE SENSE FROM

1 THE OTHER TOXICITY OR MANIFESTATIONS OF TOXICITY THAT WE  
2 KNOW ABOUT THE SUBSTANCE?

3 SO YOU NEED TO KNOW SOMETHING A LITTLE BIT  
4 MORE THAN JUST DOING STATISTICAL ASSOCIATIONS. I  
5 SUPPOSE ANYBODY CAN DO THAT. YOU HAVE TO TRY TO MAKE  
6 SENSE OUT OF IT IN TERMS OF WHAT ELSE IS KNOWN ABOUT THE  
7 SUBSTANCE THAT YOU'RE STUDYING.

8 Q OKAY.

9 A SO THE TOXICITY RELATED TO, LET'S SAY, THE  
10 CANCER OR OTHER DISEASE THAT YOU MIGHT BE STUDYING.

11 Q LET'S TALK A LITTLE ABOUT DOSE-RESPONSE  
12 RELATIONSHIPS. FIRST OF ALL, HAVE YOU PUBLISHED  
13 ARTICLES REGARDING THAT TOPIC?

14 A YES, I HAVE.

15 Q OKAY. AND ARE THERE DIFFERENT MODES OF  
16 EXPOSURE THAT CAN BE ASSESSED IN EVALUATING DOSE-  
17 RESPONSE RELATIONSHIPS?

18 A WELL, YES. AND THEY ALL HAVE THEIR  
19 STRENGTHS AND WEAKNESSES.

20 Q WOULD YOU TELL US ABOUT THESE.

21 A YES. WELL, THESE ARE THE MOST COMMONLY USED  
22 ONES, CERTAINLY, IN COHORT STUDIES.

23 Q OKAY.

24 A YOU HAVE LIKE DURATION -- SAY, IN AN  
25 OCCUPATIONAL STUDY, YOU HAVE DURATION OF EMPLOYMENT. SO  
26 YOU MIGHT EVALUATE YOUR DATA BY, SAY, INDIVIDUALS  
27 EXPOSED FOR 5 YEARS, THEN 5 TO 10 YEARS, THEN 10 TO 15  
28 YEARS, TO SEE IF YOU CAN FIND -- I'M SORRY. I'M TALKING

1 ABOUT EMPLOYMENT NOW. THAT'S THE MOST CRUDE ONE.

2 Q RIGHT.

3 A AND EVALUATE THE DATA TO SEE, WITH AN  
4 INCREASE IN EMPLOYMENT, IS THERE AN INCREASE IN THE  
5 RISK? BUT THERE ARE HAZARDS TO THAT, AS I'LL POINT OUT  
6 LATER.

7 Q OKAY.

8 A THEN NEXT IS DURATION OF EXPOSURE. YOU LOOK  
9 AT THE NUMBER OF YEARS THEY'RE EXPOSED AND SEE IF YOU  
10 HAVE -- WHEN YOU HAVE AN INCREASE IN THE EXPOSURE, DO  
11 YOU HAVE AN INCREASE IN RISK?

12 Q OKAY.

13 A SO THAT'S ANOTHER ONE.

14 BUT THERE ARE PROBLEMS WITH DURATION OF  
15 EXPOSURE. FOR EXAMPLE, WE KNOW THAT OVER TIME IN THE  
16 INDUSTRIAL SETTING THAT EXPOSURES HAVE PRETTY MUCH  
17 DECLINED OVER TIME BECAUSE THERE HAVE BEEN STANDARDS.  
18 COMPANIES HAVE IMPROVED THEIR INDUSTRIAL HYGIENE.

19 SO AS PEOPLE ARE EMPLOYED, THE EXPOSURES ARE  
20 REDUCED. SO YOU DON'T HAVE AS HIGH EXPOSURES, LET'S  
21 SAY, TODAY IN THE WORKPLACE TO MANY, MANY SUBSTANCES  
22 THAT YOU DID 50, 40 YEARS AGO.

23 Q OKAY.

24 A SO WHEN YOU'RE LOOKING AT DURATION OF  
25 EXPOSURE, THE QUESTION IS, WELL -- AND YOU ONLY SEE AN  
26 ANALYSIS BY THAT, THE QUESTION IS, WELL, WHEN WERE THEY  
27 EXPOSED? BECAUSE 5 YEARS' DURATION OF EXPOSURE, SAY,  
28 FROM 1950 TO 1955 MAY BE A LOT MORE THAN 20 YEARS'

1 EXPOSURE FROM 1970 TO 1990.

2 SO BY JUST DOING AN ANALYSIS BY DURATION OF  
3 EXPOSURE, YOU HAVE TO GET A SENSE OF, WELL, WHEN THIS  
4 COHORT WAS EXPOSED.

5 NOW, DURATION OF EXPOSURE WOULD BE A VERY  
6 GOOD MEASURE OF EXPOSURE IF THE EXPOSURE WAS THE SAME  
7 THROUGHOUT THE ENTIRE EMPLOYMENT PERIOD, BUT THAT'S  
8 USUALLY NOT THE CASE IN THE OCCUPATIONAL SETTING. BUT  
9 IT WOULD BE, IF THAT WERE THE CASE; BUT IT ISN'T.

10 Q WHAT ARE THE OTHER MODES OF EXPOSURE FOR  
11 DOSE-RESPONSE ANALYSIS?

12 A WELL, YOU CAN ANALYZE DATA BY THE AVERAGE  
13 LEVEL OF EXPOSURE OR BY THE MAXIMUM LEVEL OF EXPOSURE OR  
14 BY CUMULATIVE EXPOSURE.

15 Q AND WHAT DOES THAT MEAN?

16 A CUMULATIVE EXPOSURE WOULD BE -- IT WOULD BE  
17 DETERMINED BY MEASURING THE DURATION OF EXPOSURE BY THE  
18 LEVEL OF EXPOSURE DURING THAT DURATION TIME PERIOD.

19 Q OKAY.

20 A AND AS YOU'RE DOING CUMULATIVE EXPOSURE, OF  
21 COURSE, THAT WILL CHANGE OVER TIME, DEPENDING ON WHEN  
22 THE EXPOSURES OCCURRED.

23 FOR EXAMPLE, LET'S SAY THAT BETWEEN 1950 TO  
24 1960 -- THAT'S TEN YEARS -- YOU WERE EXPOSED TO 5 PARTS  
25 PER MILLION OF BENZENE, 5 PARTS PER MILLION FOR TEN  
26 YEARS IN THAT PERIOD.

27 SO LET'S SAY, OKAY, A WORKER THAT WORKED  
28 THERE DURING THAT TEN-YEAR PERIOD WAS EXPOSED TO 5 PARTS

1 PER MILLION TIMES TEN YEARS. THAT PERSON'S EXPOSURE  
2 WOULD BE 50 PARTS PER MILLION YEARS. IT'S SIMPLY A  
3 PRODUCT OF THOSE TWO NUMBERS.

4 AND YOU COULD SAY THE SAME PERSON, HE WAS  
5 EXPOSED FROM 1980 TO 1990, ANOTHER TEN-YEAR PERIOD, BUT  
6 TO 1 PART PER MILLION. SO YOU WOULD MULTIPLY THE 1 PART  
7 PER MILLION TIMES 10, AND YOU'D GET 10 PARTS PER MILLION  
8 FOR THAT EXPOSURE PERIOD.

9 SO IF YOU ADD IT ALL UP, THEN IT WOULD BE 60  
10 PARTS PER MILLION OF CUMULATIVE EXPOSURE -- 60 PARTS PER  
11 MILLION YEARS OF CUMULATIVE EXPOSURE.

12 Q ALL RIGHT. NOW, ARE DOSE-RESPONSE  
13 RELATIONSHIPS IMPORTANT IN ASSESSING CAUSALITY?

14 A YES.

15 Q WHO SAYS SO?

16 A WELL, I MEAN, THERE ARE A LOT OF -- I MEAN,  
17 IT'S GENERALLY ACCEPTED IN THE FIELD OF EPIDEMIOLOGY.  
18 AND I KNOW I POINTED UP SOME CITATIONS HERE.

19 Q INCLUDING THE INTERNATIONAL AGENCY FOR  
20 RESEARCH ON CANCER?

21 A YES.

22 Q WHICH SAYS, SLIDE 57:

23 "IF THE RISK OF THE DISEASE IN QUESTION  
24 INCREASES WITH THE AMOUNT OF EXPOSURE, THIS IS  
25 CONSIDERED TO BE A STRONG INDICATION OF  
26 CAUSALITY."

27 A YES; CORRECT.

28 MR. SCHURZ: OBJECTION; HEARSAY. HE'S JUST

1 READING.

2 THE COURT: OVERRULED.

3 Q BY MR. METZGER: AND DO YOU AGREE WITH THAT?

4 A YES, ABSOLUTELY. I MEAN, I'VE LECTURED --  
5 SOME OF THOSE PAPERS AND LECTURES YOU HAD EARLIER, THESE  
6 ARE SOME OF THE POINTS I RAISE -- I PRESENT IN THOSE  
7 LECTURES.

8 Q OKAY. LET'S TALK ABOUT THIS CASE AND START  
9 WITH ACRYLAMIDE, IF WE COULD. LET ME FIRST ASK YOU TO  
10 TELL THE COURT WHAT --

11 THE COURT: WELL, IF WE'RE MOVING TO A NEW  
12 SUBJECT, WE'RE GOING TO TAKE OUR MORNING RECESS AT THIS  
13 TIME.

14 MR. METZGER: VERY GOOD, YOUR HONOR.

15 THE COURT: AND THEN I'LL CALL SOME OTHER CASES.

16 WE'LL BE IN RECESS FOR TEN MINUTES.

17 DR. INFANTE, YOU MAY STEP DOWN FOR A FEW  
18 MINUTES.

19 THE WITNESS: THANK YOU.

20 (RECESS.)

21 THE COURT: GOOD MORNING AGAIN. BACK ON THE  
22 RECORD IN CERT VS. STARBUCKS. ALL COUNSEL ARE PRESENT.  
23 DR. INFANTE IS BACK ON THE STAND.

24 DO YOU UNDERSTAND YOU'RE STILL UNDER OATH?

25 THE WITNESS: YES.

26 THE COURT: RESTATE YOUR NAME FOR THE RECORD.

27 THE WITNESS: PETER FRANCIS INFANTE.

28 THE COURT: MR. METZGER WAS INQUIRING.

1 COUNSEL, YOU MAY PROCEED.

2 MR. METZGER: THANK YOU, YOUR HONOR.

3 Q DR. INFANTE, WOULD YOU INFORM THE COURT WHAT  
4 I ASKED YOU TO DO INITIALLY FOR THIS CASE.

5 A YES. YOU ASKED ME TO EVALUATE THE RISK OF  
6 CANCER AMONG ACRYLAMIDE-EXPOSED POPULATIONS.

7 Q AND DID YOU DO THAT?

8 A YES.

9 Q AND HOW DID YOU GO ABOUT DOING THAT?

10 A WELL, BY SELECTING POPULATIONS EXPOSED TO  
11 ACRYLAMIDE AND EVALUATING THOSE STUDIES.

12 Q AND WHAT TYPES OF POPULATIONS WERE THEY?

13 A WELL, THE FIRST ONE THAT I SELECTED FOR  
14 EVALUATION WAS OCCUPATIONAL EXPOSURES TO ACRYLAMIDE.

15 Q AND WHY DID YOU SELECT THAT FIRST?

16 A I SELECTED THE WORKERS BECAUSE THEY HAVE THE  
17 HIGHEST EXPOSURES TO ACRYLAMIDE.

18 Q AND WHAT TYPE THE WORKERS ARE THOSE? THOSE  
19 ARE INDUSTRIAL WORKERS INVOLVED IN THE PRODUCTION OF  
20 ACRYLAMIDE?

21 A YES.

22 MR. METZGER: OKAY.

23 THE COURT: WHEN YOU SAY "PRODUCTION OF  
24 ACRYLAMIDE," IS IT ACTUAL PRODUCTION OF THE CHEMICAL FOR  
25 SOME PURPOSE, OR IS IT AN OFFSHOOT OF PRODUCTION OF  
26 SOMETHING ELSE?

27 MR. METZGER: ACRYLAMIDE IS A MAJOR COMMODITY  
28 CHEMICAL USED IN --

1 THE COURT: YOU DON'T HAVE TO ANSWER THE QUESTION.  
2 LET THE WITNESS ANSWER IT.

3 MR. METZGER: OH, I'M SORRY; I'M SORRY.

4 THE COURT: WHEN YOU SAY "PRODUCTION OF  
5 ACRYLAMIDE," WHAT DO YOU MEAN BY THAT?

6 THE WITNESS: WELL, THEY'RE MANUFACTURING  
7 ACRYLAMIDE. IT'S BEEN USED AS -- LIKE IT'S A VERY GOOD  
8 AGENT TO USE FOR GROUT, FOR EXAMPLE.

9 THE COURT: SO IT'S A SPECIFIC PRODUCTION FOR THE  
10 PURPOSE OF PRODUCING ACRYLAMIDE; IT'S NOT AN OFFSHOOT  
11 CHEMICAL OF SOMETHING ELSE?

12 THE WITNESS: CORRECT.

13 THE COURT: ALL RIGHT. THANK YOU.

14 COUNSEL.

15 Q BY MR. METZGER: AND WHAT WAS THE NEXT  
16 ACRYLAMIDE-EXPOSED POPULATION THAT YOU CONSIDERED?

17 A I LOOKED AT THE EPIDEMIOLOGY RELATED TO THE  
18 CONSUMPTION OF POTATOES.

19 Q AND CANCER?

20 A YES.

21 Q AND WHY DID YOU LOOK AT THAT NEXT?

22 A BECAUSE FRIED POTATOES HAVE THE HIGHEST  
23 LEVELS IN ACRYLAMIDES IN THEM, OF FOODS.

24 Q OKAY. AND WHAT WAS THE THIRD POPULATION  
25 THAT YOU CONSIDERED IN EVALUATING THE RISK OF CANCER  
26 FROM ACRYLAMIDE?

27 A I LOOKED AT THE DIETARY STUDIES THAT WERE  
28 DONE TO EVALUATE ACRYLAMIDE EXPOSURE AND RISK OF CANCER,

1 MINUS THE POTATO STUDIES.

2 Q ALL RIGHT. SO LET'S START WITH THE  
3 OCCUPATIONAL STUDIES. AND WHAT STUDIES -- OR HOW MANY  
4 STUDIES DID YOU IDENTIFY?

5 A I IDENTIFIED -- WELL, I HAVE A SLIDE WITH  
6 THAT ON IT.

7 Q GO TO SLIDE 62.

8 A YES. THESE ARE THE STUDIES THAT I  
9 IDENTIFIED OF WORKERS EXPOSED TO ACRYLAMIDE.

10 Q SOBEL --

11 A SOBEL, COLLINS, MARSH '99. THEN MARSH  
12 CONTINUED FOLLOW-UP IN 2007. AND THEN THERE'S THE SWAEN  
13 2007 STUDY.

14 Q OKAY. AND DID YOU EVALUATE ANY PARTICULAR  
15 CANCERS FROM THESE STUDIES?

16 A WELL, I LOOKED AT THE CANCERS THAT WERE  
17 PRESENTED IN THE RESULTS, YES.

18 Q WHAT DID YOU FIND?

19 A WELL, I FOUND THAT THERE WAS AN INCREASED  
20 RISK OF PANCREATIC CANCER IDENTIFIED.

21 Q ALL RIGHT. AND WOULD YOU TELL THE COURT  
22 WHAT THE DATA WAS REGARDING THAT.

23 A WELL, YES. IF YOU LOOK AT THE SOBEL, THE  
24 1986 STUDY, YOU SEE THAT THE RELATIVE RISK OF CANCER WAS  
25 2.2, AND THAT WAS NOT STATISTICALLY SIGNIFICANT.

26 Q SO IT WAS DOUBLE BUT NOT SIGNIFICANT?

27 A CORRECT.

28 Q GOT IT.

1           A       DO YOU'D LOOK AT THE 95 PERCENT CONFIDENCE  
2 INTERVAL. IT'S BELOW 1.

3           Q       OKAY.

4           A       THEN THE '99 STUDY BY COLLINS, ET AL.

5           Q       1989?

6           A       1989; I'M SORRY, YES.

7                    AND THAT STUDY WAS OF WORKERS EXPOSED TO  
8 ACRYLAMIDE. AND THERE, THEY ALSO DID DOSE ESTIMATIONS,  
9 LIKE HOW MUCH ACRYLAMIDE WERE THEY EXPOSED TO?

10           THE COURT: WHEN YOU SAY "EXPOSURE TO ACRYLAMIDE,"  
11 ARE THESE JUST BECAUSE ACRYLAMIDE IS IN THE AIR, OR  
12 THERE HAS TO BE SOME INGESTION OF ACRYLAMIDE?

13           THE WITNESS: WELL, THAT'S A GOOD POINT. THESE  
14 ARE ATMOSPHERIC EXPOSURES. I MEAN, WHETHER THERE'S SOME  
15 ADDITIONAL INGESTION OR NOT, THEY DON'T MENTION IN THE  
16 STUDY, BUT THAT WOULD --

17           THE COURT: SO THESE WORKERS WEREN'T --

18           THE WITNESS: MOSTLY, IT'S ATMOSPHERIC EXPOSURE.

19           THE COURT: THEY WEREN'T SITTING AROUND DRINKING  
20 ACRYLAMIDE --

21           THE WITNESS: NO.

22           THE COURT: -- BUT THEY WERE EXPOSED BY SOME  
23 AIRBORNE --

24           THE WITNESS: EXACTLY, YES.

25           THE COURT: ALL RIGHT. THANK YOU.

26                    COUNSEL.

27           Q       BY MR. METZGER: AND WHAT DID YOU NOTE FROM  
28 THE COLLINS 1989 STUDY?

1           A           WELL, IN THE COLLINS '89 STUDY, IT SHOWS THE  
2           RELATIVE RISK FOR PANCREATIC CANCER, WHICH IS 2.03. IT  
3           DIDN'T STATE WHETHER IT WAS SIGNIFICANT OR NOT.

4                        BUT WHEN YOU LOOK AT THE DATA -- WAIT A  
5           MINUTE. WHEN YOU LOOK AT THE DATA FOR INDIVIDUALS WHO  
6           HAD CUMULATIVE EXPOSURES OF GREATER THAN .001 MICROGRAM  
7           PER CUBIC METER YEARS, THE RISK WAS SIGNIFICANTLY  
8           ELEVATED WHEN YOU ADJUST THE DATA FOR THAT.

9                        I MADE THAT ADJUSTMENT BECAUSE I ADJUSTED  
10          THE DATA FOR WHAT'S CALLED A "HEALTHY WORKER EFFECT."

11          Q           WHAT IS THE "HEALTHY WORKER EFFECT"?

12          A           WELL, THE "HEALTHY WORKER EFFECT" IS A  
13          PHENOMENON FOUND WHEN YOU STUDY WORKERS, BECAUSE WORKERS  
14          ARE HEALTHIER THAN THE GENERAL POPULATION. THEY HAVE TO  
15          PASS A PHYSICAL EXAMINATION IN ORDER TO BE EMPLOYED. SO  
16          THEY'RE HEALTHIER, IN GENERAL, THAN THE GENERAL  
17          POPULATION FOR WHICH THEIR DISEASE RISK IS COMPARED TO.

18                        LIKE FOR EXAMPLE, IF I WERE TO, SAY, TAKE  
19          THE PEOPLE IN THIS ROOM IN A LARGE GROUP RIGHT NOW AND  
20          COMPARE YOUR -- THE MORTALITY IN THIS GROUP TO THE  
21          GENERAL POPULATION, THERE ARE PEOPLE RIGHT NOW, AS WE  
22          SIT HERE, THAT ARE DYING FROM CANCER. SO WE WOULD BE  
23          RELATIVELY HEALTHIER THAN THE GENERAL POPULATION.

24          Q           OKAY.

25          A           SO IT'S A PHENOMENON THAT IS CORRECTED FOR  
26          WHEN YOU ARE REVIEWING DATA, AND THERE ARE TEXTBOOKS  
27          THAT INDICATE HOW TO CORRECT FOR THE "HEALTHY WORKER  
28          EFFECT."

1 Q AND HOW DID YOU ADJUST FOR THE "HEALTHY  
2 WORKER EFFECT" HERE?

3 A WELL, IN THE COLLINS STUDY, WHERE YOU SEE  
4 THAT THE RELATIVE RISK WAS 2.03, I ADJUSTED FOR THE --  
5 THE "HEALTHY WORKER EFFECT" IN THAT STUDY WAS .081 FOR  
6 ALL CAUSES OF DEATH.

7 SO WHAT THAT TELLS YOU IS THAT FOR ALL  
8 CAUSES OF DEATH, THE ENTIRE COHORT ONLY HAS 81 PERCENT  
9 OF MORTALITY AS COMPARED TO THE GENERAL POPULATION. SO  
10 THEY'RE HEALTHIER.

11 IF THEY DIED AT THE SAME RATE AS THE GENERAL  
12 POPULATION, THEN THE RELATIVE RISK WOULD BE 1; IT WOULD  
13 BE THE SAME. IT'S 0.81. SO IT INDICATES THAT THEY'RE  
14 HEALTHIER THAN THE GENERAL POPULATION.

15 THE COURT: IS THERE A REASON THAT YOU CAN  
16 ATTRIBUTE WHY THEY'RE HEALTHIER THAN THE GENERAL  
17 POPULATION?

18 THE WITNESS: YES. THEY'RE HEALTHIER BECAUSE IN  
19 ORDER TO GET A BLUE-COLLAR JOB, YOU HAVE TO PASS A  
20 PHYSICAL EXAMINATION. SO YOU'RE HEALTHIER THAN THE  
21 GENERAL POPULATION.

22 THE COURT: AND THE FACT THAT THEY'RE WORKING,  
23 PERIOD, PSYCHOLOGICALLY, I ASSUME, IS A HEALTHIER  
24 ATMOSPHERE.

25 THE WITNESS: YES. AND OF COURSE, THEY HAVE OTHER  
26 BENEFITS, TOO. THEY HAVE HEALTH CARE FROM THE JOB,  
27 WHICH OTHER PEOPLE DON'T HAVE. AND THESE ARE MORTALITY  
28 STUDIES. SO -- BUT IT'S WRITTEN, AND THERE ARE

1 SEVERAL --

2 THE COURT: LET ME ASK YOU THIS: WHEN YOU SAY  
3 "HEALTHIER THAN THE GENERAL POPULATION," DOES THE  
4 GENERAL POPULATION COVER ALL AGES AND ALL DEMOGRAPHICS?

5 THE WITNESS: THESE STUDIES ARE ADJUSTED FOR AGE,  
6 SEX, AND RACE. THESE ARE MEN, SO IT WOULD BE --

7 THE COURT: ALL RIGHT. SO IF YOU HAVE A WORKER  
8 GROUP THAT'S GENERALLY WORKERS BETWEEN AGE 25 AND 65,  
9 COMPARED TO THE GENERAL POPULATION, DO YOU USE THE SAME  
10 FACTORS --

11 THE WITNESS: YOU MATCH -- THAT'S A GOOD POINT.  
12 YOU MATCH THEIR AGES TO THE GENERAL POPULATION. YOU  
13 TAKE THEIR PERSON-YEARS, HOW OLD THEY ARE. AND THEN YOU  
14 TAKE PEOPLE IN THE GENERAL POPULATION OF THAT SAME AGE  
15 AND SEX. IF IT WAS MEN, YOU SAY, OKAY, BASED ON THAT,  
16 HOW MANY WOULD YOU EXPECT?

17 AND THEN ONE OF THE CALCULATIONS IS HOW MANY  
18 DEATHS FROM ALL CAUSES. AND WHEN YOU SEE THAT .81, IT  
19 TELLS YOU THAT THERE'S A "HEALTHY WORKER EFFECT," WHICH  
20 YOU SEE IN MOST OCCUPATIONAL STUDIES.

21 THE COURT: THANK YOU.

22 THE WITNESS: SO --

23 Q BY MR. METZGER: SO DR. INFANTE -- I'M  
24 SORRY. HOW DID YOU ADJUST FOR THE "HEALTHY WORKER  
25 EFFECT"? CAN YOU JUST GENERALLY EXPLAIN THAT.

26 A YES. YOU TAKE THE -- YOU'VE GOT THE RISK  
27 RATIO OF 2.03. AND SO, IN ESSENCE, YOU DIVIDE THAT BY  
28 .81, AND YOU COME UP WITH 2.51.

1                   AND THAT RESULT IS STATISTICALLY SIGNIFICANT  
2 BECAUSE THE 95 PERCENT CONFIDENCE INTERVAL I CALCULATED  
3 FOR IT IS 1.08 TO 4.94.

4           Q        OKAY.

5           A        SO I'VE MADE THAT ADJUSTMENT FOR THE  
6 "HEALTHY WORKER EFFECT."

7           Q        ALL RIGHT.  AND WHAT IS THE SIGNIFICANCE TO  
8 YOU, AS AN EPIDEMIOLOGIST, THAT THE WORKERS WHO HAD A  
9 CUMULATIVE EXPOSURE OF GREATER THAN .001 MILLIGRAM PER  
10 CUBIC METER YEARS HAD A 2.5-FOLD RISK OF PANCREATIC  
11 CANCER THAT WAS STATISTICALLY SIGNIFICANT WHEN ADJUSTED  
12 FOR THE "HEALTHY WORKER EFFECT"?

13          A        WELL, IT TELLS YOU THEY HAVE AN ELEVATED  
14 RISK OF PANCREATIC CANCER IN RELATION TO THE GENERAL  
15 POPULATION.

16          Q        OKAY.  AND DID YOU NOTE ABOUT THE MARSH 1999  
17 STUDY?

18          A        WELL, IF YOU LOOK AT THE MARSH 1999 STUDY,  
19 AND IF YOU TAKE WORKERS THAT HAD IN THAT STUDY THE  
20 HIGHEST CUMULATIVE EXPOSURE, YOU SEE THAT FOR THOSE WHO  
21 WERE EXPOSED TO GREATER THAN .3 MILLIGRAMS PER CUBIC  
22 METER YEARS, THEIR RELATIVE RISK IS 2.26.  AND THAT WAS  
23 STATISTICALLY SIGNIFICANT.

24          Q        OKAY.  AND WHAT DID YOU CONSIDER ABOUT THE  
25 MARSH 2007 UPDATE?

26          A        WELL, THE MARSH 2007 UPDATE, WHEN YOU LOOK  
27 AT -- AND I HAD TO GO BY THE CATEGORIES OF EXPOSURE THAT  
28 THEY HAD.  AND YOU LOOK AT INDIVIDUALS WHO HAD

1 CUMULATIVE EXPOSURES ABOVE 0.001 MILLIGRAMS PER CUBIC  
2 METER, THE RISK THAT THEY CALCULATED WAS 1.41. AND THAT  
3 RESULT WAS NOT STATISTICALLY SIGNIFICANT.

4 AND THAT WAS BASED ON A COMPARISON TO LOCAL  
5 RATES. AND SO WHEN YOU LOOK AT THEIR OVERALL MORTALITY  
6 COMPARED TO -- SO ANYHOW, THAT WAS BASED ON USING LOCAL  
7 RATES. RATHER THAN NATIONAL RATES, THEY USED LOCAL  
8 RATES TO COMPARE IT TO.

9 THEN WHEN I LOOKED AT THOSE WHO WERE  
10 UNEXPOSED -- IN THE SAME PLANT, WHO WERE UNEXPOSED TO  
11 ACRYLAMIDE, THEIR RATE FOR PANCREATIC CANCER WAS 0.78.

12 SO THAT TELLS ME THAT THESE WORKERS WHO WORK  
13 AT THAT PLANT, WERE INDUSTRIAL WORKERS, AND WHO WERE NOT  
14 EXPOSED TO ACRYLAMIDE, THEIR BACKGROUND RISK IS 0.78  
15 COMPARED TO THE GENERAL POPULATION. IN OTHER WORDS,  
16 THEY HAVE A FAVORABLE MORTALITY RATE FROM PANCREATIC  
17 CANCER.

18 SO THAT SHOULD BE THE -- THAT'S THE MOST  
19 APPROPRIATE COMPARISON POPULATION, OTHER WORKERS WHO ARE  
20 NOT EXPOSED. BECAUSE IT MATCHES FOR HEALTH CARE,  
21 SOCIOECONOMIC STATUS, OTHER FACTORS THAT YOU CAN'T  
22 CONTROL FOR, BECAUSE THEY WORK AT THE SAME PLANT EXCEPT  
23 THEY NOT EXPOSED; SAME PLANT, BUT THEY'RE NOT EXPOSED.

24 SO WHEN I TAKE THE DEATH RATE FROM  
25 PANCREATIC CANCER FOR THE UNEXPOSED, WHICH WAS .78, AND  
26 I TAKE THE 1.41, I DIVIDE IT BY THE .78 AND SAY, LOOK,  
27 THEIR RISK, THEN, FOR THE EXPOSED IS 1.81. AND THAT'S  
28 STATISTICALLY SIGNIFICANT.

1 Q OKAY.

2 A AND WHEN I HAVE VERSUS UNEXPOSED, THAT MEANS  
3 UNEXPOSED IN THE SAME INDUSTRIAL PLANTS. AND IT'S WELL  
4 ACCEPTED IN OCCUPATIONAL EPIDEMIOLOGY THAT THE MOST  
5 FAVORABLE COMPARISON GROUP ARE OTHER WORKERS AT THE SAME  
6 FACILITIES WHO WERE NOT EXPOSED.

7 THE COURT: ALL RIGHT. THANK YOU.

8 MR. METZGER, THIS IS ALL VERY INTERESTING.  
9 WHAT IS THE RELEVANCE TO THIS CASE?

10 MR. METZGER: OH, IT IS EXTREMELY RELEVANT, YOUR  
11 HONOR. BECAUSE BELIEVE IT OR NOT, THIS CASE IS ACTUALLY  
12 ABOUT ACRYLAMIDE AND WHETHER ACRYLAMIDE CAUSES CANCER.

13 THE COURT: ALL RIGHT. BUT PEOPLE WALKING IN THE  
14 SUPERMARKET AND BUYING COFFEE OR GOING INTO STARBUCKS,  
15 UNLESS THEY'RE SNIFFING AT THE COFFEE- MAKING MACHINE,  
16 THEY'RE NOT -- AT LEAST THERE'S NO ALLEGATION ABOUT  
17 BEING EXPOSED TO ACRYLAMIDE EXCEPT THROUGH THE PROCESS  
18 OF DRINKING COFFEE.

19 MR. METZGER: OKAY. WELL, THERE'S OTHER  
20 RELEVANCE, YOUR HONOR. FOR EXAMPLE, DR. BOFFETTA  
21 RENDERED AN OPINION THAT ACRYLAMIDE DOES NOT CAUSE HUMAN  
22 CANCER. THIS IS SHOWING THAT, IN FACT, ACRYLAMIDE  
23 EXPOSURE DOES SIGNIFICANTLY INCREASE THE RISK OF CANCER,  
24 AT LEAST PANCREATIC CANCER.

25 SO I MEAN, THERE'S MULTIPLE RELEVANCE TO  
26 THIS. I'M NOT SAYING THAT THIS -- THIS IS ONE PIECE OF  
27 THE PUZZLE. IT'S A COMPLEX PUZZLE IN THIS CASE.

28 THE COURT: ALL RIGHT. WELL, I GUESS WE'LL

1     EVENTUALLY GET TO A DISCUSSION ABOUT THE EFFECT OF  
2     DILUTION IN TERMS OF ACRYLAMIDE.

3                     AND I UNDERSTAND YOUR POSITION IS THAT  
4     ACRYLAMIDE IS CARCINOGENIC, A TOXIC CHEMICAL; AND IT'S  
5     CARCINOGENIC, AND IT'S CARCINOGENIC.

6                     BUT THE QUESTION IS -- IT COMES BACK TO THE  
7     ISSUE, WHICH I GUESS IS THE MAJOR ISSUE BETWEEN THE  
8     PARTIES, AS TO THE EFFECT WITH REGARD TO CONSUMPTION OF  
9     COFFEE. ARE WE GOING TO LOOK AT IT ONLY AS ACRYLAMIDE  
10    AS ITSELF, AND THEREFORE THE WARNING IS NECESSARY; OR  
11    RATHER, IN THE CONTEXT OF IT BEING DILUTED IN COFFEE?

12                    MR. METZGER: RIGHT. AND AS WE GET THROUGH THE  
13    LOWER EXPOSURE TO ACRYLAMIDE, I THINK WE'LL SEE THIS.  
14    BUT RIGHT NOW, THIS IS THE HIGHEST EXPOSED ACRYLAMIDE  
15    GROUP.

16                    WE'RE THEN GOING TO TALK ABOUT THE POTATO  
17    CONSUMPTION, WHICH IS THE NEXT HIGHEST. AND THEN THE  
18    DIETARY. SO WE'LL BE GETTING THERE.

19                    THE COURT: ALL RIGHT.

20                    MR. METZGER: OKAY.

21                    THE COURT: GO AHEAD.

22                    Q     BY MR. METZGER: SO LASTLY, DR. INFANTE, I  
23    THINK WE'RE NOW UP TO THE SWAEN 2007 UPDATE. AND THIS  
24    IS THE DUTCH ACRYLAMIDE PRODUCTION WORKERS. WHAT DID  
25    YOU NOTE OF SIGNIFICANCE IN THAT STUDY?

26                    A     WELL, IN THIS STUDY, THERE'S AN ELEVATED  
27    RISK, LIKE A 2.66-FOLD INCREASED RISK, FOR PANCREATIC  
28    CANCER, BUT THE RESULT IS NOT STATISTICALLY SIGNIFICANT;

1 BUT IT'S A HIGH RISK.

2 AND THE REASON IT ISN'T STATISTICALLY  
3 SIGNIFICANT WITH SUCH A HIGH RISK IS BECAUSE IT'S A  
4 SMALL POPULATION. IT DOESN'T HAVE A LOT OF STATISTICAL  
5 POWER.

6 Q ALL RIGHT. NOW, DID YOU ALSO ASSESS DOSE-  
7 RESPONSE RELATIONSHIPS FOR THE ACRYLAMIDE PRODUCTION  
8 WORKERS IN RELATIONSHIP TO PANCREATIC CANCER?

9 A YES.

10 Q ALL RIGHT. WILL YOU GO TO SLIDE 65 --

11 THE COURT: LET ME ASK DEFENDANTS: DO DEFENDANTS  
12 DISPUTE THAT ACRYLAMIDE CAN CAUSE THE RISK OF CANCER,  
13 ACRYLAMIDE BY ITSELF?

14 MR. SCHURZ: YES, YOUR HONOR, WE DO. AND WE WILL  
15 SHOW -- AND AS THIS TABLE SHOWS, THE OCCUPATIONAL  
16 EPIDEMIOLOGY DOES NOT SHOW THAT EXPOSURE TO ACRYLAMIDE  
17 CAUSES CANCER IN WORKERS. DR. INFANTE WAS ABLE TO  
18 ACHIEVE THE STATISTICAL SIGNIFICANCE BY --

19 THE COURT: WELL, YOU DON'T HAVE TO ARGUE IT. I  
20 JUST WANT TO KNOW WHAT YOUR POSITION IS.

21 SO YOU'RE CONTESTING WHETHER ACRYLAMIDE IN  
22 ITSELF, IN ITS PUREST FORM -- IF SUCH EXISTS -- WHETHER  
23 IT'S IN THE AIR OR IN SOME PRODUCT, THAT YOU'RE  
24 CONTESTING THAT IT HAS ANY RISK OF CAUSING CANCER.

25 MR. SCHURZ: TWO-PART ANSWER, YOUR HONOR.

26 FIRST, WE THINK THE RELEVANT EVIDENCE HERE  
27 IS COFFEE. WE THINK THE RELEVANT EVIDENCE --

28 THE COURT: I KNOW. WE'RE GOING TO GET TO THAT,

1 WHEN THEY DILUTE IT IN COFFEE, OR WHATEVER.

2 MR. SCHURZ: YES. AND SO WE QUESTION THE  
3 RELEVANCE WITH RESPECT TO OCCUPATIONAL STUDIES RELATING  
4 TO THOSE WHO ARE EXPOSED TO AIRBORNE ACRYLAMIDE.

5 HAVING SAID THAT, WE -- AS DR. BOFFETTA  
6 TESTIFIED, THE DIETARY ACRYLAMIDE STUDIES, AS WELL AS  
7 THE OCCUPATIONAL ACRYLAMIDE STUDIES, DO NOT ESTABLISH  
8 THAT ACRYLAMIDE, IN THE EXPOSURES THAT ARE EXPERIENCED  
9 IN THESE TWO CONTEXTS, RESULT IN INCREASED RISK OF  
10 CANCER.

11 THE COURT: ALL RIGHT. THANK YOU.

12 MR. METZGER, YOU MAY PROCEED.

13 MR. METZGER: ALL RIGHT.

14 Q SO WOULD YOU EXPLAIN TO THE COURT HOW YOU  
15 WENT ABOUT ASSESSING EXPOSURE -- OR DOSE-RESPONSE  
16 RELATIONSHIPS FROM THESE OCCUPATIONAL COHORT STUDIES.

17 A YES. WELL, I TOOK THE DATA FROM THE TABLE.  
18 THIS IS FROM TABLE 7 IN MARSH 1999. AND IF YOU LOOK AT  
19 IT, YOU'LL GET DURATION OF EXPOSURE.

20 AND THEN YOU LOOK AT THE STANDARDIZED  
21 MORTALITY RATIO, YOU CAN SEE THAT -- I MEAN, DURATION OF  
22 EMPLOYMENT. AS IT INCREASES, THE RISK OF PANCREATIC  
23 CANCER INCREASES.

24 NOW, YOU SAY, WELL, THAT SEEMS LIKE A SMALL  
25 RISK. HOWEVER, OF THOSE 44 CASES UNDER DURATION OF  
26 EMPLOYMENT, 30 OF THEM ARE ACTUALLY NOT EVEN EXPOSED TO  
27 ACRYLAMIDE. SO THAT'S GOING TO -- THAT WILL DILUTE OUT  
28 THE FINDINGS FOR THOSE THAT ARE EXPOSED TO ACRYLAMIDE,

1 BECAUSE YOU'VE GOT ALL THE DENOMINATORS FOR THOSE PEOPLE  
2 IN THAT POPULATION ALSO.

3 SO NOW, AS YOU GO TO DURATION OF EXPOSURE --

4 Q HOLD ON, DR. INFANTE.

5 A YEAH.

6 Q JUST A MINUTE. SO YOU LOOKED AT DURATION OF  
7 EMPLOYMENT, AND YOU LOOKED AT DURATION OF EXPOSURE. AND  
8 DID YOU ALSO LOOK AT OTHER FACTORS IN ASSESSING DOSE-  
9 RESPONSE RELATIONSHIPS?

10 A YES.

11 Q WHAT OTHER FACTORS?

12 A WELL, I LOOKED AT THE MEAN INTENSITY OF  
13 EXPOSURE, WHICH IS PRESENTED IN THIS TABLE, AND ALSO  
14 CUMULATIVE EXPOSURE.

15 Q ALL RIGHT. SO YOU LOOKED AT FOUR METRICS OF  
16 EXPOSURE IN RELATIONSHIP TO DOSE RESPONSE?

17 A YES, THAT ARE PRESENTED BY THE AUTHORS.

18 Q ALL RIGHT. SO THE FIRST TABLE YOU HAVE HERE  
19 IS REGARDING DURATIONS OF EMPLOYMENT. AND YOU HAVE LESS  
20 THAN 1 YEAR, 1 TO 14 YEARS, AND 15 OR MORE YEARS. AND  
21 THE STANDARDIZED MORTALITY RATIO GOES FROM 0.87 TO 0.95  
22 TO 1.19; IS THAT CORRECT?

23 A CORRECT.

24 Q AND WHAT DID THAT INDICATE TO YOU?

25 A WELL, THAT INDICATES A DOSE RESPONSE BY  
26 DURATION OF EMPLOYMENT.

27 Q BECAUSE AS THE DURATION OF EMPLOYMENT  
28 INCREASES, THE MORTALITY RATIO -- STANDARDIZED MORTALITY

1 RATIO INCREASES?

2 A CORRECT.

3 Q ALL RIGHT. AND IS THAT A STATISTICALLY  
4 SIGNIFICANT DOSE RESPONSE?

5 A NO, IT IS NOT STATISTICALLY SIGNIFICANT.

6 Q OKAY.

7 A BUT NEVERTHELESS, IT'S A DOSE RESPONSE. BUT  
8 AS I INDICATED, THE REASONS I INDICATED, IT'S DILUTED  
9 OUT A LOT BECAUSE THERE ARE 30 INDIVIDUALS IN THAT FIRST  
10 ANALYSIS THAT AREN'T EVEN EXPOSED TO ACRYLAMIDE.

11 Q OKAY. NOW, IF WE GO TO THE NEXT METRIC THAT  
12 YOU CONSIDERED, DURATION OF EXPOSURE, YOU HAVE HERE THE  
13 NUMBER OF YEARS OF EXPOSURE, NOT JUST EMPLOYMENT;  
14 CORRECT?

15 A YES; CORRECT.

16 Q ALL RIGHT. AND WHAT YOU HAVE HERE IS FOUR  
17 CATEGORIES: THE FIRST ONE "UNEXPOSED," AND THEN THREE  
18 INCREASING CATEGORIES OF NUMBER OF YEARS. AND THEN YOU  
19 HAVE THE STANDARDIZED MORTALITY RATIO.

20 AND IT GOES FROM 0.80 FOR THE UNEXPOSED, TO  
21 1.46 FOR THE FIRST EXPOSURE LEVEL -- DURATION LEVEL, AND  
22 THEN 1.79 FOR THOSE EXPOSED 5 TO 15 YEARS -- TO 19  
23 YEARS, AND 2.42 FOR THOSE EXPOSED 20 OR MORE YEARS; IS  
24 THAT CORRECT?

25 A YES.

26 Q OKAY. AND THE REASON I'M ACTUALLY READING  
27 THIS IS BECAUSE THAT WILL NOW BE IN EVIDENCE, JUST SO  
28 YOU UNDERSTAND. WHAT'S ON THE SLIDE IS NOT IN EVIDENCE.

1 ALL RIGHT. AND WHAT DID YOU NOTE OF  
2 SIGNIFICANCE OR IMPORTANCE TO YOU FROM THE STANDARDIZED  
3 MORTALITY RATIOS BY DURATION OF EXPOSURE?

4 A YOU SEE A DOSE RESPONSE BY DURATION OF  
5 EXPOSURE. IN OTHER WORDS, AS YOU HAVE AN INCREASE IN  
6 THE DURATION OF EXPOSURE, YOU HAVE AN INCREASE IN THE  
7 RISK OF PANCREATIC CANCER.

8 Q OKAY. LET'S GO TO THE NEXT SLIDE. AND  
9 HERE, YOU EVALUATED MEAN INTENSITY OF EXPOSURE. FIRST,  
10 WILL YOU TELL THE COURT WHAT THAT IS.

11 A WELL, THAT WOULD BE THE AVERAGE LEVEL OF  
12 EXPOSURE FOR THOSE WORKERS.

13 Q OKAY. YOU HAVE FOUR CATEGORIES HERE, THE  
14 FIRST BEING MEAN INTENSITY OF EXPOSURE EXPRESSED IN  
15 MILLIGRAMS PER CUBIC METER OF AIR; IS THAT CORRECT?

16 A YES.

17 Q ALL RIGHT. AND THOSE -- YOU HAVE FOUR  
18 CATEGORIES, FROM ZERO UP TO 0.3 OR ABOVE; CORRECT?

19 A YES.

20 Q AND THEN THE STANDARDIZED MORTALITY RATIO IS  
21 0.80 FOR THE UNEXPOSED, AND 2.31 FOR THOSE EXPOSED TO  
22 THE HIGHEST MEAN INTENSITY OF EXPOSURE. AND THE NUMBERS  
23 GO -- WOULD YOU EXPLAIN -- WELL, THE NUMBERS GO FROM  
24 0.80, TO 1.69, TO 1.50, TO 2.31; IS THAT CORRECT?

25 A YES.

26 Q AND WHAT DID YOU -- WHAT ELSE DID YOU DO  
27 HERE REGARDING THE STANDARDIZED MORTALITY RATIO?

28 A WELL, WHAT I DID THERE IS THAT -- IT LOOKS

1 LIKE IT'S A DOSE RESPONSE, BUT IN FACT, IF YOU COMBINE  
2 THE TWO LOWER EXPOSURE GROUPS, YOU GET A MONOTONIC DOSE  
3 RESPONSE.

4 SO IT GOES FROM .8 TO THE UNEXPOSED, TO 1.57  
5 FOR THE TWO LOWEST EXPOSURE GROUPS, THEN UP TO 2.31.

6 Q AND WHERE DID THE 1.57 COME FROM?

7 A IT COMES FROM COMBINING THE DATA FOR THE  
8 ZERO POINT -- FOR THE SECOND AND THIRD EXPOSURE GROUPS.

9 Q WHO DID THAT?

10 A WELL, I'M PRESENTING IT HERE. I DID THAT  
11 FOR THIS ANALYSIS, BUT I GOT THE IDEA OF COMBINING THAT  
12 FROM SHULZ 2001, WHO DID IT FOR, IN FACT, CUMULATIVE  
13 EXPOSURE, WHICH IS IN THE NEXT SLIDE.

14 Q AND IS THAT A PUBLISHED STUDY?

15 A YES.

16 Q ALL RIGHT. AND SO SCHULZ DID IT FOR  
17 CUMULATIVE EXPOSURE. AND AGAIN, YOU HAVE FOUR  
18 CATEGORIES HERE OF CUMULATIVE EXPOSURE, WITH THE  
19 STANDARDIZED MORTALITY RATIO GOING FROM 0.80, TO 2.77,  
20 TO 0.73, TO 2.26.

21 AND WHAT DID YOU ASSESS FROM THAT?

22 A WELL, I ASSESSED FROM THAT THAT THERE IS A  
23 DOSE RESPONSE, AGAIN, BUT THIS TIME BY CUMULATIVE  
24 EXPOSURE. AND THAT HIGHEST DOSE GROUP, THE 2.26, THAT  
25 RESULT IS STATISTICALLY SIGNIFICANT. I DIDN'T PUT ANY  
26 CONFIDENCE INTERVALS, BUT THE 2.26 IS STATISTICALLY  
27 SIGNIFICANT.

28 NOW, I COMBINED THE TWO LOWER DOSE GROUPS

1 TOGETHER, THE ONE THAT HAS THREE DEATHS AND THE ONE THAT  
2 HAS TWO DEATHS. AND I DID THAT BECAUSE I THOUGHT IT WAS  
3 A GOOD ANALYSIS TO DO BECAUSE THE NUMBERS ARE SO SMALL,  
4 SO YOU GET A LITTLE MORE STRENGTH FOR THOSE DATA POINTS.

5 AND IN FACT, SCHULZ HAD PUBLISHED THE  
6 IDENTICAL ANALYSIS IN 2001, SAYING, "HEY, IF YOU ANALYZE  
7 THE DATA IN THE STUDY FOR PROSTATE CANCER, YOU COMBINE  
8 THE TWO -- THE DATA IN THE TWO LOWER DOSE GROUPS, YOU,  
9 IN FACT, HAVE A MONOTONIC DOSE RESPONSE FOR EXPOSURE TO  
10 ACRYLAMIDE AND PANCREATIC CANCER."

11 Q ALL RIGHT. WOULD YOU GO TO THE NEXT SLIDE.  
12 AND IS THIS THE TABLE FROM SCHULZ THAT  
13 YOU'RE REFERRING TO?

14 A YES, IT IS. AND THAT WAS PUBLISHED IN 2001  
15 IN THE "JOURNAL OF OCCUPATIONAL AND ENVIRONMENTAL  
16 MEDICINE."

17 Q ALL RIGHT. FOR HIS SECOND EXPOSURE GROUP,  
18 HE HAS AN SMR -- STANDARDIZED MORTALITY RATIO -- OF  
19 1.31.

20 AND IF YOU GO BACK ONE SLIDE, THAT'S WHERE  
21 YOU GOT THAT?

22 A CORRECT.

23 Q ALL RIGHT. GO FORWARD ONE SLIDE.

24 AND I THINK YOU TOLD US THAT IN THE HIGHEST  
25 EXPOSURE GROUP, CUMULATIVE EXPOSURE GROUP, THE  
26 STANDARDIZED MORTALITY RATIO OF 2.26 WAS STATISTICALLY  
27 SIGNIFICANT. AND IS THAT SHOWN HERE IN THE SCHULZ  
28 TABLE?

1           A           YES, BECAUSE THE LOWER BOUND OF THE 95  
2 PERCENT CONFIDENCE INTERVAL IS ABOVE 1.

3           Q           OKAY. NOW, DID YOU PERFORM A SIMILAR  
4 ANALYSIS FOR THE MARSH 2007 UPDATE OF THE ACRYLAMIDE  
5 PRODUCTION WORKER COHORT STUDY?

6           A           YES.

7           Q           ALL RIGHT. COULD YOU GO TO THE NEXT SLIDE.  
8                        AND FOR DURATION OF EMPLOYMENT FOR THE THREE  
9 CATEGORIES, THE STANDARDIZED MORTALITY RATIO WENT FROM  
10 0.82, TO 0.84, TO 1.17; CORRECT?

11          A           CORRECT.

12          Q           AND WHAT DID YOU CONSIDER ABOUT THAT?

13          A           WELL, IT'S SHOWING A SLIGHT DOSE RESPONSE;  
14 BUT AGAIN, THERE'S A LOT OF DILUTION IN IT.

15          Q           OKAY. AND FOR DURATION OF EXPOSURE FOR THE  
16 FOUR EXPOSURE CATEGORIES -- DURATION OF EXPOSURE  
17 CATEGORIES, THE STANDARDIZED MORTALITY RATIO WENT FROM  
18 0.78, TO 1.12, TO 1.55, TO 1.81 IN THE HIGHEST DURATION  
19 OF EXPOSURE GROUP; IS THAT CORRECT?

20          A           YES.

21          Q           AND WHAT DID YOU MAKE OF THAT?

22          A           WELL, IT'S SHOWING A DOSE RESPONSE BY  
23 DURATION OF EXPOSURE.

24          Q           OKAY. AND IF WE GO TO THE NEXT SLIDE.  
25                        FOR THE MARSH 2007 UPDATE, DID YOU ALSO SHOW  
26 A MEAN INTENSITY OF EXPOSURE DOSE RESPONSE WHEN  
27 COMBINING THE MIDDLE EXPOSURE GROUPS, AS SCHULZ DID?

28          A           YEAH. WELL, THE TWO LOWER EXPOSURE GROUPS,

1 YES.

2 Q I'M SORRY.

3 A WELL, I GUESS THEY'RE IN THE MIDDLE IF YOU  
4 CONSIDER, I GUESS, UNEXPOSED AS AN EXPOSURE; CORRECT.  
5 SORRY.

6 Q ALL RIGHT. AND THAT WENT FROM 0.78, TO  
7 1.34, TO 1.11, TO 1.85, WITH THE TWO -- WITH THE  
8 COMBINED GROUP OF 1.22; IS THAT CORRECT?

9 A YES.

10 Q ALL RIGHT. AND THEN FOR THE CUMULATIVE  
11 EXPOSURE, DID YOU FIND A SIMILAR DOSE-RESPONSE  
12 RELATIONSHIP?

13 A YES, I DID. AND COMBINING -- AS I'M  
14 SHOWING, IF YOU COMBINE THE TWO MIDDLE GROUPS, YOU HAVE  
15 A MONOTONIC DOSE RESPONSE: FROM .78, TO 1.15, TO 1.71.

16 Q OKAY. WELL, WHAT WAS YOUR ULTIMATE  
17 CONCLUSION, DR. INFANTE, FROM THESE ANALYSES -- THESE  
18 DOSE-RESPONSE ANALYSES THAT YOU DID REGARDING THE  
19 OCCUPATIONAL COHORT STUDIES FOR ACRYLAMIDE PRODUCTION  
20 WORKERS IN RELATIONSHIP TO THEIR DEVELOPMENT OF  
21 PANCREATIC CANCER?

22 A WELL, MY CONCLUSION WAS THAT THE DATA SHOW  
23 AN INCREASED RISK OF PANCREATIC CANCER AMONG PRODUCTION  
24 WORKERS EXPOSED TO ACRYLAMIDE.

25 Q AND WHAT DID YOU CONCLUDE REGARDING DOSE  
26 RESPONSE?

27 A WELL, THEY ALSO DEMONSTRATED -- IT'S A  
28 LARGER STUDY THAT DEMONSTRATES A DOSE RESPONSE, WHICH IS

1 A POWERFUL TOOL IN EPIDEMIOLOGY.

2 Q WHY IS IT A POWERFUL TOOL?

3 A WELL, IT'S A POWERFUL TOOL, AS I EXPLAINED  
4 EARLIER, BECAUSE ALL OF YOUR ERRORS IN EXPOSURE  
5 ASSESSMENT ARE GOING TO BIAS YOU TOWARDS NOT FINDING A  
6 DOSE RESPONSE.

7 Q OKAY. SO WHAT WAS THE SIGNIFICANCE TO YOU  
8 OF FINDING A DOSE RESPONSE IN THESE STUDIES THAT WAS  
9 APPARENT USING FOUR DIFFERENT METRICS OF EXPOSURE?

10 A WELL, TO ME, I THINK IT PROVIDES STRONG  
11 EVIDENCE OF AN ASSOCIATION AMONG THESE WORKERS BETWEEN  
12 EXPOSURE TO ACRYLAMIDE AND RISK OF PANCREATIC CANCER.

13 MR. METZGER: ALL RIGHT. THANK YOU.

14 YOUR HONOR, WE'RE GOING TO START A NEW  
15 TOPIC. DO WE HAVE TIME?

16 THE COURT: YES. GO AHEAD.

17 MR. METZGER: ALL RIGHT.

18 Q SO YOU TOLD US, DR. INFANTE, THAT THE NEXT  
19 TYPE OF EPIDEMIOLOGIC STUDIES THAT YOU EVALUATED  
20 REGARDING ACRYLAMIDE AND CANCER WAS STUDIES REGARDING  
21 CANCER AND CONSUMPTION OF POTATOES.

22 A YES.

23 Q OKAY. AND I THINK YOU INDICATED THAT WAS  
24 BECAUSE POTATOES CONTAIN THE HIGHEST LEVELS OF  
25 ACRYLAMIDE IN THE HUMAN DIET?

26 A THAT'S MY UNDERSTANDING, YES.

27 Q OKAY. NOW, WAS THIS ISSUE OF WHETHER  
28 CONSUMPTION OF COOKED POTATOES INCREASES THE RISK OF

1 CANCER SOMETHING THAT HAD BEEN EVALUATED BY DR. BOFFETTA  
2 IN HIS 2011 REVIEW?

3 A YES.

4 Q AND DID YOU READ DR. BOFFETTA'S 2011 REVIEW  
5 REGARDING THIS ISSUE?

6 A YES. WELL, THERE WERE OTHER CO-AUTHORS ON  
7 THIS REVIEW; BUT YES, I DID.

8 Q YES. COULD YOU GO TO THE NEXT SLIDE. GO TO  
9 SLIDE 74; I'M SORRY. ALL RIGHT.

10 AND WHAT DID YOU FIND FROM DR. BOFFETTA'S  
11 REVIEW REGARDING STUDIES OF POTATO CONSUMPTION AND  
12 CANCER?

13 A WELL, HE WAS DOING A REVIEW OF ACRYLAMIDE IN  
14 THE DIET AND CANCER RISK, AND THERE'S ONE SECTION WHERE  
15 HE FOCUSED ON POTATO CONSUMPTION BECAUSE POTATOES HAVE  
16 THE HIGHEST AMOUNT OF ACRYLAMIDE IN DIETARY FOODS.

17 AND WHAT I HAD NOTICED IS THAT --

18 THE COURT: IS THAT POTATOES IN THEMSELVES, OR IS  
19 IT THE FRYING OF POTATOES?

20 THE WITNESS: THE FRYING OF THE POTATOES. AND THE  
21 MORE YOU FRY THEM, THE CRISPER YOU GET, THE MORE  
22 ACRYLAMIDE THEY HAVE.

23 THE COURT: BUT THE POTATOES THEMSELVES DON'T  
24 CONTAIN ACRYLAMIDE; IS THAT RIGHT?

25 THE WITNESS: I THINK YOU HAVE TO -- IT'S THE  
26 HEATING PROCESS THAT FORMS THE ACRYLAMIDE.

27 THE COURT: OKAY.

28 Q BY MR. METZGER: OKAY. AND HOW MANY STUDIES

1 DID DR. BOFFETTA, IN HIS 2011 REVIEW, IDENTIFY REPORTING  
2 INCREASED RISKS OF CANCER FROM CONSUMPTION OF POTATOES?

3 A NINE STUDIES.

4 Q ALL RIGHT. AND DID ANY OF THOSE STUDIES  
5 THAT DR. BOFFETTA IDENTIFIED IN HIS REVIEW REFLECT A  
6 DOSE-RESPONSE RELATIONSHIP?

7 A NO.

8 Q OKAY. AND WHAT WAS DR. BOFFETTA'S  
9 CONCLUSION?

10 NEXT SLIDE.

11 A WELL, HE CONCLUDED THAT THE -- HE SAYS:  
12 "THE STUDIES ON CANCER RISK FROM INTAKE  
13 OF ACRYLAMIDE-RICH FOODS -- AND IN PARTICULAR,  
14 POTATOES COOKED AT HIGH TEMPERATURE -- OFFER  
15 ONLY A LIMITED CONTRIBUTION TO THE  
16 INVESTIGATION OF THE POSSIBLE CARCINOGENIC  
17 EFFECT OF ACRYLAMIDE IN HUMANS."

18 Q ALL RIGHT. NOW, DID YOU SEARCH FOR STUDIES  
19 EVALUATING CANCERS IN RELATIONSHIP TO CONSUMPTION OF  
20 COOKED POTATOES?

21 A YES.

22 Q AND WHAT DID YOU FIND?

23 A WELL, I HAVE A SUMMARY SLIDE HERE THAT I  
24 IDENTIFIED LIKE AN ADDITIONAL 18 STUDIES THAT WERE  
25 PUBLISHED BEFORE 2011, WHICH WAS THE DATE OF HIS REVIEW,  
26 THAT REPORTED INCREASED RISKS OF CANCER IN RELATION TO  
27 CONSUMPTION OF POTATOES.

28 Q AND DID ANY OF THOSE STUDIES THAT YOU FOUND

1 REPORT DOSE-RESPONSE RELATIONSHIPS FOR CONSUMPTION OF  
2 COOKED POTATOES AND CANCER?

3 A YES. THERE WERE SIX.

4 Q OKAY. AND DID YOU UPDATE -- WELL, DID YOU  
5 ALSO LOOK FOR STUDIES POST-DATING 2011, TO SEE WHETHER  
6 OTHER EPIDEMIOLOGIC STUDIES, MORE RECENT STUDIES,  
7 REPORTED INCREASED RISKS OF CANCER IN RELATIONSHIP TO  
8 CONSUMPTION OF COOKED POTATOES?

9 A YES.

10 Q AND WHAT DID YOU FIND?

11 A THERE WERE FIVE ADDITIONAL.

12 Q OKAY. AND DID YOU CHART THE DATA FROM THESE  
13 STUDIES IN YOUR NOTES?

14 A YES. THESE WERE THE RESULTS THAT I HAD AT  
15 MY DEPOSITION.

16 Q OKAY. COULD WE GO TO THE NEXT SLIDE.

17 SO I'D LIKE YOU TO TELL US ABOUT SOME OF  
18 THESE STUDIES. WE'RE NOT GOING TO GO THROUGH EVERY ONE.  
19 BUT THE FIRST ONE, FROM 1975, PHILLIPS.

20 BEFORE WE DO THAT, WHAT TYPES OF STUDIES ARE  
21 THESE?

22 A WELL, THEY'RE EPIDEMIOLOGICAL STUDIES.  
23 THEY'RE CASE-CONTROL STUDIES.

24 Q OKAY. SO THESE ARE STUDIES WHERE  
25 INVESTIGATORS GOT TOGETHER A GROUP OF PATIENTS WHO HAD A  
26 PARTICULAR CANCER, AND THEY LOOKED RETROSPECTIVELY TO  
27 SEE WHETHER THEY LOOKED -- WHAT THEY WERE EXPOSED TO.  
28 AND ONE OF THOSE FACTORS WAS COOKED POTATOES?

1           A        YES.

2           THE COURT:   LET ME ASK THIS:   ARE THERE ANY OTHER  
3   FOODS BESIDES POTATOES AND COFFEE THAT RELEASE OR CAUSE  
4   PRODUCTION OF ACRYLAMIDE IN THE HEATING PROCESS?

5                    IN PARTICULAR, WHAT INGREDIENT IN POTATOES  
6   CREATES THIS PROCESS?  IS IT SOME STARCH PART OF THE  
7   POTATO, OR WOULD A SIMILAR REACTION OCCUR IN OTHER FOOD  
8   TYPES?

9           THE WITNESS:  YOU KNOW, I -- THERE'S TWO ANSWERS  
10   TO YOUR QUESTIONS.  ONE, IT WAS A SWEDE THAT DETERMINED  
11   THIS, I THINK, IN AROUND 2002.  AND I DON'T RECALL  
12   THE -- LIKE THE CHEMICAL PROCESS OF HOW IT WORKS.

13                    SO IT FORMS AS THE POTATOES ARE HEATED.  AND  
14   THE MORE YOU HEAT THEM -- SO IF YOU WERE TO ORDER A  
15   BUNCH OF FRIES, IF YOU ORDERED SOME THAT ARE CRISPY,  
16   LIKE A LOT OF PEOPLE LIKE BEST, THEY HAVE A LOT MORE  
17   ACRYLAMIDE IN THEM.

18           THE COURT:  BUT WHAT ABOUT IF YOU FRIED ONIONS?

19           THE WITNESS:  I DON'T KNOW ABOUT ONIONS, BUT BREAD  
20   WILL FORM ACRYLAMIDE; NOT AS MUCH AS POTATOES.  POTATOES  
21   FORMS THE MOST.

22                    AND SOME OF THESE SURVEYS THAT HAVE BEEN  
23   DONE, LOOKING AT ACRYLAMIDE AND THE DIET OUTSIDE OF  
24   POTATOES --

25           THE COURT:  YES.

26           THE WITNESS:  -- I THINK THEY INCLUDE ANYWHERE  
27   FROM LIKE 17 TO 24 ITEMS THAT THEY CONSIDERED HAD  
28   ACRYLAMIDE IN THEM.

1 THE COURT: OKAY. THANK YOU.

2 COUNSEL.

3 Q BY MR. METZGER: ALL RIGHT. SO PHILLIPS WAS  
4 A STUDY -- NOW, THIS WAS A STUDY DONE, WHAT, 27 YEARS  
5 BEFORE IT WAS KNOWN THAT ACRYLAMIDE IS IN THE HUMAN  
6 DIET?

7 A YES. 1975.

8 Q ALL RIGHT. AND WHAT PHILLIPS DID IS, HE  
9 LOOKED AT BREAST CANCER AND COLON CANCER IN RELATIONSHIP  
10 TO VARIOUS FACTORS. IS THAT HOW IT WORKED?

11 A YES.

12 Q ALL RIGHT. AND FOR POTATO CONSUMPTION, WHAT  
13 WAS REPORTED IN THAT STUDY THAT YOU FOUND IMPORTANT?

14 A WELL, THEY FOUND A SIGNIFICANT INCREASE IN  
15 BREAST CANCER AND COLON CANCER.

16 Q IN RELATIONSHIP TO WHAT?

17 A IN RELATIONSHIP TO POTATO CONSUMPTION.

18 Q OKAY. AND IF WE GO DOWN TO -- WELL, THE  
19 NEXT ONE, STEINECK 1990, UROTHELIAL CANCER. WHAT DID  
20 YOU FIND OF NOTE IN THAT STUDY?

21 A WELL, THEY REPORTED A SIGNIFICANT INCREASE  
22 IN UROTHELIAL CANCERS.

23 Q IN RELATION TO?

24 A TO POTATOES IN THE DIET.

25 Q OKAY. AND FRANCESCHI 1991?

26 A YES.

27 Q WHAT DID YOU FIND OF NOTE IN THAT STUDY?

28 A A SIGNIFICANT INCREASE IN THYROID CANCER.

1 Q IN RELATIONSHIP TO?

2 A TO POTATO CONSUMPTION.

3 Q OKAY. AND FRANCESCHI 1997?

4 A YES. AN INCREASE IN COLORECTAL CANCER, BUT  
5 THE DATA ALSO DEMONSTRATE A SIGNIFICANT DOSE RESPONSE.  
6 AND THAT'S WHEN I HAVE "YES" UNDER "DOSE RESPONSE."

7 Q I SEE.

8 A BECAUSE IF THE DOSE RESPONSE WAS  
9 SIGNIFICANT, I WOULD PUT A "YES."

10 Q WHAT DOES THAT ACTUALLY MEAN, THAT THE DOSE  
11 RESPONSE WAS SIGNIFICANT?

12 A IT MEANS THAT WHEN YOU HAD AN INCREASE IN  
13 THE AMOUNT OF CONSUMPTION, YOU HAVE AN INCREASE IN THE  
14 RISK OF THE CANCER; BUT IN THE DOSE RESPONSE, THE TREND  
15 WAS STATISTICALLY SIGNIFICANT.

16 Q IS THERE A CALCULATION THAT ONE DOES TO  
17 DETERMINE WHETHER THE TREND IS STATISTICALLY  
18 SIGNIFICANT?

19 A YES.

20 Q ALL RIGHT. AND WHEN IT IS STATISTICALLY  
21 SIGNIFICANT, DOES IT MEAN THAT THE ODDS OF THAT DOSE-  
22 RESPONSE TREND OCCURRING -- BEING DUE TO CHANCE IS LESS  
23 THAN 5 PERCENT?

24 A YES.

25 Q ALL RIGHT. NOW, PING 1998. THAT ONE  
26 INDICATED AN INCREASED RISK, BUT IT WAS NOT  
27 STATISTICALLY SIGNIFICANT?

28 A CORRECT.

1 Q ALL RIGHT. AND HU, 1998, A SIGNIFICANT  
2 INCREASE IN GASTRIC CANCER?

3 A YES.

4 Q FROM POTATO CONSUMPTION?

5 A YES.

6 Q ALL RIGHT. BOSETTI 2002, A SIGNIFICANT  
7 INCREASE IN LARYNGEAL CANCER FROM -- IN ASSOCIATION WITH  
8 POTATO CONSUMPTION. IS THAT WHAT THAT INDICATES?

9 A YES.

10 Q AND WAS THAT -- WAS THERE ANY STATISTICALLY  
11 SIGNIFICANT DOSE-RESPONSE RELATIONSHIP BETWEEN  
12 CONSUMPTION OF POTATOES AND THE DEVELOPMENT OF LARYNGEAL  
13 CANCER?

14 A YES.

15 Q ALL RIGHT. AND DID HU 2002 ALSO REPORT AN  
16 INCREASED RISK OF CANCER -- IN THIS CASE, LUNG CANCER --  
17 FROM POTATO CONSUMPTION, WITH A SIGNIFICANT DOSE-  
18 RESPONSE RELATIONSHIP?

19 A IT WAS BORDERLINE. THE LOWER BOUND IS 1.0,  
20 BUT YET.

21 Q OKAY.

22 A AND THERE'S A SIGNIFICANT DOSE RESPONSE --

23 Q OKAY.

24 A -- WHICH IS REALLY MORE POWERFUL THAN THE  
25 1.7, THE ONE-POINT ESTIMATE. BECAUSE DOSE RESPONSE,  
26 YOU'RE CONSIDERING ALL THE DATA IN THE STUDY, NOT JUST  
27 ONE DATA POINT.

28 Q AND LEE 2003 FOUND A STATISTICALLY

1 SIGNIFICANT INCREASED RISK OF BREAST CANCER FROM POTATO  
2 CONSUMPTION; IS THAT CORRECT?

3 A YES.

4 Q DE STEFANI 2004, A SIGNIFICANT INCREASE IN  
5 GASTRIC CANCER IN WOMEN; TRUE?

6 A YES.

7 Q ALL THIS IS IN RELATIONSHIP TO POTATO  
8 CONSUMPTION; RIGHT?

9 A CORRECT.

10 Q AND BUNIN 2005 FOUND MORE THAN A DOUBLING OF  
11 THE RISK OF MEDULLOBLASTOMA THAT WAS STATISTICALLY  
12 SIGNIFICANT, AND ALSO SHOWED A DOSE-RESPONSE  
13 RELATIONSHIP?

14 A YES.

15 Q ALL RIGHT. CHAN 2005, PANCREATIC CANCER  
16 INCREASED, AS WELL?

17 A YES.

18 Q AND RADOSAVLJEVIC, FROM SERBIA, IN 2005, A  
19 GREATER THAN SIX-FOLD INCREASED RISK OF BLADDER CANCER;  
20 IS THAT CORRECT?

21 A YES.

22 Q AND LASTLY, MICHELS 2006, BREAST CANCER  
23 SIGNIFICANTLY INCREASED; IS THAT RIGHT?

24 A YES.

25 MR. METZGER: YOUR HONOR, I SEE THAT IT'S ALMOST  
26 NOON. SHALL WE BREAK AT THIS POINT?

27 THE COURT: WE'LL TAKE A RECESS AT THIS TIME.

28 MR. METZGER: THANK YOU.

1 THE COURT: HOW MUCH LONGER ARE YOU GOING TO BE  
2 WITH DR. INFANTE?

3 MR. METZGER: I WILL BE ALL DAY WITH HIM AND  
4 PROBABLY INTO THE NEXT DAY. HE'S GOING TO GO THROUGH  
5 ALL THE DATA ON ACRYLAMIDE AND ALL THE DATA ON COFFEE  
6 FOR THOSE PARTICULAR TYPES OF CANCER THAT HE'S  
7 EVALUATED. IT'S A LOT OF INFORMATION.

8 THE COURT: WHAT'S THE ANTICIPATED LENGTH OF  
9 CROSS-EXAMINATION.

10 MR. SCHURZ: IF MR. METZGER TURNS DR. INFANTE OVER  
11 BY MID-MORNING TOMORROW, WE WILL -- I WOULD EXPECT WE  
12 WOULD CONCLUDE DR. INFANTE BY THE END OF THE DAY. I'M  
13 NOT GOING TO GO MUCH --

14 THE COURT: WHO ELSE DO WE HAVE FOR THIS WEEK?

15 MR. METZGER: WE THEN HAVE DR. HUFF, WHO IS COMING  
16 IN FROM THE EAST COAST. AND HE'LL BE HERE -- I THINK  
17 HE'S ARRIVING TOMORROW NIGHT. HE'LL BE AVAILABLE ON  
18 WEDNESDAY.

19 THE COURT: HOW LONG WILL HIS TESTIMONY TAKE?

20 MR. METZGER: I THINK IT WILL TAKE A DAY. BUT I  
21 THINK THAT DR. INFANTE IS PROBABLY GOING TO END UP  
22 TAKING THREE DAYS, THERE'S SO MUCH INFORMATION. I COULD  
23 BE WRONG.

24 THE COURT: OKAY. WE'LL BE IN RECESS TILL 1:30.

25 (AT 11:59 A.M., A LUNCH RECESS WAS TAKEN  
26 UNTIL 1:30 P.M. OF THE SAME DAY.)

27 (TRANSCRIPT CONTINUES ON PAGE 151.)

28

# **EXHIBIT “D”**

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 323

HON. ELIHU M. BERLE, JUDGE

COUNCIL FOR EDUCATION AND RESEARCH ON )  
TOXICS, A CALIFORNIA CORPORATION, )

PLAINTIFF, )

VS. )

CASE NO.  
BC435759

STARBUCKS CORPORATION, A CALIFORNIA )  
CORPORATION, ET AL., )

DEFENDANTS. )

\_\_\_\_\_  
AND CONSOLIDATED ACTION. )

REPORTER'S TRANSCRIPT OF TRIAL PROCEEDINGS

MONDAY, OCTOBER 20, 2014

AFTERNOON SESSION

APPEARANCES:

FOR THE PLAINTIFF: METZGER LAW GROUP  
BY: RAPHAEL METZGER, ESQ.  
KENNETH HOLDREN, ESQ.  
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LONG BEACH, CALIFORNIA 90802

FOR THE DEFENDANT: MORRISON & FOERSTER  
BY: JAMES SCHURZ, ESQ.  
MICHELE B. CORASH, ESQ.  
425 MARKET STREET  
SAN FRANCISCO, CALIFORNIA 94105

CCROLA JOB  
NO. 114684

KAREN VILICICH, CSR. NO. 7634  
OFFICIAL REPORTER PRO TEMPORE

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I N D E X

MONDAY, OCTOBER 20, 2014 (P.M.)

CHRONOLOGICAL AND ALPHABETICAL INDEX OF WITNESSES

<u>PLAINTIFF WITNESS:</u>	<u>PAGE</u>
PETER FRANCIS INFANTE, DR.P.H. DIRECT BY MR. METZGER	151

EXHIBIT INDEX  
(NONE OFFERED.)

1 CASE NUMBER: BC435759  
2 CASE NAME: CERT VS. STARBUCKS  
3 LOS ANGELES, CALIFORNIA MONDAY, OCTOBER 20, 2014  
4 DEPARTMENT 323 HON. ELIHU M. BERLE, JUDGE  
5 REPORTER: KAREN VILICICH, CSR NO. 7634  
6 TIME: P.M. SESSION  
7

8 (THE FOLLOWING PROCEEDINGS WERE HELD  
9 IN OPEN COURT:)

10

11 THE COURT: BACK ON THE RECORD IN THE CASE OF CERT  
12 VERSUS STARBUCKS. ALL COUNSEL ARE PRESENT. DR. INFANTE  
13 IS ON THE STAND.

14 DR. INFANTE, YOU UNDERSTAND YOU ARE STILL  
15 UNDER OATH?

16 THE WITNESS: YES, SIR.

17 THE COURT: PLEASE RESTATE YOUR NAME FOR THE  
18 RECORD.

19 THE WITNESS: PETER FRANCIS INFANTE, I-N-F-A-N-T-E.

20 THE COURT: MR. METZGER WAS INQUIRING.

21 COUNSEL, YOU MAY PROCEED.

22 MR. METZGER: THANK YOU, YOUR HONOR.  
23

24 DIRECT EXAMINATION (CONTINUED)

25

26 BY MR. METZGER:

27 Q WHEN WE BROKE FOR LUNCH, WE WERE DISCUSSING  
28 THE CASE-CONTROL STUDIES OF CANCER IN RELATIONSHIP TO

1 POTATO CONSUMPTION.

2 YOU HAD MENTIONED, DR. INFANTE, THE CHAN  
3 STUDY FROM 2005 WHICH SHOWED AN INCREASED RISK OF  
4 PANCREATIC CANCER IN RELATIONSHIP TO POTATO CONSUMPTION.

5 WAS THERE ANYTHING IN THAT STUDY THAT YOU  
6 FOUND TO BE PARTICULARLY SIGNIFICANT?

7 A YES.

8 Q WHAT WAS THAT?

9 A IT WAS THAT POTATOES IS THE ONLY VEGETABLE  
10 CONSIDERED OR ANALYZED FOR IN THE STUDY THAT DEMONSTRATED  
11 AN INCREASE IN RISK WITH AN INCREASE IN CONSUMPTION. IN  
12 FACT, IF YOU LOOK AT "TOTAL VEGETABLES WITHOUT POTATOES,"  
13 IT SHOWED AN INVERSE RELATION, MEANING THAT THE MORE YOU  
14 CONSUMED, THE LOWER WAS YOUR RISK FOR PANCREATIC CANCER.

15 Q IS THAT SET FORTH IN TABLE 2 OF THE CHAN  
16 STUDY?

17 A I DON'T KNOW -- YES, IT IS.

18 Q COULD WE HAVE THE NEXT SLIDE.

19 IS THAT THE STUDY TITLED, "VEGETABLE AND  
20 FRUIT INTAKE AND PANCREATIC CANCER IN A POPULATION-BASED  
21 CASE-CONTROL STUDY IN THE SAN FRANCISCO BAY AREA"?

22 A YES, IT IS.

23 Q AND TABLE 2 PROVIDES THE ODDS RATIOS OF 95  
24 PERCENT, CONFIDENCE INTERVALS BY QUARTILE OF VEGETABLE  
25 INTAKE IN THE STUDY; IS THAT CORRECT?

26 A YES, BY THE TYPE OF VEGETABLE.

27 Q IF WE LOOK AT THE TABLE, I SEE THAT POTATOES  
28 IS AT THE VERY BOTTOM AND ALL THE OTHER VEGETABLES ARE

1 ABOVE IT; IS THAT CORRECT?

2 A YES.

3 Q ALL RIGHT. IF WE LOOK AT THE FIRST THREE  
4 ROWS, "TOTAL FRUITS AND VEGETABLES," "TOTAL VEGETABLES"  
5 AND "TOTAL VEGETABLES WITHOUT POTATOES," IF WE LOOK AT  
6 THE TREND, IT IS HARD TO SEE, BUT -- WELL, LET'S LOOK AT  
7 THE FIRST ROW, "TOTAL FRUITS AND VEGETABLES."

8 FOR THE FIRST QUARTILE, 1.0 RISK. FOR THE  
9 SECOND QUARTILE, 0.83. FOR THE THIRD QUARTILE, 0.70.  
10 FOR THE FOURTH QUARTILE, 0.47.

11 THOSE NUMBERS ARE DECREASING?

12 A CORRECT.

13 MR. SCHURZ: OBJECTION. THE DOCUMENT SPEAKS FOR  
14 ITSELF. ALSO A HEARSAY OBJECTION. COUNSEL IS READING  
15 THE TABLE INTO THE RECORD.

16 THE COURT: I ASSUME WE WILL GET TO A QUESTION.

17 Q BY MR. METZGER: IS THAT WHAT YOU MEANT BY  
18 AN INVERSE RELATIONSHIP?

19 A YES, IT IS. THE MORE YOU CONSUME, THEN THE  
20 LOWER IS YOUR RISK FOR PANCREATIC CANCER.

21 Q AND THE LAST COLUMN INDICATES A P-TREND OF  
22 LESS THAN 0.0001.

23 WHAT DOES THAT INDICATE?

24 A THAT MEANS THAT THAT TREND WOULD OCCUR DUE  
25 TO CHANCE ONE TIME OUT OF 10,000. DUE TO CHANCE ALONE,  
26 ONE TIME OUT OF 10,000.

27 Q ALL RIGHT. AND IF YOU LOOK AT THE DATA FOR  
28 ALL OF THE VEGETABLE CATEGORIES EXCEPT POTATOES, IS THERE

1 A GENERAL RESULT THAT YOU SEE HERE?

2 A YES.

3 Q WHAT IS THAT?

4 A THAT THE MORE YOU CONSUME, THE LOWER AND  
5 LOWER IS YOUR RISK FOR DEVELOPING PANCREATIC CANCER.

6 Q OKAY. AND THEN IF YOU LOOK AT POTATOES, THE  
7 LAST ROW IN THE TABLE SHOWS THE RISK FOR QUARTILE 1 AT  
8 1.0. QUARTILE 2 AT 1.3. QUARTILE 3 AT 1.1. QUARTILE 4  
9 AT 1.4. AND THE ODDS RATIO -- I'M SORRY, THE 95 PERCENT  
10 CONFIDENCE INTERVAL FOR THE 1.4 VALUE, THE POTATOES IN  
11 THE HIGHEST CONSUMPTION CATEGORY IS 1.0 TO 1.9; IS THAT  
12 CORRECT?

13 MR. SCHURZ: OBJECTION; HEARSAY.

14 THE COURT: THE OBJECTION IS SUSTAINED. I READ THE  
15 CHART. ALL THE WITNESS IS SAYING, "YES. YES." I  
16 THOUGHT THIS WAS LEADING TO SOME ANALYTICAL QUESTION.

17 MR. METZGER: IT IS, YOUR HONOR. I DON'T KNOW HOW  
18 TO DO THIS OTHER -- BECAUSE WE NEED A RECORD. THIS  
19 DOCUMENT IS NOT -- THE POWERPOINT IS NOT COMING INTO  
20 EVIDENCE. I THINK I NEED TO GET THE RESULTS INTO  
21 EVIDENCE.

22 THE COURT: WELL, TRY TO SHORTEN IT WITHOUT  
23 RECITING EVERYTHING THAT IS ON THE CHART.

24 MR. METZGER: I WILL TRY, YOUR HONOR. THANK YOU.

25 Q DR. INFANTE, WHAT IS THE SIGNIFICANCE TO YOU  
26 OF THAT DATA FOR POTATOES IN THIS CASE-CONTROL STUDY OF  
27 PANCREATIC CANCER?

28 A IT WAS THE ONLY -- IT IS THE ONLY FOOD ITEM

1 ANALYZED FOR THAT SHOWS AN INCREASE IN THE RISK WITH AN  
2 INCREASE IN CONSUMPTION WHEREAS ALL THE OTHERS, AND  
3 PARTICULARLY THE THIRD ENTRY, "TOTAL VEGETABLES WITHOUT  
4 POTATOES," SHOWS AN INVERSE RELATION. SO IT IS VERY  
5 STRIKING THAT IT IS THE ONLY ONE OF ALL THE FOOD ITEMS  
6 MENTIONED THAT GOES IN THE OPPOSITE DIRECTION.

7 Q THE ONLY ONE OF ALL THE VEGETABLES?

8 A OF ALL THE VEGETABLES, YES.

9 Q ALL RIGHT. NOW, WE HAD NOT QUITE FINISHED  
10 WITH THE STUDIES THAT YOU EVALUATED REGARDING CANCER IN  
11 RELATIONSHIP TO CONSUMPTION OF POTATOES. I THINK WE LEFT  
12 OFF WITH MICHELS AT 2006.

13 ARE THERE MORE STUDIES?

14 A YES.

15 Q COULD WE HAVE THE NEXT SLIDE.

16 YOU HAVE ISO FROM JAPAN IN 2007 SHOWING AN  
17 INCREASED RISK FOR COLON CANCER IN RELATIONSHIP TO POTATO  
18 CONSUMPTION; IS THAT CORRECT?

19 A YES.

20 Q AND DID THAT STUDY REPORT A DOSE-RESPONSE  
21 RELATIONSHIP FOR CONSUMPTION OF POTATOES AND COLON  
22 CANCER?

23 A YES, IN BOTH MEN AND WOMEN SEPARATELY.

24 Q AND MARCHIONI 2007, WHAT DID YOU -- A  
25 2.2-FOLD INCREASED RISK OF ORAL CANCER?

26 A YES, IT WAS DEMONSTRATED THE DOSE-  
27 RESPONSE --

28 MR. SCHURZ: OBJECTION; HEARSAY. HE IS READING

1 TABLES AGAIN.

2 THE COURT: I COULD NOT HEAR A THING. EVERYONE WAS  
3 TALKING OVER EACH OTHER. START OVER, ASK THE QUESTION,  
4 TAKE A BREATH SO I CAN HEAR IF THERE IS AN OBJECTION.

5 Q BY MR. METZGER: DR. INFANTE, WHAT DID YOU  
6 NOTE FROM THE MARCHIONI STUDY OF 2007?

7 A THAT IT DEMONSTRATED A SIGNIFICANT INCREASE  
8 OF RISK OF ORAL CANCER, AND ALSO THERE WAS A  
9 DOSE-RESPONSE INDICATING THAT THE MORE POTATO  
10 CONSUMPTION, THE HIGHER THE RISK.

11 Q WHAT DID YOU NOTE REGARDING THE LUCENTEFORTE  
12 STUDY FROM 2008 IN ITALY?

13 A IT DEMONSTRATED A SIGNIFICANT INCREASE IN  
14 STOMACH CANCER, AND ALSO A DOSE-RESPONSE BY THE AMOUNT OF  
15 POTATOES CONSUMED.

16 Q WHAT DID YOU NOTE REGARDING THE NASHAR STUDY  
17 FROM 2008 IN SAUDI ARABIA?

18 A IT SHOWS A HIGHER RISK, BUT THE RESULT IS  
19 NOT QUITE -- IT IS ONLY SIGNIFICANT AT THE .14 LEVEL, SO  
20 IT IS NOT AT THE .05 LEVEL. SO THAT RESULT ONLY OCCURRED  
21 14 TIMES OUT OF 100 DUE TO CHANCE.

22 Q OKAY. SONESTEDT 2008, SWEDEN, REGARDING  
23 BREAST CANCER. WHAT DID YOU NOTE REGARDING THAT STUDY?

24 A WELL, I NOTICED THAT FOR THE BREAST CANCER  
25 THAT IS NOT SENSITIVE TO ESTROGENS -- THERE ARE DIFFERENT  
26 KINDS OF BREAST CANCER, AND THE ONE THAT IS NOT SENSITIVE  
27 TO ESTROGENS, THERE IS A SIGNIFICANT INCREASE IN RELATION  
28 TO POTATO CONSUMPTION.

1 THE COURT: LET ME ASK THIS, MR. METZGER: IS THERE  
2 A REASON WHY WE HAVE TO GO THROUGH ALL OF THESE STUDIES  
3 AND HAVE DR. INFANTE TESTIFY WHAT THESE STUDIES MEAN AND  
4 WHAT THEY FOUND IN EACH STUDIES?

5 MR. METZGER: I THINK SO, YOUR HONOR.

6 THE COURT: WHY?

7 MR. METZGER: THESE STUDIES ARE SHOWING THAT THE --  
8 ONE --

9 THE COURT: THEY MAY. WHATEVER THEY SHOW, THEY  
10 SHOW. THOSE STUDIES ARE NOT IN EVIDENCE. DR. INFANTE IS  
11 ON THE STAND, HE WILL TESTIFY TO HIS OPINIONS AND THE  
12 BASES OF HIS OPINIONS. DO WE NEED TO GO INTO THE STUDY?

13 THE WITNESS CAN COME INTO COURT AND SAY, "I  
14 COME TO THE CONCLUSION THAT THE MOON IS MADE OUT OF SWISS  
15 CHEESE."

16 "FINE. WHAT DO YOU BASE THE OPINION ON?"

17 "BEING ADVISED BY READING THE ENCYCLOPEDIA  
18 BRITANNICA FROM COVER TO COVER."

19 OKAY. DOES THAT MEAN WE ARE GOING TO HAVE  
20 SOMEONE TESTIFY AS TO WHAT EVERY -- WHAT IS IN EVERY  
21 VOLUME, I DON'T KNOW IF IT EVEN EXISTS ANYMORE, OF THE  
22 ENCYCLOPEDIA BRITANNICA?

23 MR. METZGER: I UNDERSTAND YOUR POINT, YOUR HONOR.

24 THE COURT: LET'S TRY TO SHORTEN IT UP.

25 MR. METZGER: I WILL TRY TO SHORTEN IT UP, YES.

26 Q WE WILL TALK ABOUT A FEW OF THESE. THERE IS  
27 ANOTHER STUDY HERE REGARDING PANCREATIC CANCER BY POLESEL  
28 IN 2010.

1                   FIRST, WOULD YOU TELL US WHAT THE RESULTS  
2 WERE OF -- THE MAIN RESULT OF THAT STUDY WAS REGARDING  
3 POTATO CONSUMPTION, DR. INFANTE?

4           A           IT DEMONSTRATES A SIGNIFICANT INCREASED RISK  
5 OF PANCREATIC CANCER AND ALSO A SIGNIFICANT  
6 DOSE-RESPONSE.

7           Q           WAS THERE ANYTHING IN PARTICULAR ABOUT THAT  
8 STUDY THAT YOU FOUND IMPORTANT IN THIS CONTEXT?

9           A           YES.

10          Q           IS THAT INFORMATION THAT IS SET FORTH IN  
11 TABLE 4 OF THE POLESEL STUDY?

12          A           YES, IT IS.

13          Q           COULD WE HAVE THE NEXT SLIDE.

14                    WOULD YOU TELL US WHAT THAT IS?

15          A           WHEN YOU LOOK AT POTATO CONSUMPTION, YOU SEE  
16 AT THE BOTTOM, YOU SEE A POSITIVE DOSE-RESPONSE BY  
17 CONSUMPTION CATEGORY, AND RISK OF PANCREATIC CANCER.  
18 THEN IF YOU LOOK RIGHT ABOVE IT, FOR EXAMPLE, AT "COOKED  
19 VEGETABLES," ALL COOKED VEGETABLES, YOU, IN FACT, SEE AN  
20 INVERSE RELATION. THAT THE MORE OF THEM YOU ATE, THE  
21 LOWER WAS YOUR RISK FOR PANCREATIC CANCER.

22          Q           WHAT IS THE SIGNIFICANCE OF THAT TO YOU?

23          A           WELL, IT IS SIGNIFICANT BECAUSE IT LOOKS  
24 LIKE, YOU KNOW, EATING COOKED VEGETABLES IS, YOU KNOW,  
25 THE MORE THAT YOU EAT, IT LOWERS YOUR RISK OF PANCREATIC  
26 CANCER, WITH THE EXCEPTION OF POTATOES, WHERE THE MORE  
27 THAT YOU EAT, YOU HAVE A HIGHER AND HIGHER RISK OF  
28 DEVELOPING PANCREATIC CANCER.

1 Q OKAY. ALL RIGHT. NOW, IF WE COULD GO BACK  
2 ONE SLIDE.

3 ALL OF THE STUDIES UP TO 2010 HERE, THERE  
4 WAS A PREVIOUS SLIDE THAT HAD STUDIES GOING BACK TO 1975,  
5 ARE MOST OF THESE STUDIES STUDIES THAT DR. BOFFETTA  
6 MISSED IN HIS 2011 REVIEW?

7 A YES.

8 Q ALL RIGHT. AND DID YOU ALSO FIND STUDIES  
9 SUBSEQUENT TO DR. BOFFETTA'S 2011 REVIEW WHICH REPORTED  
10 INCREASED RISKS OF VARIOUS CANCERS IN RELATIONSHIP TO  
11 POTATO CONSUMPTION?

12 A YES.

13 Q AND HOW MANY SUCH STUDIES WERE THERE?

14 A WELL, THERE ARE FOUR INDICATED IN THIS  
15 SLIDE, THE BROVI, SHAMSI, STOTT-MILLER AND DE STEFANI.

16 Q HOW MANY OF THOSE FOUR SHOWED STATISTICALLY  
17 SIGNIFICANT DOSE-RESPONSE RELATIONSHIPS OF PANCREATIC  
18 CANCER WITH POTATO CONSUMPTION?

19 A WELL, THEY DON'T SHOW PANCREATIC CANCER.  
20 THEY SHOW ORO-PHARYNGEAL, BREAST.

21 Q I'M SORRY. HOW MANY OF THEM SHOWED  
22 STATISTICALLY SIGNIFICANT DOSE-RESPONSE RELATIONSHIPS  
23 WITH THE CANCERS THAT THEY EVALUATED?

24 A THREE.

25 Q SO DID YOU REACH SOME CONCLUSIONS REGARDING  
26 THIS BODY OF LITERATURE?

27 A YES.

28 Q NEXT SLIDE.

1                   NEXT ONE.

2                   WHAT WERE THOSE?

3           A           WELL, OF THE 28 STUDIES, 23 REPORTED  
4   STATISTICALLY SIGNIFICANT INCREASED RISKS OF CANCER. OF  
5   THE 28 STUDIES, NINE REPORT MORE THAN A DOUBLING OF THE  
6   CANCER RISK. AND OF THE SAME STUDIES, 13 REPORT  
7   STATISTICALLY SIGNIFICANT DOSE-RESPONSE RELATIONSHIPS.

8           Q           WHAT DID YOU CONCLUDE AS A RESULT OF THESE  
9   STUDIES?

10          A           THAT THE CASE-CONTROL STUDIES OF CANCERS AND  
11   POTATO CONSUMPTION PROVIDE SUPPORTIVE EVIDENCE FOR THE  
12   HUMAN CARCINOGENICITY OF ACRYLAMIDE.

13          MR. SCHURZ: OBJECTION; MOVE TO STRIKE AS LACKS  
14   FOUNDATION. THERE IS NO INDICATION THAT ANY OF THESE  
15   STUDIES HAD ANYTHING TO DO WITH ACRYLAMIDE. THEY DEAL  
16   WITH FRIED POTATO STUDIES.

17          THE COURT: OVERRULED. THE ANSWER WILL STAND.  
18   COUNSEL CAN ARGUE IT.

19          Q           BY MR. METZGER: DR. INFANTE, WE HAVE  
20   DISCUSSED THE OCCUPATIONAL EPIDEMIOLOGY STUDIES OF  
21   ACRYLAMIDE PRODUCTION WORKERS AND THE CASE-CONTROL  
22   STUDIES OF CANCERS IN RELATION TO POTATO CONSUMPTION.  
23   YOU INDICATED, I THINK, THAT THE THIRD TYPE OF  
24   EPIDEMIOLOGIC STUDY THAT YOU EVALUATED REGARDING  
25   ACRYLAMIDE WAS DIETARY ACRYLAMIDE STUDIES; IS THAT  
26   CORRECT?

27          A           YES.

28          Q           WHAT ARE THOSE STUDIES?

1           A           WELL, THESE ARE EPIDEMIOLOGICAL STUDIES OF,  
2 YOU KNOW, EVALUATING THE DIETS OF INDIVIDUALS AND IN  
3 RELATION TO THEIR CANCERS.

4           Q           NOW, IN EVALUATING THIS BODY OF LITERATURE,  
5 DID YOU CONSIDER WHETHER THESE STUDIES HAD ADEQUATE  
6 STATISTICAL POWER TO DETECT CANCER EFFECTS AT DIETARY  
7 EXPOSURE LEVELS?

8           A           IN GENERAL, YES.

9           Q           WHAT DID YOU CONCLUDE?

10          A           THAT THEY LACKED STATISTICAL POWER TO, YOU  
11 KNOW, ADEQUATELY EVALUATE THE CANCER RISK FROM DIETARY  
12 EXPOSURE TO ACRYLAMIDE.

13          Q           ALTHOUGH THEY LACK STATISTICAL POWER, DID  
14 SOME OF THE STUDIES NEVERTHELESS YIELD INCREASED RISKS?

15          A           YES.

16          Q           ALL RIGHT. IF WE CAN GO TO THE NEXT SLIDE.  
17 GO AHEAD.

18                    ALL RIGHT. AND YOU HAVE PREPARED THE DATA  
19 FOR THESE BEGINNING WITH HOGERVORST 2007; IS THAT  
20 CORRECT?

21          A           YES.

22          Q           AND WOULD YOU TELL US WHAT DATA FROM THAT  
23 STUDY YOU FOUND SIGNIFICANT?

24          A           WELL, THERE ARE -- FOR OVARIAN CANCER IN THE  
25 HIGHEST QUINTILE, YOU HAVE A SIGNIFICANT INCREASE. FOR  
26 ENDOMETRIAL CANCER AMONG NEVER-SMOKERS AND OVARIAN CANCER  
27 IN NEVER-SMOKERS.

28          Q           WHY DO YOU FIND THE DATA REGARDING

1 NEVER-SMOKERS TO BE IMPORTANT?

2 A BECAUSE YOU MAY HAVE CONFOUNDING FROM  
3 CIGARETTE SMOKING IN SOME OF THESE STUDIES. WHEN YOU  
4 EVALUATE THE DATA FOR NON-SMOKERS, YOU DON'T HAVE TO, YOU  
5 KNOW, CONSIDER THE CONFOUNDING FROM CIGARETTE SMOKING.

6 Q THE NEXT STUDY THAT YOU LIST IS OLESEN 2008,  
7 ESTROGEN-RECEPTOR POSITIVE BREAST CANCER. WHAT DID YOU  
8 FIND OF IMPORT FROM THAT STUDY?

9 A THAT DEMONSTRATES A SIGNIFICANT INCREASE.

10 Q HOGERVORST 2008 REGARDING KIDNEY CANCER,  
11 WHAT DID YOU FIND IN THAT STUDY OF SIGNIFICANCE?

12 A SAME THING, IT DEMONSTRATED A SIGNIFICANT  
13 INCREASE, AS WELL AS THE SCHOUTEN STUDY FOR ORAL CANCER  
14 IN NON-SMOKERS, WHICH, AGAIN, IS IMPORTANT BECAUSE  
15 CIGARETTES -- THERE IS A RISK OF ORAL CANCER FROM  
16 CIGARETTE SMOKING.

17 Q WHAT ABOUT WILSON 2010, WHAT DID YOU FIND OF  
18 NOTE IN THAT STUDY?

19 A I FOUND THAT THERE WAS A SIGNIFICANT  
20 INCREASE IN ENDOMETRIAL CANCER AND OVARIAN SEROUS CANCER,  
21 A TYPE OF OVARIAN CANCER WITH A SIGNIFICANT P-TREND.

22 Q WHAT DID YOU FIND OF SIGNIFICANCE IN THE LIN  
23 STUDY FROM 2010?

24 A WELL, THERE IT EVALUATED ESOPHAGEAL CANCER  
25 AND YOU SEE THAT IN THE HIGHEST QUARTILE OF CONSUMPTION,  
26 YOU HAVE A SIGNIFICANT INCREASE IN ESOPHAGEAL CANCER.  
27 THEN ALSO IN THE NON-SMOKERS, YOU HAVE ALMOST A  
28 THREE-FOLD RISK, WHICH IS STATISTICALLY SIGNIFICANT.

1                   AGAIN, THAT IS IMPORTANT BECAUSE ES --  
2 CIGARETTE SMOKING IS ASSOCIATED WITH ESOPHAGEAL CANCER.  
3 SO YOU ARE ELIMINATING THE CIGARETTE SMOKING AS PART OF  
4 THE CONTRIBUTION OF THIS ELEVATED RISK.

5           Q           SO EVEN WHEN SMOKING -- WHEN THE STUDY WAS  
6 DONE IN NON-SMOKERS, THEY FOUND AN ALMOST THREE-FOLD RISK  
7 OF SQUAMOUS CELL ESOPHAGEAL CANCER?

8           A           YES.

9           Q           WHAT DID YOU FIND OF NOTE IN THE 2010 STUDY  
10 BY HIRVONEN?

11          A           THERE IS A SIGNIFICANT INCREASE OF LUNG  
12 CANCER IN MALE SMOKERS.

13          Q           WHAT DID YOU FIND OF NOTE IN THE 2010 STUDY  
14 BY BURLEY?

15          A           BORDERLINE SIGNIFICANT INCREASE OF BREAST  
16 CANCER IN PRE-MENOPAUSAL WOMEN.

17          Q           WHAT DID YOU FIND OF NOTE IN THE 2012 STUDY  
18 BY BONGERS?

19          A           I FOUND A SIGNIFICANT INCREASE IN THE RISK  
20 OF LYMPHOMA AND MULTIPLE MYELOMA.

21          Q           AND ALL OF THESE STUDIES ARE OF DIETARY  
22 ACRYLAMIDE?

23          A           YES.

24          Q           WHAT DID YOU FIND OF NOTE IN THE HOGERVORST  
25 2014 STUDY?

26          A           THE COLORECTAL CANCER THAT HAD A SPECIFIC  
27 GENE MUTATION, K-RAS MUTATION, THAT IN THE HIGHEST  
28 QUARTILE OF CONSUMPTION IN MEN, THERE WAS A SIGNIFICANT

1 INCREASE.

2 Q WHAT DID YOU FIND OF SIGNIFICANCE IN THE  
3 LUJAN-BARROSO STUDY FROM 2014?

4 A YOU HAVE AN INCREASE IN RISK RELATED TO  
5 ESOPHAGEAL CANCER, BUT THE HIGHEST RISK WAS FOUND IN  
6 NON-SMOKERS.

7 Q LASTLY, WHAT DID YOU FIND OF SIGNIFICANCE IN  
8 THE OBON-SANTACANA 2014 STUDY?

9 A A SIGNIFICANT INCREASE IN THE ENDOMETRIAL  
10 CANCER, WITH ALSO A SIGNIFICANT DOSE-RESPONSE.

11 Q ALL RIGHT. NOW, WHAT DID YOU CONCLUDE  
12 REGARDING THE BODY OF EPIDEMIOLOGIC STUDIES OF VARIOUS  
13 CANCERS IN RELATIONSHIP TO DIETARY ACRYLAMIDE EXPOSURE?

14 A WELL, I CONCLUDED THAT ALTHOUGH, AS I  
15 MENTIONED AT THE BEGINNING, THE STUDIES LACK ADEQUATE  
16 STATISTICAL POWER TO DETECT INCREASED CANCER RISKS AT  
17 DIETARY LEVELS OF ACRYLAMIDE EXPOSURE, SIGNIFICANTLY  
18 INCREASED RISKS HAVE BEEN REPORTED FOR BREAST CANCER,  
19 COLORECTAL CANCER WITH K-RAS MUTATIONS, ENDOMETRIAL  
20 CANCER, ESOPHAGEAL CANCER, KIDNEY CANCER, LUNG CANCER,  
21 LYMPHOMA, MULTIPLE MYELOMA, ORAL CANCER AND OVARIAN  
22 CANCERS.

23 Q DID YOU ASSESS WHETHER THE RESULTS OF THESE  
24 STUDIES SHOWED SOME CONSISTENCY AMONG CANCER SITES OR  
25 TYPES?

26 A YES.

27 Q WHAT DID YOU FIND?

28 A I FOUND THAT WITH ENDOMETRIAL CANCER, THERE

1 WERE THREE STUDIES.

2 IF YOU GO TO THE NEXT SLIDE.

3 WITH BREAST CANCER, THERE WERE TWO STUDIES;  
4 OVARIAN CANCER, THERE WERE TWO STUDIES; AND WITH  
5 ESOPHAGEAL CANCER, THERE WERE TWO STUDIES.

6 Q WHAT DID YOU CONCLUDE FROM THIS ANALYSIS?

7 A I CONCLUDED THAT THE DIETARY ACRYLAMIDE  
8 STUDIES RELATED TO CANCER PROVIDE SOME EVIDENCE OF A  
9 HUMAN CANCER RISK FROM EXPOSURE TO ACRYLAMIDE IN THE  
10 DIET.

11 Q ALL RIGHT. NOW, HAVE YOU NOW TOLD THE COURT  
12 THE OPINIONS THAT YOU FORMED REGARDING ACRYLAMIDE IN  
13 HUMAN CANCER?

14 A YES.

15 Q ALL RIGHT. DID I ASK YOU TO DO ADDITIONAL  
16 WORK IN THIS CASE IN ADDITION TO EVALUATING HUMAN CANCER  
17 IN RELATIONSHIP TO ACRYLAMIDE EXPOSURE?

18 A YES.

19 Q WHAT DID I ADDITIONALLY ASK YOU TO DO?

20 A YOU ASKED ME TO EVALUATE THE LITERATURE  
21 RELATED TO COFFEE CONSUMPTION AND CANCER RISK.

22 Q OKAY. DID YOU HAVE AN UNDERSTANDING AS TO  
23 WHY I ASKED YOU TO EVALUATE THAT?

24 THE COURT: SUSTAINED.

25 MR. METZGER: DID YOU SAY SOMETHING, YOUR HONOR?

26 THE COURT: YES, THE OBJECTION IS SUSTAINED.

27 MR. METZGER: I DID NOT HEAR. I'M SORRY. OKAY.

28 THE COURT: YOU ARE ASKING HIM TO SPECULATE AS TO

1 WHY YOU ASKED HIM TO DO SOMETHING?

2 IF YOU TOLD HIM WHY IT IS A DIFFERENT STORY.  
3 HOW COULD HE READ YOUR MIND?

4 Q BY MR. METZGER: DID I TELL YOU WHY I WAS  
5 ASKING YOU TO EVALUATE COFFEE CONSUMPTION AND CANCER?

6 A YES. WELL, I MEAN, YOU SAID THAT YOU WANTED  
7 ME TO EVALUATE THE LITERATURE TO SEE IF THERE WAS AN  
8 ELEVATED RISK FROM -- OF CANCER FROM COFFEE CONSUMPTION.

9 Q DID YOU UNDERTAKE THAT EFFORT?

10 A YES, I DID.

11 Q HOW DID YOU GO ABOUT DOING THAT?

12 A WELL, AFTER LOOKING AT THE LITERATURE ON  
13 PUB-MED AND TOXLINE, I REALIZED THERE WAS A TREMENDOUS  
14 AMOUNT OF LITERATURE ON COFFEE CONSUMPTION AND VARIOUS  
15 CANCERS. SO I NEEDED TO TRY TO FOCUS ON, YOU KNOW, SOME  
16 OF THE CANCERS, BECAUSE I DID NOT HAVE TIME TO EVALUATE  
17 ALL OF THE LITERATURE ON COFFEE CONSUMPTION AND ALL OF  
18 THE CANCERS THAT HAVE BEEN EVALUATED TO DATE.

19 Q HOW -- WHAT CANCERS DID YOU DECIDE TO  
20 EVALUATE?

21 A I DECIDED TO EVALUATE BLADDER CANCER,  
22 PANCREATIC CANCER AND CHILDHOOD LEUKEMIA INITIALLY.

23 Q WHY DID YOU DECIDE TO EVALUATE THE  
24 LITERATURE REGARDING COFFEE CONSUMPTION AND BLADDER  
25 CANCER?

26 A WELL, THE FIRST THING I DID WAS I SAID,  
27 WELL, WHAT DID IARC, THE INTERNATIONAL AGENCY ON RESEARCH  
28 ON CANCER HAVE TO SAY ABOUT COFFEE CONSUMPTION AND

1     CANCER.

2                     IN THEIR MONOGRAPH THAT WAS PUBLISHED IN  
3     1991, THEY STATED THAT THERE WAS WEAK EVIDENCE OF BLADDER  
4     CANCER AND PANCREATIC CANCER.    SO THAT TOLD ME THAT THEY  
5     CONSIDERED THAT THERE WAS SOME EVIDENCE.

6                     SO I THOUGHT, WELL, LET ME LOOK, THEN, AT  
7     THOSE SITES WHERE THEY CONCLUDED, WHAT 20 -- 1990, A  
8     LITTLE OVER 20 YEARS AGO THAT THERE WAS SOME EVIDENCE.  
9     THAT IS WHY I PICKED THOSE TWO SITES.    I ACTUALLY PICKED  
10    LUNG CANCER TOO, BUT I DID NOT REALLY HAVE ENOUGH TIME TO  
11    GET THROUGH ALL THE LITERATURE AND I STOPPED ON THAT ONE.

12            Q            ARE THERE ANY OTHER SITES OR TYPES OF CANCER  
13    THAT YOU CONSIDERED?

14            A            YEAH, I CONSIDERED CHILDHOOD LEUKEMIA FROM  
15    MATERNAL CONSUMPTION.

16            Q            WHY DID YOU CONSIDER THAT LITERATURE?

17            A            WELL, I HAVE -- CHILDHOOD LEUKEMIA HAS  
18    ALWAYS BEEN AN INTEREST OF MINE.    MY BACKGROUND, MY  
19    TRAINING AT MICHIGAN WAS FROM THE CENTER FOR HUMAN GROWTH  
20    AND DEVELOPMENT, AND I PUBLISHED A LOT OF PAPERS ON  
21    LEUKEMIA.    IN FACT, THE FIRST PAPER I PUBLISHED IN MY  
22    PROFESSIONAL CAREER RELATED TO ENVIRONMENTAL CANCER WAS  
23    LOOKING AT LEUKEMIA IN PRESCHOOL CHILDREN.    SO I ALWAYS  
24    HAD THAT INTEREST.

25                     SO I THOUGHT LET ME LOOK AT CHILDHOOD  
26    LEUKEMIA.    THEN WHILE I WAS DOING THAT I THOUGHT, WELL,  
27    YOU KNOW, THERE IS ONLY TWO -- WHAT ARE THE TWO MAIN  
28    CAUSES OF CANCER IN CHILDREN?    IT IS LEUKEMIA AND BRAIN

1 CANCER. THOSE ARE THE CANCERS THAT SHOW THE TWO HIGHEST  
2 RISKS.

3 SO I SAID, WELL, IS THERE ANY EVIDENCE ON  
4 BRAIN CANCER ALSO?

5 SO I LOOKED AT THOSE. THERE IS ONLY TWO OR  
6 THREE OF THEM, BUT NEVERTHELESS, I LOOKED AT THOSE. THAT  
7 IS HOW I GOT THERE.

8 MR. SCHURZ: YOUR HONOR, AT THIS TIME WE WOULD MOVE  
9 TO STRIKE AND PRECLUDE ANY TESTIMONY FROM DR. INFANTE  
10 WITH RESPECT TO CHILDHOOD BRAIN CANCER. THIS WAS AN  
11 ISSUE THAT WAS THE SUBJECT OF OUR IN LIMINE MOTION BEFORE  
12 TRIAL. THIS WAS THE VERY CONCERN THAT WE HAD. WE HAVE  
13 PROVIDED YOUR HONOR WITH A BRIEF ON THIS ISSUE.

14 WE WOULD ASK TO BE HEARD TO PRECLUDE ANY  
15 TESTIMONY FROM DR. INFANTE WITH RESPECT TO CANCER END  
16 POINTS THAT WERE NOT THE SUBJECT OF HIS DEPOSITION. HE  
17 INDICATED THAT HE LOOKED AT THREE SITES INITIALLY. HE  
18 DID NOT LOOK AT BRAIN CANCER. HE DID NOT TESTIFY ABOUT  
19 IT. WE GOT VERY CLEAR STATEMENTS IN THE DEPOSITION WITH  
20 RESPECT TO THAT, WHICH ARE CITED FOR YOUR HONOR IN THE  
21 CONTEXT OF THE BRIEF BEFORE YOU.

22 WE WOULD ALSO NOTE THAT YOU HAVE ALREADY  
23 HEARD ABOUT CHILDHOOD BRAIN CANCER FROM DR. MELNICK WHO  
24 DID SPEAK ABOUT THIS ISSUE AT HIS DEPOSITION. SO IT IS  
25 BOTH DUPLICATIVE AND REDUNDANT OF MATERIAL WE HAVE HEARD.  
26 BUT IN THE FIRST INSTANCE, THIS WITNESS WAS VERY CLEAR,  
27 "I EVALUATED THESE SITES AND THESE SITES ONLY," AND NOW  
28 WE LEARNED FOR THE FIRST TIME YESTERDAY WHEN WE RECEIVED

1 THOSE DEMONSTRATIVES THAT HE HAS ADDED ANOTHER SITE.

2 THE COURT: MR. METZGER, ANY REASON WHY THIS  
3 WITNESS'S TESTIMONY SHOULD NOT BE LIMITED TO THE OPINIONS  
4 EXPRESSED IN THE DEPOSITION?

5 MR. METZGER: WELL, I AGREE THAT THEY SHOULD BE  
6 LIMITED, BUT DR. INFANTE, IN EXHIBIT 222, WHICH WAS NOTES  
7 THAT HE PREPARED FOR THE DEPOSITION, PROVIDED HIS  
8 ANALYSIS FOR CHILDHOOD BRAIN CANCER.

9 THE COURT: WHATEVER THE NOTES SAY, IF HE DID  
10 TESTIFY THAT HE DID NOT REVIEW THE SITE, CERTAIN SITES  
11 FOR CANCER, WHY SHOULD HE BE ASKED CERTAIN QUESTIONS NOW  
12 ON THAT SAME SUBJECT?

13 MR. METZGER: DR. INFANTE DID NOT TESTIFY THAT HE  
14 DID NOT REVIEW CHILDHOOD BRAIN CANCER.

15 THE COURT: I THOUGHT HE LIMITED -- AS I RECALL, I  
16 DON'T HAVE IT IN FRONT OF ME RIGHT NOW, BUT AS I RECALL,  
17 HE WAS ASKED SPECIFICALLY ABOUT THE SCOPE OF HIS  
18 TESTIMONY.

19 MR. METZGER: HE WAS ASKED ABOUT THE SITES THAT HE  
20 INTENDED TO TESTIFY ABOUT AND HE MENTIONED THESE SITES.  
21 THERE WAS ALSO CHILDHOOD BRAIN CANCER IN HIS NOTES.

22 THE COURT: DO YOU HAVE THE PORTION OF THE  
23 DEPOSITION?

24 MR. SCHURZ: YES, YOUR HONOR, WE DO.

25 AND WE DIRECT YOUR HONOR TO -- THERE ARE A  
26 COUPLE OF PLACES THAT ARE QUITE CLEAR WITH RESPECT TO  
27 THIS ISSUE. IF YOU GO TO -- IT IS EXHIBIT C OF THE  
28 MATERIALS THAT PROVIDE THE DEPOSITION OF DR. PETER

1 INFANTE, AND IF YOUR HONOR GOES TO PAGE 21 OF EXHIBIT C,  
2 YOU WILL SEE.

3 THE COURT: ALL RIGHT. LET ME LOOK HERE.

4 MR. SCHURZ: BEGINNING AT LINE 18, YOUR HONOR.

5 THE COURT: OKAY, THE QUESTION WAS: "WHAT END  
6 POINTS DO YOU INTEND TO OFFER TESTIMONY THAT CONSUMPTION  
7 OF COFFEE RESULTS IN AN INCREASE INCIDENCE OF CANCER END  
8 POINTS?"

9 THE ANSWER: "PANCREATIC CANCER, BLADDER  
10 CANCER AND CHILDHOOD LEUKEMIA."

11 "ANY OTHERS?"

12 "THOSE ARE THE THREE FOR NOW THAT I HAVE  
13 GOTTEN TO. LOOKS LIKE THERE WAS SOME EVIDENCE WITH LUNG  
14 CANCER. I THINK I SENT YOU SOME NOTES I HAD ON THOSE.  
15 LOOKS TO ME THAT THE ROLE OF COFFEE IN LUNG CANCER IS  
16 LIKE POTENTIATING LUNG CANCER THERE PERHAPS WITH OTHER  
17 EXPOSURES."

18 I WILL LOOK A LITTLE FURTHER. JUST ONE  
19 SECOND.

20 THEN ON PAGE 22, THE WITNESS IS ASKED:

21 "ANY OTHER SITES YOU INTEND TO OFFER  
22 OPINIONS WITH RESPECT TO AN INCREASE INCIDENCE OF CANCER  
23 RESULTING FROM CONSUMPTION OF COFFEE?"

24 THE ANSWER: "THAT IS AS FAR AS I HAVE  
25 GOTTEN IN THE LITERATURE AT THIS POINT.

26 "HAVE YOU CONCLUDED YOUR WORK IN THIS  
27 MATTER?"

28 "I DON'T KNOW. I HAVE DONE WHAT I HAVE DONE

1 UP TO THIS POINT IN TIME. IF I AM ASKED TO DO MORE, I  
2 WILL."

3 ALL RIGHT. SO BASED UPON THAT TESTIMONY,  
4 WHY SHOULDN'T THE WITNESS BE LIMITED TO THE TESTIMONY AT  
5 THE DEPOSITION?

6 MR. METZGER: WHY SHOULD HE NOT BE LIMITED?

7 THE COURT: YES.

8 MR. METZGER: WELL, BECAUSE HE PREPARED NOTES WHICH  
9 HE PRODUCED AT THE DEPOSITION SETTING FORTH OPINIONS  
10 REGARDING CHILDHOOD BRAIN CANCER.

11 THE COURT: SO HE COULD HAVE TAKEN NOTES ON A LOT  
12 OF OTHER SUBJECTS.

13 MR. METZGER: I MEAN --

14 THE COURT: YOU BRING A WHOLE TRUCKLOAD OF  
15 DOCUMENTS AND HE IS ASKED, "ARE YOU GOING TO TESTIFY  
16 ABOUT THIS TRUCKLOAD?"

17 THE WITNESS SAYS, "NO."

18 WHAT GOOD ARE THE DOCUMENTS?

19 MR. METZGER: IF MR. SCHURZ -- THESE NOTES WERE  
20 PRODUCED FOR THE DEPOSITION. IF MR. SCHURZ ASKED HIM  
21 DIRECTLY, "WELL, I SEE THERE ARE NOTES HERE ABOUT  
22 CHILDHOOD BRAIN CANCER. ARE YOU GOING TO TESTIFY ABOUT  
23 THAT," THEN WE WOULD KNOW CLEARLY, BUT HE IS ASKING HIM,  
24 "WHAT DO YOU RECALL ARE THE THINGS YOU ARE GOING TO  
25 TESTIFY ABOUT?"

26 SO HE -- IT IS WITHIN HIS OPINIONS.

27 THE COURT: YOU WERE PRESENT AT THE DEPOSITION;  
28 WERE YOU NOT?

1 MR. METZGER: I WAS PRESENT.

2 THE COURT: WHY DIDN'T YOU SAY, "THERE ARE MORE  
3 SUBJECTS. HE IS GOING TO TESTIFY ABOUT SOMETHING ELSE."

4 HE COULD BRING A WHOLE BIBLE OF DOCUMENTS  
5 ABOUT EBOLA, AND THAT DOESN'T MEAN HE IS GOING TO TESTIFY  
6 ABOUT EBOLA.

7 MR. METZGER: I SUPPOSE THAT IS TRUE, YOUR HONOR.

8 THE COURT: ALL RIGHT. LET'S MOVE ON. THANK YOU.

9 THE OBJECTION IS SUSTAINED.

10 MR. METZGER: OKAY.

11 Q SO DR. INFANTE, DID YOU BEGIN YOUR REVIEW OF  
12 THE COFFEE/CANCER ISSUE BY REVIEWING THE IARC MONOGRAPH  
13 ON COFFEE?

14 A YES.

15 Q AND IS THAT VOLUME 51 OF THE IARC MONOGRAPH  
16 THAT WAS OF A 1990 REVIEW PUBLISHED IN 1991?

17 A YES.

18 Q WHAT DID YOU FIND IN REVIEWING THE IARC  
19 MONOGRAPH REGARDING COFFEE AND CANCER AT THAT TIME?

20 A WELL, AT THAT TIME, THEY STATED THAT THERE  
21 WAS LIMITED EVIDENCE FOR BLADDER CANCER IN HUMANS.

22 Q WHAT DID THAT MEAN TO YOU?

23 A LIMITED EVIDENCE MEANS THERE IS SOME  
24 EVIDENCE, BUT THAT, YOU KNOW, THEY COULD NOT RULE OUT  
25 CHANCE, BIAS OR CONFOUNDING. SO THERE WAS SOME EVIDENCE,  
26 BUT THERE IS NOT SUFFICIENT EVIDENCE.

27 Q IS THE TECHNICAL DEFINITION BY IARC THAT A  
28 POSITIVE ASSOCIATION HAS BEEN OBSERVED BETWEEN EXPOSURE

1 TO THE MIXTURE AND CANCER FOR WHICH A CAUSAL  
2 INTERPRETATION IS CONSIDERED BY THE WORKING GROUP TO BE  
3 CREDIBLE, BUT CHANCE, BIAS OR CONFOUNDING COULD NOT BE  
4 RULED OUT WITH REASONABLE CONFIDENCE?

5 MR. SCHURZ: OBJECTION; HEARSAY. ALL MR. METZGER  
6 IS DOING NOW IS READING INTO THE RECORD ACTUALLY A  
7 PARAPHRASED VERSION OF AN IARC DOCUMENT THAT IS NOT IN  
8 EVIDENCE.

9 THE COURT: OVERRULED.

10 MR. METZGER: OKAY.

11 THE COURT: YOU MAY ANSWER THE QUESTION.

12 COULD YOU PLEASE REPEAT THE QUESTION.

13

14 (RECORD READ.)

15

16 THE WITNESS: YES, THAT IS THEIR TECHNICAL  
17 DEFINITION, BUT THAT IS WHAT I SAID BEFORE YOU ASKED ME  
18 THAT.

19 MR. METZGER: OKAY.

20 Q WERE THERE CERTAIN CONCLUSIONS IN THE  
21 MONOGRAPH REGARDING BLADDER CANCER AND PANCREATIC CANCER  
22 THAT YOU CONSIDERED OF NOTE?

23 A YES.

24 Q AND WOULD YOU TELL THE COURT WHAT THOSE  
25 WERE?

26 A WELL, IN ADDITION TO THE BLADDER CANCER,  
27 THEY SAID THAT IN THE DATA TAKEN AS A WHOLE, THERE WAS  
28 SUGGESTIVE EVIDENCE OF A WEAK RELATIONSHIP BETWEEN COFFEE

1 CONSUMPTION AND PANCREATIC CANCER.

2 Q OKAY.

3 A BUT, AGAIN, YOU KNOW, THE POSSIBILITY DUE TO  
4 CHANCE, BIAS AND CONFOUNDING COULD NOT BE RULED OUT.

5 Q DID YOU CONSIDER IARC'S OVERALL CONCLUSION  
6 REGARDING THE CARCINOGENICITY OF COFFEE AS OF 1990/1991?

7 A WELL, ACTUALLY I CONSIDERED -- YES, I  
8 CONSIDERED THE EVALUATION AS THEN MY STARTING POINT FOR  
9 WHAT LITERATURE I WAS GOING TO SELECT.

10 Q ALL RIGHT. SO HOW DID YOU GO ABOUT  
11 ASSESSING THE EPIDEMIOLOGIC LITERATURE REGARDING COFFEE  
12 CONSUMPTION AND BLADDER CANCER?

13 A WELL, I LOOKED AT THE -- YOU KNOW, THE  
14 EPIDEMIOLOGICAL LITERATURE RELATED TO BLADDER CANCER AND  
15 PANCREATIC CANCER.

16 Q I AM ASKING FIRST ABOUT BLADDER CANCER,  
17 DR. INFANTE.

18 DID YOU ATTEMPT TO GET YOUR HANDS ON AND  
19 READ EVERY STUDY THAT HAD BEEN PUBLISHED REGARDING COFFEE  
20 CONSUMPTION AND BLADDER CANCER?

21 A WELL, TO THE BEST OF MY ABILITY, YES.

22 Q SO WAS IT YOUR ATTEMPT TO DO A COMPREHENSIVE  
23 REVIEW OF ALL THE STUDIES THAT HAVE BEEN PUBLISHED ON  
24 THAT TOPIC?

25 A YES.

26 Q HOW DID YOU GO ABOUT IDENTIFYING THEM?

27 A WELL, THEY ARE IDENTIFIED -- YOU CAN GET  
28 ONTO PUB-MED OR TOXLINE AND DO A LITERATURE SEARCH. YOU

1 KNOW, A DIFFERENT LITERATURE SEARCH GIVES YOU DIFFERENT  
2 HITS FOR THE STUDIES, BUT BETWEEN THE COMBINATION OF THE  
3 TWO, THEN YOU, YOU KNOW, IDENTIFY THE STUDIES. THEN, YOU  
4 KNOW, THEN I THINK I ASKED, YOU KNOW, YOUR OFFICE IF YOU  
5 COULD PROVIDE ME WITH THOSE -- COPIES OF THOSE ARTICLES  
6 SO I DID NOT HAVE TO, YOU KNOW, REQUEST THEM ALL.

7 Q DID YOU ATTEMPT TO REVIEW ALL OF THE  
8 EPIDEMIOLOGIC STUDIES THAT -- REGARDING COFFEE  
9 CONSUMPTION AND BLADDER CANCER THAT WERE CASE-CONTROL  
10 STUDIES?

11 A YES.

12 Q AND COHORT STUDIES?

13 A YES.

14 Q AND META-ANALYSES?

15 A YES.

16 Q DID YOU EXTRACT THE DATA FROM THESE STUDIES  
17 INTO TABLES THAT YOU PREPARED AS WRITTEN NOTES?

18 A WHICH I PROVIDED AT MY DEPOSITION, YES.

19 Q SO GO TO SLIDE 97, IF YOU WOULD.

20 ALL RIGHT.

21 IN ANALYZING THE STUDIES, DID YOU LIST THEM  
22 BY DIFFERENT STUDY TYPE?

23 A YES. WELL, I HAD THE CASE-CONTROL STUDIES  
24 FIRST, YES.

25 Q HERE WE HAVE SOME OF THE CASE-CONTROL  
26 STUDIES THAT YOU EVALUATED. WILL YOU TELL US WHAT YOU  
27 FOUND OF IMPORT TO YOU IN SOME OF THESE EARLY CASE-  
28 CONTROL STUDIES FROM THE 1960S AND 70S?

1           A           WELL, THERE ARE STUDIES THAT SHOW LIKE  
2 SIGNIFICANT ASSOCIATIONS BETWEEN COFFEE CONSUMPTION AND  
3 BLADDER CANCER.

4           Q           WOULD YOU IDENTIFY THOSE STUDIES BY AUTHOR  
5 AND YEAR?

6           A           YES, THE DUNHAM 1968. COLE 1971. FRAUMENI  
7 1971. SIMON 1975 IN FEMALES. WYNDER 1977 IN MALES.

8           Q           ALL RIGHT. WHILE WE ARE THERE ON THE WYNDER  
9 STUDY, WHAT DID YOU FIND OF IMPORT ABOUT THAT STUDY?

10          A           I MEAN, IT ALSO DEMONSTRATED A SIGNIFICANT  
11 DOSE-RESPONSE.

12          Q           CONTINUING ON, PLEASE.

13          A           YES. THE HOWE 1980 STUDY FROM CANADA  
14 DEMONSTRATED A BORDERLINE STATISTICALLY-SIGNIFICANT  
15 INCREASE IN BLADDER CANCER IN MALES. AND THEN WITH  
16 INSTANT COFFEE DEMONSTRATED A SIGNIFICANT INCREASE.  
17 THE HARTGE STUDY, 1973.

18          Q           1983?

19          A           1983, I AM SORRY. YES, IT DEMONSTRATED A  
20 SIGNIFICANT INCREASE IN MEN AND WOMEN.

21                    THE MARRETT STUDY, 1983, DEMONSTRATED AN  
22 INCREASE IN MALE DRINKERS, BUT IN MALES AND FEMALES  
23 COMBINED AMONG NON-SMOKERS, AGAIN, IT DEMONSTRATES A  
24 SIGNIFICANT INCREASE. AGAIN, WHICH IS IMPORTANT BECAUSE  
25 CIGARETTE SMOKING IS A CONFOUNDER FOR BLADDER CANCER. SO  
26 BY FINDING THIS OBSERVATION IN NON-SMOKERS, IT IS A  
27 STRONGER FINDING.

28          Q           OKAY.

1           A           BRAVO 1986 DEMONSTRATED A SIGNIFICANT  
2 INCREASE IN MEN AND WOMEN.

3           Q           YOU DID NOT MENTION REBEKOLAS, WHAT DID YOU  
4 THINK OF THAT STUDY?

5           A           THE ONE FROM GREECE?

6           Q           YES.

7           A           WELL, IT SHOWED IF YOU DRANK TWO OR MORE  
8 CUPS A DAY, YOU HAD -- IN MEN AND WOMEN, THERE WAS A  
9 SIGNIFICANT INCREASE IN BLADDER CANCER.

10          Q           CONTINUE ON, PLEASE.

11          A           THE PIPER 1986 STUDY. HERE IS A STUDY THAT  
12 USED CUMULATIVE EXPOSURE IN TERMS OF CONSUMING COFFEE.  
13 IN FEMALES, THEY FOUND A SIGNIFICANT TREND.

14          Q           THAT IS A DOSE-RESPONSE TREND?

15          A           YES. THE INDIVIDUAL DATA POINTS ARE NOT  
16 STATISTICALLY SIGNIFICANT, BUT THE TREND THAT GOES FROM  
17 0.9 -- THAT THE ODDS RATIO THAT GOES FROM 0.9 TO 1.9 TO  
18 2.1 IS THE TREND ANALYSIS FOR THOSE ODDS RATIOS BY  
19 INCREASING CUMULATIVE CONSUMPTION OF COFFEE IS  
20 SIGNIFICANT AT THE 0.004 LEVEL. THAT MEANS THAT  
21 OBSERVATION WOULD ONLY OCCUR FOUR TIMES OUT OF 1,000 DUE  
22 TO CHANCE.

23          Q           PLEASE CONTINUE.

24          A           THE ISCOVICH STUDY, ARGENTINA, SHOWS A  
25 LITTLE OVER FOUR-FOLD INCREASE AMONG MEN AND WOMEN  
26 CONSUMING COFFEE.

27                    THE CANTER STUDY DONE IN THE U.S. SHOWS A  
28 SIGNIFICANT INCREASE IN ADENOCARCINOMA AND TRANSITIONAL

1 CELL CARCINOMA OF THE BLADDER, AND THE TREND WITH  
2 INCREASE IN CONSUMPTION WAS STATISTICALLY SIGNIFICANT.

3 THE RISCH STUDY, 1988, CANADA, FOR THOSE WHO  
4 WERE EVER REGULAR USERS OF COFFEE, AND IT DOESN'T SHOW AN  
5 INCREASE IN MALES, BUT IN FEMALES THERE IS ALMOST A  
6 TWO-FOLD RISK. THAT IS STATISTICALLY SIGNIFICANT.

7 IN THE LA VECCHIA 1989 STUDY, THERE IS AN  
8 ODDS RATIO OF 1.8, THAT THEY SAY -- THE AUTHORS SAY WAS  
9 STATISTICALLY SIGNIFICANT, BUT THEY DID NOT -- I COULD  
10 NOT FIND A CONFIDENCE INTERVAL IN THAT REPORT.

11 Q HAVE YOU NOW DESCRIBED FOR THE COURT THOSE  
12 STUDIES PUBLISHED BEFORE THE IARC REVIEW IN 1990 THAT YOU  
13 CONSIDERED OF IMPORT?

14 A YES.

15 Q AND DID YOU ALSO CONSIDER THE STUDIES  
16 PUBLISHED AFTER IARC?

17 A YES.

18 Q COULD WE HAVE THE NEXT SLIDE THEN.  
19 WOULD YOU TELL US WHAT YOU FOUND OF  
20 SIGNIFICANCE IN THOSE STUDIES REGARDING BLADDER CANCER?

21 A YES. WELL, THE CLAVEL 1991 STUDY SHOWS A  
22 SIGNIFICANT DOSE-RESPONSE WITH MEN AND WOMEN COMBINED IN  
23 NON-SMOKERS AS WELL AS SMOKERS. SO THAT IS IMPORTANT  
24 SINCE SMOKING IS A CONFOUNDER FOR BLADDER CANCER. I  
25 MEAN, IF THEY FIND A DOSE-RESPONSE IN SMOKERS, YOU SAY,  
26 "WELL, BUT HOW MUCH IS THAT CONFOUNDED?"

27 THEN THEY COME BACK AND ON THE SAME STUDY  
28 THEY SHOW NON-SMOKERS HAVE EVEN A HIGHER TREND, WHICH IS

1 SIGNIFICANT.

2 Q WHAT ELSE?

3 A AND THE KUNZE STUDY OF 1991 FROM GERMANY, IF  
4 YOU LOOK AT EXPOSURE BY CUPS PER DAY, THERE IS A  
5 SIGNIFICANT TREND IN MEN AS WELL AS WOMEN.

6 IN THE D'AVANZO STUDY FROM ITALY, 1992, IN  
7 MEN AND WOMEN, YOU SEE BY NUMBER OF CUPS CONSUMED PER  
8 DAY, YOU SEE A -- YOU SEE AN INCREASE. THE AUTHORS  
9 REPORTED THERE WAS A SIGNIFICANT DOSE-RESPONSE TREND.

10 Q PLEASE KEEP YOUR VOICE UP, DR. INFANTE.

11 A I'M SORRY, I NEED A DRINK OF WATER.

12 Q GO AHEAD, TAKE A DRINK.

13 A IN THE CHYOU 1991 STUDY OF -- THIS WAS -- IT  
14 SAYS U.S.A., BUT IT IS REALLY JAPANESE MALES IN HAWAII.  
15 JAPANESE-AMERICAN MALES IN HAWAII.

16 WELL, HERE IT IS INTERESTING, THEY REPORTED  
17 THAT TWO TO FOUR CUPS, HIGHLY-ELEVATED RISK, AND FIVE  
18 CUPS, THEY DON'T. THEY HAVE A TWO-FOLD RISK, BUT IT IS  
19 NOT SIGNIFICANT.

20 THE COURT: IS THERE A QUESTION PENDING OR IS THIS  
21 JUST STREAM OF CONSCIOUSNESS TESTIMONY?

22 MR. METZGER: I WILL DO IT QUESTION BY QUESTION.

23 Q LET'S GO ON TO THE NEXT SLIDE.

24 WOULD YOU TELL THE COURT WHAT YOU FOUND OF  
25 IMPORT REGARDING THE VENA STUDY FROM 1993?

26 A YES, IT SHOWS A SIGNIFICANT DOSE-RESPONSE  
27 WITH THE AMOUNT OF COFFEE CONSUMED IN MALES.

28 Q OKAY.

1           A           AND ALSO THE MC GEEHIN 1993 STUDY IN MALES  
2 AND FEMALES, THERE IS A SIGNIFICANT INCREASE IN BLADDER  
3 CANCER.

4                       AND IN THE MOMA 1994 STUDY, IT SHOWS A  
5 SIGNIFICANT DOSE-RESPONSE, WHICH MEANS AN INCREASE IN  
6 RISK OF BLADDER CANCER WITH AN INCREASE IN COFFEE  
7 CONSUMPTION. THIS IS A CUMULATIVE EXPOSURE ANALYSIS.

8                       AND THE DONATO 1997 STUDY SHOWS A  
9 SIGNIFICANT DOSE-RESPONSE BY AMOUNT OF COFFEE CONSUMED.

10           Q           ALL RIGHT. WHAT DID YOU FIND OF  
11 SIGNIFICANCE, IF ANYTHING, IN THE GEOFFREY-PEREZ STUDY  
12 FROM FRANCE IN 2001?

13           A           YES, AMONG NON-SMOKERS, THERE IS A  
14 SIGNIFICANT DOSE-RESPONSE TREND.

15                       THEN IN THE RADOSAVLJEC 2003 STUDY FROM  
16 SERBIA, THEY HAVE A SIGNIFICANTLY INCREASED RISK OF  
17 BLADDER CANCER FROM -- BY MILLILITERS OF COFFEE CONSUMED  
18 PER DAY.

19                       IN THE DE STEFANI 2007 STUDY, THEY REPORT A  
20 SIGNIFICANT TREND BY AMOUNT CONSUMED. IN THE  
21 NON-SMOKERS, THEY HAVE A TWO-FOLD RISK, BUT IT IS NOT  
22 STATISTICALLY SIGNIFICANT.

23           THE COURT: IS THERE A PURPOSE FOR THIS TESTIMONY?

24           MR. METZGER: YES, YOUR HONOR, THERE IS.

25           THE COURT: CAN WE GET TO THE CONCLUSION?

26                       HE IS JUST RECITING WHAT IS IN SOMEBODY  
27 ELSE'S REPORT. IT IS NOT MEANINGFUL.

28           Q           BY MR. METZGER: WELL, DR. INFANTE, WHAT DID

1 YOU CONCLUDE REGARDING THE EPIDEMIOLOGIC STUDIES  
2 REGARDING COFFEE CONSUMPTION AND BLADDER CANCER?

3 REGARDING THE CASE-CONTROL STUDIES, THAT IS.

4 A WELL, I CONCLUDED THAT THERE WERE QUITE A  
5 LARGE NUMBER OF THEM THAT REPORT STATISTICALLY  
6 SIGNIFICANT INCREASED RISKS OF BLADDER CANCER IN RELATION  
7 TO COFFEE CONSUMPTION. LIKE THERE ARE 11 CASE-CONTROL  
8 STUDIES THAT SHOWS SIGNIFICANT DOSE-RESPONSE  
9 RELATIONSHIPS. THERE ARE TWO META-ANALYSES THAT ALSO  
10 DEMONSTRATE SIGNIFICANTLY INCREASED DOSE-RESPONSE  
11 RELATIONSHIPS AMONG NON-SMOKERS.

12 Q HOLD ON, DR. INFANTE. WE WILL GET TO THE  
13 META-ANALYSES.

14 REGARDING THE CASE-CONTROL STUDIES, OF WHAT  
15 IMPORT IS TO YOU THAT YOU FOUND NUMEROUS STUDIES  
16 REPORTING SIGNIFICANTLY INCREASED RISKS AND SO MANY  
17 STUDIES REPORTING STATISTICALLY SIGNIFICANT DOSE-RESPONSE  
18 RELATIONSHIPS FOR COFFEE CONSUMPTION AND BLADDER CANCER  
19 INCLUDING STUDIES AMONG NON-SMOKERS?

20 MR. SCHURZ: OBJECTION; LEADING. COUNSEL IS  
21 TESTIFYING.

22 THE COURT: OVERRULED.

23 THE WITNESS: WELL, TO ME IT INDICATES THAT THERE  
24 IS -- THERE IS AN ELEVATED RISK BEING DEMONSTRATED IN  
25 THESE STUDIES OF PEOPLE CONSUMING COFFEE, AN INCREASED  
26 RISK OF BLADDER CANCER. THEN THAT IS SUPPORTED BY  
27 STUDIES THAT ALSO SHOW -- SOME OF THE STUDIES SHOW A  
28 DOSE-RESPONSE RELATIONSHIP, WHICH ADDS WEIGHT TO THOSE

1 OBSERVATIONS.

2 Q BY MR. METZGER: OKAY, DID YOU ALSO REVIEW  
3 THE COHORT STUDIES REGARDING BLADDER CANCER AND COFFEE  
4 CONSUMPTION?

5 A YES, I DID.

6 Q WHAT DID YOU FIND REGARDING THOSE STUDIES?

7 A WELL, I FOUND IN THESE STUDIES, LIKE IN  
8 GENERAL, THERE WERE SOME STUDIES THAT SHOWED, YOU KNOW,  
9 EVALUATED RISKS, BUT MOST -- BUT MANY OF THEM, THE  
10 MAJORITY OF THEM, DO NOT. SO THERE IS A DIFFERENCE  
11 BETWEEN THE -- WHAT YOU ARE SEEING IN THE CASE-CONTROL  
12 STUDIES VERSUS THE COHORT STUDIES.

13 Q DID YOU REVIEW THE META-ANALYSES THAT HAD  
14 BEEN PUBLISHED REGARDING COFFEE CONSUMPTION AND BLADDER  
15 CANCER?

16 A YES, I DID.

17 Q WOULD YOU TELL US, FIRST OF ALL, HOW MANY  
18 META-ANALYSES YOU FOUND ON THAT TOPIC?

19 A FIVE.

20 Q LET'S BRIEFLY GO OVER EACH OF THEM.

21 WOULD YOU TELL US WHAT YOU FOUND OF  
22 SIGNIFICANCE REGARDING THE SALA 2000 META-ANALYSIS OR  
23 POOLED ANALYSIS OF 10 CASE-CONTROL STUDIES?

24 A YES, IN NON-SMOKERS IN THE POOLED ANALYSIS,  
25 THERE WAS A SIGNIFICANTLY INCREASED RISK OF BLADDER  
26 CANCER IN MALES AND FEMALES COMBINED.

27 AND IN THE ZEEGERS 2001 META-ANALYSIS, BASED  
28 ON 34 CASE-CONTROL STUDIES, AGAIN WITH MALES AND FEMALES

1 COMBINED, THE STUDY DEMONSTRATES A SIGNIFICANT INCREASED  
2 RISK OF BLADDER CANCER.

3 Q OKAY, AND WHAT DID YOU FIND REGARDING THE  
4 ZHOU 2012 STUDY?

5 A WELL, IT ALSO -- IF YOU LOOK IN THAT STUDY  
6 WITH THE HIGHEST VERSUS THE LOWEST EXPOSURE TO, YOU KNOW,  
7 COFFEE CONSUMPTION, YOU FIND A SIGNIFICANTLY INCREASED  
8 RISK OF BLADDER CANCER BASED ON A META-ANALYSIS OF 23  
9 CASE-CONTROL STUDIES. AND YOU ALSO SEE A, YOU KNOW,  
10 SOMEWHAT OF A DOSE-RESPONSE IN THAT STUDY.

11 WHEN YOU LOOK AT THE -- ALSO THE  
12 META-ANALYSIS OF NON-SMOKERS, YOU EVEN SEE A MORE  
13 PERSUASIVE RISK, CLEAR DOWN ON THE BOTTOM. OF THE  
14 NON-SMOKERS FROM THE 23 CASE-CONTROL STUDIES, THE RISK  
15 GOES FROM 1.2 TO 1.4 TO 1.6 TO 1.77. SO THERE IS THAT  
16 TYPE OF ANALYSIS WHICH WOULD NOT HAVE CONFOUNDING FROM  
17 CIGARETTE SMOKING. IT SHOWS A VERY SIGNIFICANT  
18 DOSE-RESPONSE.

19 ON THE OTHER HAND, THE META-ANALYSIS OF FIVE  
20 COHORT STUDIES, YOU KNOW, DOES NOT SHOW AN ASSOCIATION.

21 Q WHAT DID YOU CONCLUDE REGARDING THE LAST  
22 STUDY, THE BAI 2014 STUDY?

23 A IN THAT STUDY, BASED ON 17 CASE-CONTROL  
24 STUDIES AND FOUR COHORT STUDIES, IF YOU LOOK AT THE  
25 HIGHEST VERSUS THE LOWEST COFFEE CONSUMPTION, YOU SEE  
26 ABOUT A 17 PERCENT INCREASE. THAT IS STATISTICALLY  
27 SIGNIFICANT FOR BLADDER CANCER.

28 Q AND WAS THERE ANYTHING IN PARTICULAR THAT

1 YOU FOUND IMPORTANT REGARDING THE BAI STUDY?

2 A WELL, YES. I HAVE THAT ON THE NEXT SLIDE  
3 THAT IF YOU ARE LOOKING AT FLUID INTAKE, IT WAS EVALUATED  
4 IN THE STUDY, THE ONLY ONE, THE ONLY FLUID THAT WAS  
5 ASSOCIATED WITH A SIGNIFICANT INCREASE IN BLADDER CANCER  
6 WAS COFFEE CONSUMPTION. ALL THE REST OF THEM, THE RISK  
7 WAS ABOUT 1.0 OR IT IS BELOW, SLIGHTLY BELOW 1.0.

8 Q SO WHAT DID YOU ULTIMATELY CONCLUDE  
9 REGARDING THE EPIDEMIOLOGIC STUDIES CONCERNING COFFEE  
10 CONSUMPTION AND BLADDER CANCER?

11 A SPECIFICALLY I IDENTIFIED 28 CASE-CONTROL  
12 STUDIES THAT REPORTED SIGNIFICANTLY INCREASED RISKS OF  
13 BLADDER CANCER, AND 11 CASE-CONTROL STUDIES, AND TWO  
14 COHORT STUDIES REPORTED SIGNIFICANT DOSE-RESPONSE  
15 RELATIONSHIPS. AND THREE META-ANALYSES BASED ON  
16 CASE-CONTROL STUDIES DEMONSTRATED SIGNIFICANT  
17 ASSOCIATIONS. TWO META-ANALYSES BASED ON COHORT STUDIES  
18 DID NOT SHOW ANY ASSOCIATION. THEN TWO CASE-CONTROL  
19 STUDIES AND TWO META-ANALYSES DEMONSTRATE STATISTICALLY  
20 SIGNIFICANT DOSE-RESPONSE RELATIONSHIPS AMONG -- FOR  
21 BLADDER CANCER AMONG NON-SMOKERS.

22 Q ALL RIGHT. SO WHAT DID YOU ULTIMATELY  
23 CONCLUDE REGARDING THE STATE OF THE EPIDEMIOLOGIC  
24 LITERATURE REGARDING COFFEE CONSUMPTION AND BLADDER  
25 CANCER THAT POST-DATES IARC'S 1990 REVIEW OF THE ISSUE?

26 A WELL, THE LITERATURE REVIEW CLEARLY  
27 INDICATES THAT THERE IS QUITE A BIT OF EVIDENCE RELATED  
28 TO COFFEE CONSUMPTION AND BLADDER CANCER SINCE THE IARC

1 1990 REVIEW.

2 Q DOES THIS BODY OF LITERATURE, IN YOUR  
3 OPINION, EVIDENCE AN ABSENCE OF HUMAN BLADDER CANCER RISK  
4 FROM CONSUMPTION OF COFFEE?

5 A OF COURSE NOT.

6 Q OKAY. AND WHAT IS YOUR ASSESSMENT OF THE  
7 STRENGTH OF THIS ASSOCIATION THAT YOU HAVE OBSERVED  
8 BETWEEN COFFEE CONSUMPTION AND BLADDER CANCER?

9 A IT IS MY OPINION THAT THEY PROVIDE STRONG  
10 EVIDENCE OF AN ASSOCIATION BETWEEN COFFEE CONSUMPTION AND  
11 BLADDER CANCER.

12 Q ALL RIGHT. THANK YOU.

13 HAVE WE NOW COVERED YOUR OPINIONS REGARDING  
14 THE COFFEE AND BLADDER CANCER EPIDEMIOLOGY STUDIES?

15 A YES.

16 Q SHALL I PROCEED ON TO PANCREATIC CANCER OR  
17 DO YOU NEED A MOMENT?

18 A IS IT POSSIBLE TO GET A SHORT BREAK?

19 THE COURT: ALL RIGHT. WE WILL TAKE A RECESS AT  
20 THIS TIME FOR TEN MINUTES.

21 MR. METZGER: THANK YOU, YOUR HONOR.

22

23 (RECESS TAKEN.)

24

25 THE COURT: BACK ON THE RECORD IN THE CASE OF CERT  
26 VERSUS STARBUCKS. ALL COUNSEL ARE PRESENT AND SEATED.  
27 DR. INFANTE IS ON THE STAND.

28 DR. INFANTE, YOU UNDERSTAND YOU ARE STILL

1 UNDER OATH?

2 THE WITNESS: YES, SIR.

3 THE COURT: PLEASE RESTATE YOUR NAME FOR THE  
4 RECORD.

5 THE WITNESS: PETER FRANCIS INFANTE.

6 THE COURT: AND MR. METZGER WAS INQUIRING.  
7 COUNSEL MAY PROCEED.

8 MR. METZGER: THANK YOU, YOUR HONOR.

9 Q DR. INFANTE, HAVE YOU SERVED AS A MEMBER OF  
10 THE IARC WORKING GROUPS FOR THE EVALUATION OF  
11 CARCINOGENICITY TO HUMANS OF VARIOUS CHEMICALS?

12 A YES, I HAVE.

13 Q ARE YOU -- THROUGH THAT PROCESS, ARE YOU  
14 FAMILIAR WITH HOW IARC, THE INTERNATIONAL AGENCY FOR  
15 RESEARCH ON CANCER, EVALUATES CHEMICALS OR MIXTURES FOR  
16 THEIR CARCINOGENICITY?

17 A YES.

18 Q AND HOW DOES IARC CONSIDER CASE-CONTROL  
19 STUDIES IN ITS EVALUATIONS?

20 A WELL, IARC CONSIDERS THAT CASE-CONTROL  
21 STUDIES CAN CONTRIBUTE TO THE ASSESSMENT OF  
22 CARCINOGENICITY. IN OTHER WORDS, WE EVALUATE THOSE,  
23 ALONG WITH COHORT STUDIES.

24 Q HAS IARC EXPRESSED IN ITS PREAMBLE FOR THE  
25 MONOGRAPHS THAT CASE-CONTROL STUDIES CONTRIBUTE TO THE  
26 ASSESSMENT OF CARCINOGENICITY?

27 A YES, PROBABLY IN EVERY MONOGRAPH -- PREAMBLE  
28 TO EVERY MONOGRAPH SHOULD STATE THAT.

1 Q ARE YOU AWARE OF ANY ORGANIZATION THAT  
2 DISMISSES CASE-CONTROL STUDIES IN REACHING AN ASSESSMENT  
3 OF CARCINOGENICITY OF CHEMICALS?

4 A NO.

5 Q ALL RIGHT. NOW, LET'S TURN TO PANCREATIC  
6 CANCER. WHAT APPROACH DID YOU TAKE IN APPRAISING THE  
7 EPIDEMIOLOGIC STUDIES REGARDING COFFEE CONSUMPTION AND  
8 PANCREATIC CANCER?

9 A WELL, I REVIEWED THE EPIDEMIOLOGICAL  
10 STUDIES, THE CASE-CONTROL AND COHORT STUDIES.

11 Q DID YOU EXTRACT DATA FROM THOSE STUDIES AND  
12 PUT THAT INTO TABLES?

13 A YES.

14 Q ALL RIGHT. SO WOULD YOU TELL US WHAT YOU  
15 FOUND OF SIGNIFICANCE IN THE 1981 STUDY OF BRIAN  
16 MAC MAHON OF HARVARD REGARDING COFFEE CONSUMPTION AND  
17 BLADDER CANCER?

18 A YES, IT DEMONSTRATES A SIGNIFICANT  
19 ASSOCIATION BETWEEN COFFEE CONSUMPTION AND BLADDER  
20 CANCER, AND ALSO A -- IN SOME ANALYSES, A DOSE-RESPONSE.

21 Q WHAT OTHER STUDIES DID YOU CONSIDER TO BE  
22 IMPORTANT REGARDING COFFEE CONSUMPTION AND BLADDER  
23 CANCER?

24 A WELL, I MEAN, I LOOKED AT THE ENTIRE  
25 LITERATURE. DO YOU MEAN WHICH ONES DEMONSTRATE A  
26 SIGNIFICANT INCREASE BECAUSE THERE COULD BE SOME THAT ARE  
27 BORDERLINE SIGNIFICANT, THAT COULD ALSO CONTRIBUTE  
28 INFORMATION. YOU DON'T SIMPLY PICK OUT THE ONES THAT ARE

1 STATISTICALLY SIGNIFICANT AND HAVE A BLIND EYE TO ALL THE  
2 REMAINING ONES. OTHERWISE A MONKEY COULD DO THIS  
3 ANALYSIS.

4 Q WELL, TELL US WHAT YOU CONSIDER TO BE  
5 SIGNIFICANT IN YOUR ANALYSIS, PLEASE.

6 A WELL, OTHER THAN MAC MAHON, THE 1986 HSIEH  
7 STUDY THAT SHOWED THAT IN MEN, THAT IF THEY CONSUMED OVER  
8 FIVE CUPS A DAY COMPARED TO PEOPLE WHO DID NOT CONSUME  
9 COFFEE, THERE IS A TWO-FOLD RISK. THAT IS BORDERLINE  
10 STATISTICALLY SIGNIFICANT.

11 THE MACK 1986 STUDY IN MEN AND WOMEN  
12 COMBINED SHOWS A SIGNIFICANT INCREASE.

13 THE 1986 WYNDER STUDY AMONG NON-SMOKERS FOR  
14 DECAFFEINATED COFFEE SHOWS A SIGNIFICANT INCREASE IN  
15 WOMEN, BUT NOT MEN.

16 THE 1989 CLAVEL STUDY IN WOMEN DEMONSTRATES  
17 A SIGNIFICANT TREND.

18 THE 1991 GHADIRIAN STUDY FROM CANADA --  
19 WELL, FOR DECAFFEINATED COFFEE, IT DEMONSTRATES A  
20 SIGNIFICANT TREND, BUT IT DOES NOT FOR REGULAR COFFEE.  
21 SO I WOULD SAY IT PROVIDES SOME CONFLICTING EVIDENCE.

22 THE LYON 1992 STUDY SHOWS BY CUMULATIVE  
23 COFFEE CONSUMPTION A SIGNIFICANT DOSE-RESPONSE AMONG  
24 SMOKERS.

25 THE GULLO 1995 STUDY FROM ITALY DEMONSTRATES  
26 A SIGNIFICANT DOSE-RESPONSE IN BOTH MEN AND WOMEN. AND  
27 FOR THOSE THAT WERE HISTOLOGICALLY CONFIRMED, AND FOR  
28 THOSE THAT WERE NEVER-SMOKERS DEMONSTRATES A SIGNIFICANT

1 INCREASE.

2 Q IS THERE ANY SIGNIFICANCE TO YOU OF THEM  
3 FINDING A SIGNIFICANT INCREASE IN PANCREATIC CANCER AMONG  
4 PANCREATIC CANCER PATIENTS WHO HAD HISTOLOGICAL  
5 CONFIRMATION OF THEIR DISEASE?

6 A WELL, IT ADDS TO THE CONFIDENCE IN YOUR  
7 ANALYSIS BECAUSE THOSE CANCERS HAVE BEEN HISTOLOGICALLY  
8 CONFIRMED. SO YOU KNOW FOR SURE THAT IS WHAT THEY ARE.  
9 THAT WOULD BE STRONGER, SAY AN IDENTICAL FINDING, IT  
10 WOULD BE STRONGER IN A STUDY THAT HISTOLOGICALLY  
11 CONFIRMED THE -- BECAUSE THEN YOU KNOW YOU ARE TALKING  
12 ABOUT PANCREATIC CANCER.

13 Q IN THAT STUDY, WHAT WAS THE SIGNIFICANCE TO  
14 YOU OF THE SIGNIFICANT INCREASE IN PANCREATIC CANCER  
15 AMONG NEVER-SMOKERS CONSUMING MORE THAN THREE CUPS OF  
16 COFFEE PER DAY?

17 A IT IS AN IMPORTANT FINDING BECAUSE CIGARETTE  
18 SMOKING IS A RISK FACTOR FOR PANCREATIC CANCER. SO WHEN  
19 YOU FIND ALMOST A THREE-FOLD INCREASE IN NEVER-SMOKERS,  
20 THAT IS AN IMPORTANT OBSERVATION.

21 THE KOKIC STUDY FROM YUGOSLAVIA, OR HOWEVER  
22 YOU PRONOUNCE IT, IN MEN AND WOMEN DEMONSTRATES A  
23 SIGNIFICANT INCREASE IN PANCREATIC CANCER.

24 THE SILVERMAN STUDY IN THE U.S. ONLY SHOWS A  
25 SIGNIFICANT INCREASE WHICH IS BORDERLINE IN BLACKS. IT  
26 DOESN'T IN WHITES.

27 THE PORTA 1999 STUDY SHOWS A SIGNIFICANT  
28 INCREASE IN PANCREATIC CANCER RELATED TO PANCREATIC

1 CANCER THAT HAS A PARTICULAR KIND OF MUTATION TO IT,  
2 CALLED A K-RAS MUTATION, AND THE TREND WAS STATISTICALLY  
3 SIGNIFICANT IF YOU LOOK AT THOSE RESULTS.

4 Q LET ME ASK YOU A LITTLE ABOUT THAT STUDY.  
5 FIRST, REGARDING THE MAIN RESULTS OF  
6 DRINKERS VERSUS NON-DRINKERS FOR PANCREATIC CANCER WITH  
7 K-RAS MUTATIONS, WHAT, IF ANYTHING, DID YOU MAKE OF THE  
8 FACT THAT THE ODDS RATIO REPORTED FOR THAT WAS GREATER  
9 THAN FIVE AND WAS STATISTICALLY SIGNIFICANT?

10 A WELL, IT SHOWS A STRONG ASSOCIATION. THAT  
11 MEANS A HIGH ODDS RATIO.

12 Q WHAT, IF ANYTHING, DID YOU CONCLUDE  
13 REGARDING THE ODDS RATIO THAT WAS FOUND FOR PANCREATIC  
14 CANCER PATIENTS WITH K-RAS MUTATIONS WHO CONSUMED MORE  
15 THAN 15 CUPS OF COFFEE PER WEEK?

16 A WELL, I MEAN, IT SHOWS THAT IF YOU GO FROM  
17 LESS THAN 15 TO MORE THAN 15, THERE IS QUITE AN INCREASE  
18 IN THE RISK. THEY ARE BOTH STATISTICALLY SIGNIFICANT.

19 Q WHAT WAS THE --

20 A IT IS A SIGNIFICANT DOSE-RESPONSE.

21 Q WHAT WAS THE INCREASED RISK FOR CONSUMPTION  
22 OF GREATER THAN 15 CUPS OF COFFEE PER WEEK?

23 A TEN-FOLD RISK.

24 Q IS A TEN-FOLD RISK SOMETHING THAT GETS YOUR  
25 ATTENTION?

26 A YES, THAT IS VERY HIGH. I MEAN, MOST OF THE  
27 STUDIES YOU ARE TALKING ABOUT A 1.5-FOLD INCREASE, A  
28 TWO-FOLD RISK. SOMETIMES HIGHER.

1 Q WHAT IS THE SIGNIFICANCE OF A TEN-FOLD  
2 INCREASED RISK THAT IS STATISTICALLY SIGNIFICANT  
3 REGARDING THE EVALUATION OF CARCINOGENICITY?

4 A WELL, IT IS A VERY STRONG FINDING. THE  
5 STRENGTH OF THE ASSOCIATION, THAT IS QUITE A STRONG  
6 ASSOCIATION.

7 Q WHAT OTHER STUDIES REGARDING CONSUMPTION OF  
8 COFFEE AND PANCREATIC CANCER DID YOU CONSIDER TO BE --

9 A AGAIN, THE MORALES 2007 STUDY AMONG REGULAR  
10 DRINKERS WITH K-RAS MUTATION, THEY HAVE A SIGNIFICANT  
11 INCREASE. AND IF YOU LOOK AT FROM -- BY DOSE-RESPONSE,  
12 THERE IS A SIGNIFICANT TREND. AND THOSE, AGAIN, WHO  
13 DRANK MORE THAN 15 CUPS OF COFFEE A WEEK, THEY HAVE GOT  
14 AN 11-FOLD RISK. THAT IS STATISTICALLY SIGNIFICANT.

15 Q OKAY.

16 A SO THAT IS, YOU KNOW, IMPORTANT FOR THE  
17 REASONS I JUST STATED IN RELATION TO THE PORTA STUDY.

18 IN THE TURATI STUDY FROM ITALY, 2011, THEY  
19 DEMONSTRATE A SIGNIFICANT INCREASE IN THE DOSE-RESPONSE  
20 FOR PANCREATIC CANCER.

21 Q ALL RIGHT. DID YOU ALSO CONSIDER THE COHORT  
22 STUDIES THAT HAVE BEEN PUBLISHED REGARDING COFFEE  
23 CONSUMPTION AND PANCREATIC CANCER?

24 A YES, I DID. YES.

25 Q WHAT DID YOU FIND OF NOTE REGARDING THOSE  
26 STUDIES?

27 A WELL, THERE WERE SOME STUDIES THAT I  
28 THINK MAYBE FIVE OF THEM THAT DEMONSTRATED A SIGNIFICANT

1 ASSOCIATION AND THE OTHERS DID NOT. THEY ARE NOT -- SO  
2 THERE ARE SOME COHORT STUDIES AS WELL THAT DEMONSTRATE  
3 THE ASSOCIATION. THEY ARE NOT AS MANY AS WITH  
4 CASE-CONTROL STUDIES.

5 Q WHAT, IF ANYTHING, DID YOU CONSIDER  
6 IMPORTANT ABOUT THE 1989 HIRAYAMA STUDY?

7 A WELL, IF YOU LOOK AT DRINKERS VERSUS  
8 NON-DRINKERS, YOU HAVE OVER A FIVE-FOLD RISK. THAT WAS  
9 STATISTICALLY SIGNIFICANT.

10 IF YOU LOOK AT THE HARNACK 1997 STUDY, FOR  
11 THOSE THAT DRANK MORE THAN 17 AND A HALF CUPS A WEEK,  
12 VERSUS THOSE THAT DRANK LESS THAN SEVEN CUPS, YOU HAVE A  
13 TWO-FOLD RISK. AND FOR THOSE THAT DRANK EIGHT TO 17  
14 CUPS, YOU HAVE A RISK OF 1.9. IT IS NOT SIGNIFICANT, BUT  
15 THEN INCREASES WHEN YOU LOOK AT THOSE WITH MORE THAN 17  
16 CUPS.

17 SO YOU HAVE A SIGNIFICANT INCREASE IN THE  
18 HARNACK STUDY AND ALSO THE DOSE-RESPONSE.

19 Q ARE THERE ANY OTHER COHORT STUDIES THAT YOU  
20 FOUND?

21 A WELL, THE LIN STUDY OF 2002 FROM JAPAN, THEY  
22 FOUND A SIGNIFICANT INCREASE IN MEN, BUT NOT WOMEN.

23 IN THE STOLZENBERG STUDY IN THE U.S., THE  
24 FOURTH QUINTILE DEMONSTRATED A SIGNIFICANT INCREASE, BUT  
25 THEN YOU DID NOT FIND ANY INCREASE IN THE FIFTH QUINTILE.  
26 I DON'T KNOW WHAT IS GOING ON THERE. I CAN'T -- I HAVE  
27 TO LOOK BACK TO SEE WHAT THE NUMBERS WERE IN THOSE  
28 DIFFERENT CATEGORIES OF EXPOSURE.

1                   THE NILSSON 2010 STUDY, FOR TOTAL COFFEE,  
2                   THERE IS A 50 PERCENT INCREASE THAT IS NOT SIGNIFICANT,  
3                   BUT THEN WHEN THEY ANALYZED BY BOILED COFFEE, THEY FIND  
4                   THAT FROM ONE TO THREE CUPS -- I DON'T THINK IT IS ON THE  
5                   SLIDE -- THE RISK IS 1.68 AND FOR FOUR OR MORE CUPS, IT  
6                   GOES UP TO 2.51. THAT IS STATISTICALLY SIGNIFICANT AND  
7                   ALSO INDICATES A DOSE-RESPONSE.

8                   THOSE ARE THE ONES THAT I FOUND HAD SOME  
9                   EVIDENCE OF AN ASSOCIATION IN THE COHORT STUDIES WITH  
10                  COFFEE AND PANCREATIC CANCER.

11                 Q           ALL RIGHT. WOULD YOU TELL US WHAT YOU  
12                 CONCLUDED ABOUT THE STUDIES REGARDING COFFEE CONSUMPTION  
13                 AND PANCREATIC CANCER?

14                 A           YES. AS I INDICATED, I THINK I HAVE IT ON  
15                 ONE OF THE SLIDES, MAYBE 122, THAT THERE ARE 14  
16                 CASE-CONTROL STUDIES THAT REPORT SIGNIFICANTLY INCREASED  
17                 RISKS OF PANCREATIC CANCER IN RELATION TO COFFEE  
18                 CONSUMPTION, AND 11 OF THESE CASE-CONTROL STUDIES REPORT  
19                 STATISTICALLY SIGNIFICANT DOSE-RESPONSE RELATIONSHIPS.  
20                 FOUR CASE-CONTROL STUDIES DEMONSTRATE SIGNIFICANT  
21                 DOSE-RESPONSE RELATIONSHIPS AMONG NON-SMOKERS.

22                 I DON'T THINK WE HAVE DISCUSSED META-  
23                 ANALYSES YET.

24                 Q           TELL US WHAT YOU CONCLUDED REGARDING THE  
25                 META-ANALYSES, PLEASE?

26                 A           WELL, THERE ARE TWO THAT WERE BASED ON  
27                 CASE-CONTROL STUDIES, AND TWO BASED ON COHORT STUDIES  
28                 THAT REPORT INCREASED RISKS THAT ARE NOT STATISTICALLY

1       SIGNIFICANT.

2               Q           SO WHAT DID YOU ULTIMATELY CONCLUDE  
3       REGARDING THIS BODY OF EPIDEMIOLOGIC LITERATURE  
4       CONCERNING COFFEE CONSUMPTION AND PANCREATIC CANCER?

5               A           WELL, I CONCLUDED THAT THERE IS SOME  
6       EVIDENCE OF AN ASSOCIATION BETWEEN COFFEE CONSUMPTION AND  
7       PANCREATIC CANCER.

8               Q           DR. INFANTE, IN YOUR OPINION, DOES THE  
9       TOTALITY OF THIS LITERATURE DEMONSTRATE AN ABSENCE OF  
10      CARCINOGENIC RISK TO HUMANS FOR PANCREATIC CANCER FROM  
11      COFFEE CONSUMPTION?

12              A           NO.

13              Q           OKAY. NOW, DID YOU ALSO, AS PART OF YOUR  
14      WORK IN THIS CASE, REVIEW THE META-ANALYSES THAT HAVE  
15      BEEN PUBLISHED REGARDING COFFEE CONSUMPTION AND VARIOUS  
16      CANCERS?

17              A           YES.

18              Q           AND DID YOU SET FORTH SOME OF THE FINDINGS  
19      THAT YOU CONSIDERED OF NOTE IN YOUR NOTES WHICH ARE  
20      EXHIBIT 224?

21              A           YES, I DID.

22              Q           FOR THE MOMENT, I WOULD LIKE TO SET ASIDE  
23      THE CHENG META-ANALYSIS REGARDING CHILDHOOD LEUKEMIA  
24      BECAUSE WE WILL BE DISCUSSING THAT AT LENGTH, BUT WOULD  
25      YOU TELL US WHAT YOU CONCLUDED FROM YOUR REVIEW OF THE  
26      OTHER META-ANALYSES REGARDING COFFEE CONSUMPTION AND  
27      VARIOUS TYPES OF HUMAN CANCER?

28              A           YES, THERE ARE THREE --

1 MR. SCHURZ: YOUR HONOR, WE WOULD OBJECT,  
2 OBVIOUSLY, WITH RESPECT FOR THE SAME REASONS THAT WE HAVE  
3 DISCUSSED. ANY OPINIONS THAT DR. INFANTE WOULD NOW LIKE  
4 TO OFFER THAT ARE UNDISCLOSED WITH RESPECT TO OTHER  
5 CANCER SITES OTHER THAN THE THREE THAT HAVE BEEN  
6 IDENTIFIED ARE NEW UNDISCLOSED OPINIONS THAT SHOULD BE  
7 BARRED FOR THE SAME REASONING THAT WE DISCUSSED --

8 THE COURT: OBJECTION SUSTAINED.

9 MR. METZGER: YOUR HONOR, THESE ARE IN  
10 DR. INFANTE'S REPORT IN THIS CASE.

11 THE COURT: SO?

12 MR. METZGER: HE TESTIFIED TO THESE AT HIS  
13 DEPOSITION.

14 THE COURT: THAT IS THE QUESTION, WHETHER HE  
15 TESTIFIED. THE EXCERPT I WAS SHOWN INDICATES THAT HE WAS  
16 NOT PREPARED TO TESTIFY ABOUT IT.

17 MR. METZGER: DR. INFANTE TESTIFIED THAT HE HAD  
18 WRITTEN OUT HIS OPINIONS AND THOSE WERE HIS OPINIONS FOR  
19 THE CASE. IF MR. SCHURZ CHOOSES NOT TO ASK HIM ABOUT  
20 THOSE OPINIONS WHEN HE TESTIFIED THAT HE HAS WRITTEN OUT  
21 ALL HIS OPINIONS AND HERE THEY ARE, THEN THAT -- THEY ARE  
22 OPINIONS THAT HE HAS IN THE CASE.

23 THE COURT: THAT MAY BE, BUT THE TESTIMONY I SAW  
24 INDICATED THAT HE WAS NOT PREPARED, THAT HE DID NOT DO  
25 ANY REVIEW, THAT HE DID NOT EVEN READ THE ARTICLES IN  
26 CONNECTION WITH THOSE OTHER CANCER SITES.

27 THE WITNESS: YOUR HONOR, MAY I SHOW THE COURT?

28 THE COURT: WELL, LET'S REVIEW THE TESTIMONY AGAIN.

1 MR. METZGER: THIS IS IN THE CONTEXT OF HIS  
2 CRITIQUE OF DR. BOFFETTA'S TESTIMONY. HE DID CRITIQUE  
3 DR. BOFFETTA IN HIS DEPOSITION.

4 THE COURT: THAT MAY BE, BUT THE TESTIMONY THAT WAS  
5 PREVIOUSLY CITED -- IF THERE WAS SOMETHING ELSE LATER IN  
6 THE DEPOSITION WHERE HE DID EXPRESS THE OPINION  
7 PREVIOUSLY -- LET'S SEE WHAT PAGE IT WAS.

8 MR. METZGER: I THINK PAGE 148 IS WHERE THE  
9 TESTIMONY OCCURS, YOUR HONOR.

10 THE COURT: 148?

11 MR. SCHURZ: YOUR HONOR, WELL, WHEN YOU ARE -- WHEN  
12 IT IS APPROPRIATE, WE DIRECT THE COURT TO --

13 THE COURT: SHOW ME PAGE 148.

14 MR. METZGER: ON PAGE 148, AT LINE 16 THROUGH 18,  
15 DR. INFANTE --

16 THE COURT: WHERE IS THE TRANSCRIPT FOR 148?

17 DO WE HAVE A TRANSCRIPT?

18 MR. METZGER: YES. SORRY, YOUR HONOR. I THOUGHT  
19 YOU HAD IT.

20 THE COURT: ALL RIGHT. PAGE?

21 MR. METZGER: SO HE DISCUSSES THE GENKINGER STUDY  
22 ON PAGE 148.

23 MR. SCHURZ: FOR THE COURT'S ANALYSIS, GENKINGER WE  
24 ALREADY DISCUSSED. IT IS RELATING TO PANCREATIC CANCER.

25 THE COURT: PAGE AND LINE NUMBER?

26 MR. METZGER: PAGE 148, LINES 16 THROUGH 19.

27 THE COURT: OKAY.

28 SO THE ANSWER IS PANCREATIC CANCER AND THE

1 OBJECTION IS SUSTAINED.

2 ANYTHING ELSE?

3 MR. METZGER: YES, YOUR HONOR. IT WILL TAKE ME A  
4 MOMENT TO FIND IT, BUT DR. INFANTE TESTIFIED THAT HE HAD  
5 REVIEWED THE META-ANALYSES AND THAT HE HAD PREPARED THESE  
6 NOTES REGARDING THEM.

7 HE ALSO TESTIFIED THAT -- IF YOU LOOK AT  
8 PARAGRAPH 52 OF HIS REPORT, HE PROVIDES HIS OPINION THERE  
9 REGARDING THESE META-ANALYSES. IT IS RIGHT IN HIS  
10 REPORT. HE TESTIFIED THAT HIS REPORT SET FORTH HIS  
11 OPINIONS FOR THE CASE.

12 THE COURT: ALL RIGHT. OKAY. THAT IN ITSELF IS  
13 IMPORTANT, BUT DEPENDS WHAT HE WAS ASKED AT THE  
14 DEPOSITION.

15 MR. SCHURZ, YOU WANTED TO SHOW ME SOMETHING?

16 MR. SCHURZ: FIRST, WELL, BINKINGER, AS YOUR HONOR  
17 CAN SEE, IS RELATED TO PANCREATIC CANCER. WE HAVE  
18 ALREADY DISCUSSED IT AT SOME LENGTH. WE GOT THE SALA  
19 STUDY RELATING TO BLADDER CANCER. ZEEGERS RELATING TO  
20 URINARY TRACT CANCER, ALSO DISCUSSED, RELATING TO  
21 BLADDER. WE HAVE GOT THE GINZINGER, TURATI AND ZHOU ALL  
22 RELATING TO BLADDER OR PANCREAS THAT WE DISCUSSED.

23 WE WOULD DIRECT YOUR HONOR TO THOSE PORTIONS  
24 OF THE TRANSCRIPT WHERE WE SPECIFICALLY ASK WHAT CANCER  
25 END POINTS ARE YOU GOING TO TESTIFY TO. WE DISCUSSED  
26 EARLIER AT PAGES 21 AND 22, WE FURTHER DIRECT YOUR HONOR  
27 TO THE INTERCHANGE BETWEEN COUNSEL THAT BEGINS AT  
28 PAGE 23, LINE 17.

1 THE COURT: OKAY.

2 MR. SCHURZ: IF YOU CAN SEE THAT IT PRECEDES, YOUR  
3 HONOR, IF -- DR. INFANTE INDICATES:

4 "IF I AM ASKED TO DO SOME OTHER THINGS, BUT  
5 THESE ARE THE ONLY ONES I COULD GET TO AND I CHOSE THOSE  
6 BASED ON THE FACTORS THAT I GAVE YOU EARLIER."

7 MR. METZGER: YOUR HONOR, I WOULD DIRECT --

8 MR. SCHURZ: TO WHICH I ASKED:

9 "SO, IF DR. INFANTE INTENDS TO OFFER  
10 TESTIMONY WITH RESPECT TO ANY OTHER CANCER END POINTS  
11 OTHER THAN THE FOUR HE HAS JUST IDENTIFIED, WE WOULD LIKE  
12 TO -- WE WILL INSIST UPON HAVING A FURTHER DEPOSITION  
13 WITH RESPECT TO THOSE THINGS."

14 MR. METZGER RESPONDS:

15 "IF HE IS GOING TO DO THAT, I WILL, OF  
16 COURSE, PRODUCE HIM FOR ANOTHER DEPOSITION. I DON'T KNOW  
17 THAT IS GOING TO BE NECESSARY, BUT I HAVE NOT REALLY  
18 THOUGHT ABOUT IT YET. I ASSURE YOU THAT YOU ARE NOT  
19 GOING TO -- THAT WE ARE NOT GOING TO TRY TO SURPRISE YOU  
20 AT TRIAL. IF HE FORMS OTHER OPINIONS ON OTHER CANCER  
21 SITES, I WILL PRODUCE HIM FOR ANOTHER DEPOSITION.

22 MR. METZGER: YOUR HONOR --

23 MR. SCHURZ: FURTHER -- WE HAD FURTHER DISCUSSION  
24 WITH RESPECT TO THE COMPLETENESS OF THE TESTIMONY THAT  
25 DR. INFANTE OFFERED AT THE CONCLUSION OF HIS DEPOSITION,  
26 WHERE WE ASKED:

27 "IS IT CLEAR THAT WE HAVE DISCUSSED ALL OF  
28 THE OPINIONS THAT YOU INTEND TO OFFER IN THIS CASE?"

1 AT WHICH POINT DR. INFANTE CONFIRMED THAT  
2 YES, IN FACT, HE HAD.

3 WHAT WE HAVE SEEN TODAY IS THAT THE OPINIONS  
4 THAT HE HAS OFFERED WITH RESPECT TO LUNG CANCER IN THE  
5 CONTEXT OF HIS DEPOSITION, HE IS NO LONGER ADVANCING IN  
6 THIS ACTION.

7 THE COURT: ALL RIGHT. WELL, LET ME HEAR FROM  
8 MR. METZGER.

9 THE TESTIMONY GOING BACK TO 21, THE WITNESS  
10 INDICATED HE INTENDED TO OFFER TESTIMONY WITH RESPECT TO  
11 PANCREATIC CANCER, BLADDER CANCER, CHILDHOOD LEUKEMIA AND  
12 LUNG CANCER. THEN AS MR. SCHURZ QUOTED THE TRANSCRIPT,  
13 IF HE INTENDS TO OFFER ANY ADDITIONAL TESTIMONY ON OTHER  
14 SITES, AND YOU SAID YOU WOULD LET MR. SCHURZ KNOW AND  
15 PRODUCE DR. INFANTE FOR ANOTHER DEPOSITION.

16 WHERE ARE WE IN THIS?

17 MR. METZGER: HERE IS WHERE WE ARE, YOUR HONOR: IF  
18 YOU WOULD KINDLY LOOK AT PAGE 134 OF THE TRANSCRIPT.

19 THE COURT: 134?

20 MR. METZGER: YES, LINE 13.

21 THE COURT: ONE SECOND. 134, LINE 13.

22 MR. METZGER: THE WITNESS IDENTIFIES DEPOSITION  
23 EXHIBIT 16 AS HIS OPINIONS FOR THE CASE.

24 MR. SCHURZ ASKED HIM:

25 "YOU PREPARED EXHIBIT 16?"

26 "ANSWER: YES.

27 "QUESTION: WHAT IS EXHIBIT 16?"

28 "ANSWER: THESE ARE MY OPINIONS IN THIS CASE

1 RELATED TO ACRYLAMIDE AND CANCER AND COFFEE CONSUMPTION  
2 AND CANCER."

3 MR. SCHURZ ASKED: "DOES IT SET FORTH A  
4 COMPREHENSIVE LIST OF ALL THE OPINIONS YOU INTEND TO  
5 OFFER IN THIS MATTER?

6 "ANSWER: YES."

7 WELL, EXHIBIT 16 HAS PARAGRAPH 52 IN IT IN  
8 WHICH DR. INFANTE RENDERS AN OPINION REGARDING THESE  
9 META-ANALYSES. SO IT IS PART OF HIS OPINIONS, IT WAS  
10 STATED SUCH AT THE DEPOSITION

11 THE COURT: WHERE IS EXHIBIT 16?

12 ALL RIGHT. I HAVE THAT. I AM LOOKING AT  
13 EXHIBIT 16 AND PARAGRAPH 52.

14 ALL RIGHT, SO?

15 MR. METZGER: SO IN PARAGRAPH 52, DR. INFANTE  
16 RENDERS AN OPINION REGARDING THE META-ANALYSES REGARDING  
17 COFFEE CONSUMPTION AND CANCER WHICH HE INDICATES THAT  
18 DR. BOFFETTA FAILED TO CONSIDER WHICH META-ANALYSES  
19 REPORT INCREASED RISKS FOR CANCER. HE IDENTIFIES THEM  
20 HERE, AND THOSE ARE DESCRIBED WITH THE DATA IN THE NOTES  
21 THAT HE PRODUCED FOR HIS DEPOSITION, WHICH ARE  
22 EXHIBIT 224.

23 SO HE WROTE OUT HIS OPINIONS, HE SAID AT HIS  
24 DEPOSITION, "THESE ARE MY OPINIONS," AND MR. SCHURZ IS  
25 NOW TRYING TO PERSUADE THE COURT THAT THESE ARE NOT HIS  
26 OPINIONS THAT HE RENDERED AT HIS DEPOSITION.

27 THE COURT: WHERE IS HIS OPINION?

28 PARAGRAPH 52 IS A CRITICISM OF DR. BOFFETTA.

1 WHERE DOES IT GO FROM THERE?

2 HE DOES NOT LIKE DR. BOFFETTA'S WORK.

3 MR. METZGER: IT IS MORE THAN THAT. HE SAYS THAT  
4 THESE META-ANALYSES FOR COFFEE CONSUMPTION AND CANCER  
5 REPORTED INCREASED RISKS. THAT IS THE OPINION.

6 THE COURT: ALL RIGHT.

7 MR. METZGER: DR. BOFFETTA SAID ALL THE  
8 META-ANALYSES DEMONSTRATED AN ABSENCE OF RISK. SO THAT  
9 IS -- THAT IS HIS OPINION THAT THESE META-ANALYSES SHOW  
10 INCREASED RISK, CONTRARY TO WHAT DR. BOFFETTA CONCLUDED.  
11 THESE ARE OPINIONS HE PREPARED FOR THIS CASE, AND AT HIS  
12 DEPOSITION HE TESTIFIED THAT THESE ARE MY OPINIONS.

13 SO FOR MR. SCHURZ TO SAY THAT THEY ARE NOT  
14 OPINIONS THAT HE RENDERED AT HIS DEPOSITION IS SIMPLY  
15 WRONG. CLEARLY WHAT DR. INFANTE -- THE QUESTION THAT  
16 MR. SCHURZ WAS ASKING AND WHAT DR. INFANTE WAS ANSWERING  
17 WAS CONCERNING THOSE SITES OF CANCER WHERE HE HAD  
18 REVIEWED ALL OF THE STUDIES. THIS IS SOMETHING ELSE  
19 REGARDING THE META-ANALYSES. HE SAID THAT THESE ARE HIS  
20 OPINIONS AT HIS DEPOSITION.

21 THE COURT: WELL -- YES, GO AHEAD.

22 MR. SCHURZ: THERE ARE A SERIES OF  
23 MISREPRESENTATIONS, YOUR HONOR.

24 FIRST, DR. INFANTE DID NOT TESTIFY AT HIS  
25 DEPOSITION THAT HE HAD REVIEWED ALL OF THE STUDIES WITH  
26 RESPECT TO BLADDER AND PANCREAS. THAT WAS SOMETHING HE  
27 DID AFTER HIS DEPOSITION. IT IS QUITE CLEAR THAT HE HAD  
28 NOT CONCLUDED. HE READ ONLY THREE COHORT STUDIES. SO

1 THAT REPRESENTATION IS FALSE.

2 SECOND, WE HAVE NOW HEARD THAT WE ARE  
3 SUPPOSED TO BE LOOKING AT THE NOTES. THE NOTES INCLUDE  
4 STUDIES THAT ARE NOT REFLECTED IN PARAGRAPH 52. THE  
5 NOTES WERE NOT INDICATED AS "HERE IS MY REPORT." THE  
6 NOTES ARE WHAT THEY PURPORT TO BE, THEY ARE NOTES.

7 THE COURT: FORGET ABOUT THE NOTES. THE NOTES ARE  
8 NOTES. WE ARE TALKING ABOUT THE OPINIONS. THIS DOCUMENT  
9 WAS PRODUCED PURPORTING TO STATE DR. INFANTE'S OPINIONS.  
10 LET'S GO TO THE OPINIONS.

11 MR. SCHURZ: AND WHAT HE HAS IDENTIFIED AS A SERIES  
12 OF STUDIES RELATING TO PANCREATIC CANCER AND BLADDER  
13 CANCER, WHICH WE HAVE DISCUSSED A TOTAL OF SIX OF THOSE  
14 STUDIES HERE, WHAT IS NOW AT ISSUE IS WITH RESPECT TO  
15 WHETHER THIS WITNESS MAY TESTIFY WITH RESPECT TO OTHER  
16 CANCER SITES, NAMELY OVARIAN CANCER, GASTRIC CANCER, LUNG  
17 CANCER, WHICH HE HAS NOW DISOWNED, AND GASTRIC CANCER.  
18 THE POINT IS HE CANNOT.

19 IN THE ABSENCE OF AN EXPRESSION THAT -- AND  
20 A REQUEST, "WHAT ARE THE CANCER SITES YOU INTEND TO  
21 ADDRESS," HE ANSWERED, "I HAVE LOOKED AT THESE AND THESE  
22 ALONE."

23 AS YOUR HONOR KNOWS, DR. BOFFETTA LOOKED AT  
24 17 SITES AND WE WERE VERY CAREFUL ABOUT WHAT EXACTLY WAS  
25 -- WERE THE CANCER END POINTS THAT WERE GOING TO BE  
26 RAISED. WHAT WERE THE ISSUES THAT WERE IN PLAY, SO TO  
27 SPEAK, WITH RESPECT TO THE FOCUS OF DR. INFANTE'S  
28 TESTIMONY.

1                   SO WE WENT OVER THIS IN SOME DETAIL. IT IS  
2 REFERENCED REPEATEDLY IN THE TEXT AT PAGES 21, 22 AND 23.  
3 WE DID IT RIGHT AT THE OUTSET BECAUSE WE WANTED TO KNOW  
4 WHAT ARE THE PARAMETERS OF THE OPINIONS THAT THIS WITNESS  
5 IS GOING TO OFFER.

6                   MR. METZGER: DR. -- EXCUSE ME.

7                   THE COURT: YES.

8                   MR. METZGER: ON PAGE 114 OF HIS DEPOSITION, AT  
9 LINE 23, MR. SCHURZ ASKED DR. INFANTE:

10                   "CAN YOU IDENTIFY EXHIBIT 10 FOR US."

11                   HE ANSWERED: "YES, THESE ARE MY NOTES  
12 SUMMING UP THE META-ANALYSES THAT SHOW INCREASED CANCER  
13 RISKS."

14                   MR. SCHURZ ASKS: "AND SPECIFICALLY FOR ALL  
15 SITES?"

16                   DR. INFANTE ANSWERS: "FOR ALL SITES."

17                   SO MR. SCHURZ THEN ASKS: "YOU DID PERFORM A  
18 REVIEW BEYOND THE FOUR SITES THAT WE HAVE BEEN DISCUSSING  
19 THIS MORNING, BLADDER, PANCREAS, CHILDHOOD LEUKEMIA AND  
20 LUNG?"

21                   "ANSWER: IN TERMS OF META-ANALYSES, YES."

22                   THE COURT: ALL RIGHT. THE COURT IS GOING TO  
23 ALLOW, TO SOME EXTENT, SOME FURTHER QUESTIONS, BUT IT IS  
24 LIMITED -- IT IS LIMITED TO THE OPINION EXPRESSED IN  
25 PARAGRAPH 52, AND THAT IS AS SET FORTH IN THIS EXHIBIT 16  
26 TO THE DEPOSITION, CRITICISM BY DR. INFANTE OF  
27 DR. BOFFETTA'S OPINION WITH REGARD TO DR. BOFFETTA'S  
28 ALLEGED FAILURE TO CONSIDER OTHER META-ANALYSES REPORTING

1 INCREASED RISK OF COFFEE CONSUMPTION AND CANCER. ONLY  
2 THE SPECIFIC ITEMS IN THE SPECIFIC REPORTS, NOT TO GO  
3 BEYOND THAT. WE ARE NOT GOING TO OPEN IT UP FOR JUST  
4 GENERAL DISCUSSION OF OTHER SITES OF CANCER, BUT LIMIT IT  
5 TO THE OPINIONS EXPRESSED AS TO THE CRITICISM OF  
6 DR. BOFFETTA.

7 MR. METZGER: OKAY. VERY WELL. SHALL I PROCEED,  
8 YOUR HONOR?

9 THE COURT: YES.

10 Q BY MR. METZGER: DR. INFANTE, DID YOU REVIEW  
11 THE META-ANALYSES REGARDING COFFEE CONSUMPTION AND  
12 CANCERS TO DETERMINE WHETHER THE META-ANALYSES ALL  
13 DEMONSTRATED AN ABSENCE OF RISK AS DR. BOFFETTA CLAIMED?

14 MR. SCHURZ: OBJECTION. IT LACKS FOUNDATION. THAT  
15 IS NOT WHAT DR. BOFFETTA HAS TESTIFIED.

16 THE COURT: THE OBJECTION SUSTAINED.

17 LIMIT IT TO WHAT IS SAID IN PARAGRAPH 52.

18 MR. METZGER: ALL RIGHT.

19 THE COURT: NOT ANY OTHER ARTICLES, JUST WHAT IS  
20 REFERRED TO IN PARAGRAPH 52.

21 MR. METZGER: ALL RIGHT.

22 Q WELL, THEN LET'S TAKE -- DO THAT.

23 DR. INFANTE, DID YOU CONSIDER THE SALA 2000  
24 META-ANALYSIS IN YOUR EVALUATION OF DR. BOFFETTA'S  
25 OPINION OF ABSENCE OF RISK FROM COFFEE/CANCER  
26 META-ANALYSIS?

27 A YES.

28 Q WHAT DID YOU CONCLUDE REGARDING THE SALA

1 META-ANALYSIS?

2 A IT SHOWS A BORDERLINE STATISTICALLY  
3 SIGNIFICANT INCREASE FOR BLADDER CANCER.

4 Q DID YOU CONSIDER THE ZEEGERS 2001  
5 META-ANALYSIS IN THE SAME CONTEXT?

6 A YES.

7 Q WHAT DID YOU CONCLUDE REGARDING THAT  
8 META-ANALYSIS?

9 A IT DEMONSTRATES A SIGNIFICANT INCREASE OF  
10 BLADDER CANCER.

11 Q DID YOU ALSO CONSIDER THE BOTELHO,  
12 B-O-T-E-L-H-O, 2006 META-ANALYSIS REGARDING GASTRIC  
13 CANCER FROM COFFEE CONSUMPTION?

14 A YES.

15 Q AND WHAT DID YOU CONCLUDE REGARDING THAT  
16 META-ANALYSIS?

17 MR. SCHURZ: YOUR HONOR, WE WOULD FURTHER OBJECT AS  
18 LACKS FOUNDATION. WHAT HAS NOT OCCURRED HERE WITH  
19 RESPECT TO ANY OF THIS IS THE PREDICATE WHICH IS  
20 DR. INFANTE'S OPINION THAT DR. BOFFETTA FAILED TO  
21 CONSIDER THESE META-ANALYSES. THAT HAS NOT BEEN  
22 ESTABLISHED. IN FACT, ALL OF THESE META-ANALYSES WERE  
23 PART OF DR. BOFFETTA'S MATERIALS AND WERE CONSIDERED.

24 THE COURT: WELL, IF THE WITNESS FAILED TO SUPPORT  
25 THE CRITICISM, SO BE IT.

26 GO AHEAD.

27 Q BY MR. METZGER: WHAT DID YOU CONCLUDE  
28 REGARDING THE BOTELHO 2006 META-ANALYSIS OF COFFEE

1 CONSUMPTION AND GASTRIC CANCER?

2 A IT DEMONSTRATED A SIGNIFICANT INCREASED RISK  
3 FOR GASTRIC CANCER.

4 Q AND WHAT DID YOU CONCLUDE REGARDING THE  
5 STEVENS 2007 META-ANALYSIS REGARDING COFFEE CONSUMPTION  
6 AND OVARIAN CANCER?

7 A IT DEMONSTRATED AN INCREASE IN RISK OF  
8 OVARIAN CANCER THAT MISSED BY 100 BEING STATISTICALLY  
9 SIGNIFICANT.

10 Q MISSED BY WHAT?

11 A ONE ONE HUNDREDTH. IN OTHER WORDS, THE  
12 LOWER BOUNDS OF THE CONFIDENCE INTERVAL WAS .99, SO IT  
13 PROVIDES SOME EVIDENCE.

14 Q IS THAT WHAT ONE CALLS A BORDERLINE  
15 SIGNIFICANCE?

16 A YES.

17 Q WHAT DID YOU CONCLUDE REGARDING THE PARK  
18 2010 META-ANALYSIS OF COFFEE CONSUMPTION AND PROSTATE  
19 CANCER?

20 A THAT IT DEMONSTRATES A SIGNIFICANTLY  
21 INCREASED RISK OF PROSTATE CANCER.

22 Q WHAT DID YOU CONCLUDE REGARDING THE TANG  
23 2010 META-ANALYSIS OF COFFEE CONSUMPTION AND LUNG CANCER?

24 A THAT IT DEMONSTRATED A SIGNIFICANTLY  
25 INCREASED RISK OF LUNG CANCER.

26 Q WHAT DID YOU CONCLUDE REGARDING THE  
27 GENKINGER 2012 META-ANALYSIS OF COFFEE CONSUMPTION AND  
28 PANCREATIC CANCER?

1           A           WELL, IT SHOWS AN INCREASED RISK, BUT THE  
2 TREND WAS NOT SIGNIFICANT AT THE .05 LEVEL.

3           Q           WHAT DID YOU CONCLUDE REGARDING THE TURATI  
4 2012 META-ANALYSIS OF COFFEE CONSUMPTION AND PANCREATIC  
5 CANCER?

6           A           THAT IT INDICATED AN INCREASE THAT WAS VERY  
7 CLOSE TO BEING STATISTICALLY SIGNIFICANT.

8           Q           LASTLY, WHAT DID YOU CONCLUDE REGARDING THE  
9 ZHOU 2012 META-ANALYSIS OF COFFEE CONSUMPTION AND BLADDER  
10 CANCER?

11          A           THAT IT DEMONSTRATED A SIGNIFICANTLY  
12 INCREASED RISK OF BLADDER CANCER.

13          Q           BASED UPON YOUR REVIEW OF THESE  
14 META-ANALYSES OF COFFEE CONSUMPTION AND VARIOUS CANCERS,  
15 DID YOU REACH AN OPINION AS TO WHETHER THE META-ANALYSES  
16 OF COFFEE CONSUMPTION AND HUMAN CANCER DEMONSTRATED AN  
17 ABSENCE OF RISK OF HUMAN CANCER?

18          A           YES.

19          Q           WHAT WAS YOUR CONCLUSION?

20          A           THEY DO NOT DEMONSTRATE AN ABSENCE OF RISK.

21          MR. SCHURZ: YOUR HONOR, WE WOULD MOVE TO STRIKE AS  
22 NEW OPINIONS OUTSIDE THE SCOPE NOT PREVIOUSLY DISCLOSED  
23 WITH RESPECT TO ALL SITES OTHER THAN THE SALA, ZEEGERS,  
24 TURATI, GENKINGER, ZHOU, WHICH WERE PART OF THE MATERIALS  
25 THAT HE STUDIED, AND THEY WERE PART OF HIS PRIOR  
26 TESTIMONY.

27          THE COURT: OVERRULED. THE ANSWER WILL STAND.

28                    NEXT QUESTION.

1 Q BY MR. METZGER: DR. INFANTE, I THINK WE ARE  
2 NOW READY TO TALK ABOUT CHILDHOOD LEUKEMIA IF THAT IS  
3 OKAY?

4 A OKAY.

5 Q BEFORE WE GET INTO THOSE STUDIES, WILL YOU  
6 TELL THE COURT WHETHER YOU HAVE PUBLISHED ARTICLES IN THE  
7 PEER-REVIEWED LITERATURE REGARDING EPIDEMIOLOGY STUDIES  
8 FOR LEUKEMIA?

9 A YES, QUITE A FEW OF THEM I HAVE PUBLISHED.

10 Q HAS THAT BEEN A MAJOR AREA OF YOUR RESEARCH?

11 A YES. THE MAJOR AREA.

12 Q YOU MENTIONED EARLIER A STUDY REGARDING  
13 BENZENE. WAS THAT KNOWN AS THE PLIOFILM STUDY?

14 A YES.

15 Q IS THAT THE STUDY IN WHICH YOU REPORTED FOR  
16 THE FIRST TIME IN AN EPIDEMIOLOGIC STUDY SIGNIFICANTLY  
17 INCREASED RISKS OF LEUKEMIA AMONG BENZENE-EXPOSED  
18 WORKERS?

19 A IT WAS THE FIRST TIME IT WAS REPORTED IN A  
20 COHORT STUDY.

21 Q ALL RIGHT. HAVE YOU ALSO PUBLISHED STUDIES  
22 REGARDING CHILDHOOD LEUKEMIA?

23 A YES.

24 Q WOULD YOU TELL US ABOUT SOME OF THOSE  
25 STUDIES?

26 A WELL, THE -- I MEAN, IN 1974, I THINK THE  
27 FIRST PAPER THAT I PUBLISHED IN "ENVIRONMENTAL HEALTH"  
28 WAS EVALUATING SECULAR CHANGES IN CHILDHOOD LEUKEMIA

1 MORTALITY TO -- I CAN GO INTO MORE DETAIL IF YOU WANT.  
2 THAT WAS THE FIRST PUBLICATION THAT I HAD. I HAVE  
3 PUBLISHED OTHER PAPERS RELATED TO ALSO CHILDHOOD  
4 LEUKEMIA, PARTICULARLY RELATED TO BENZENE AND OTHER  
5 PETROLEUM SOLVENTS.

6 Q NOW, HOW DID YOU GO ABOUT ASSESSING THE  
7 EPIDEMIOLOGIC STUDIES REGARDING MATERNAL CONSUMPTION OF  
8 COFFEE DURING PREGNANCY AND THE DEVELOPMENT OF CHILDHOOD  
9 LEUKEMIA?

10 A I EVALUATED ALL OF THE -- I IDENTIFIED ALL  
11 OF THE STUDIES AND EVALUATED THE DATA IN ALL OF THOSE  
12 STUDIES.

13 Q WOULD YOU TELL US BY AUTHOR AND YEAR WHICH  
14 STUDIES YOU IDENTIFIED THAT EXPLORED RELATIONSHIPS  
15 BETWEEN MATERNAL CONSUMPTION OF COFFEE DURING PREGNANCY  
16 AND THE DEVELOPMENT OF CHILDHOOD LEUKEMIA?

17 A ROSS 19 -- I'M SORRY, 1996. PETRIDOU 1997.  
18 CLAVEL 2005. MENEGAUX 2005. BONAVENTURE 2011. THE  
19 CHENG META-ANALYSIS, 2014.

20 Q DID YOU REVIEW THE MENEGAUX 2007?

21 A I'M SORRY, YES, I DID. I MISSED THAT.

22 Q AND THE MILNE 2011 STUDY?

23 A YES.

24 Q NOW, ARE THESE ALL OF THE PUBLISHED STUDIES  
25 THAT ASSESS RISK OF CHILDHOOD LEUKEMIA IN RELATIONSHIP TO  
26 MATERNAL CONSUMPTION OF COFFEE DURING PREGNANCY?

27 A YES.

28 Q YOU DID NOT LEAVE OUT ANY STUDIES?

1           A           WELL, UNLESS I MISSED ONE, THEY ARE ALL I  
2    COULD FIND.

3           Q           NOW, THERE WAS A MENTION MADE EARLIER IN  
4    THIS TRIAL REGARDING A STUDY BY PETERS AND CHILDHOOD  
5    LEUKEMIA. ARE YOU FAMILIAR WITH THAT STUDY?

6           A           YEAH, JOHN PETERS FROM U.S.C.

7           Q           DID THAT STUDY EVALUATE THE RISK OF  
8    CHILDHOOD LEUKEMIA IN RELATIONSHIP TO MATERNAL  
9    CONSUMPTION OF COFFEE DURING PREGNANCY?

10          A           NO.

11          Q           WHAT DID THAT STUDY DO?

12          A           WELL, IT LOOKED AT -- IT WAS POSTNATAL  
13    EXPOSURE.

14          Q           ALL RIGHT. SO DID YOU ABSTRACT THE  
15    ESSENTIAL DATA FROM THE STUDIES THAT YOU IDENTIFIED?

16          MR. SCHURZ: OBJECTION; LEADING.

17          THE COURT: OVERRULED.

18          THE WITNESS: YES, I DID.

19          Q           BY MR. METZGER: DID YOU PREPARE THOSE IN  
20    WRITTEN NOTES THAT WERE PRODUCED AS ONE OF THE EXHIBITS  
21    TO YOUR DEPOSITION?

22          A           YES, I DID.

23          Q           HAVE YOU INCLUDED THOSE DATA IN THE  
24    POWERPOINT SLIDES SO THAT WE COULD SEE THEM?

25          A           YES.

26          Q           IS THIS SLIDE HERE REGARDING MATERNAL  
27    CONSUMPTION DURING PREGNANCY AND CHILDHOOD ACUTE  
28    LEUKEMIA, IS THAT THE FIRST PRESENTATION OF THESE?

1           A           YES.

2           Q           SO WOULD YOU TELL US REGARDING THE ROSS 1996  
3 STUDY WHAT YOU FOUND OF NOTE IN YOUR REVIEW OF THAT  
4 STUDY?

5           A           YES, THIS IS THE STUDY OF INFANT LEUKEMIAS,  
6 WHICH MEANS CHILDREN THAT DEVELOP LEUKEMIA BY THE AGE OF  
7 ONE, NOT AFTER ONE YEAR OF AGE. AND THE STUDY SHOWS  
8 THE -- BY COFFEE CONSUMPTION OF THE MOTHER -- SHOWS AN  
9 INCREASED RISK OF INFANT LEUKEMIA. AND THERE, IN FACT,  
10 IS A SIGNIFICANT DOSE-RESPONSE, WHICH IS NOT INDICATED  
11 THERE. I THINK THE P-VALUE IS .04.

12          Q           SO WHEN YOU SAY THERE WAS A SIGNIFICANT  
13 ELEVATION, WAS THAT FOR WOMEN WHO CONSUMED GREATER THAN  
14 OR EQUAL TO FOUR CUPS OF COFFEE PER WEEK?

15          A           YES, AND ALSO THE DOSE-RESPONSE IS  
16 SIGNIFICANT.

17          Q           OKAY, AND WHY DID YOU CONSIDER THAT STUDY  
18 WITH THE SIGNIFICANT ELEVATION AND THE SIGNIFICANT  
19 DOSE-RESPONSE TO BE IMPORTANT?

20          A           BECAUSE IT IS SHOWING AS THE MOTHER CONSUMES  
21 AN INCREASED AMOUNT OF COFFEE, THERE IS AN INCREASED RISK  
22 OF HER GIVING BIRTH TO A CHILD WITH LEUKEMIA.

23          Q           OKAY, AND WAS THERE ANYTHING ELSE ABOUT THIS  
24 STUDY THAT YOU FOUND OF SIGNIFICANCE?

25          A           WELL, THOSE ARE THE MAIN FINDINGS, BUT I  
26 MEAN, I HAVE THE DATA THERE BY -- THE MAJOR FORMS OF  
27 LEUKEMIA IN CHILDREN, THERE ARE TWO. THE MAJORITY IS  
28 ACUTE LYMPHATIC LEUKEMIA AND ACUTE MYELOID LEUKEMIA.

1 MAYBE YOU HAVE ONE ACUTE MYELOID LEUKEMIA FOR EVERY EIGHT  
2 ACUTE LYMPHATIC LEUKEMIAS. SO ACUTE LYMPHATIC LEUKEMIA  
3 REALLY IS A DISEASE OF CHILDREN.

4 SO THE DATA SHOWS WHEN I HAVE "INFANT  
5 LEUKEMIAS," THAT IS COMBINING THE RESULTS OF A.L.L. AND  
6 A.M.L., AND THEN THEY ARE SPLIT OUT BELOW.

7 Q ALL RIGHT. WHAT WAS THE NEXT STUDY THAT  
8 EVALUATED MATERNAL CONSUMPTION OF COFFEE AND CHILDHOOD  
9 LEUKEMIA THAT YOU CONSIDERED?

10 A THE PETRIDOU STUDY FROM GREECE.

11 Q WHAT WAS THE RESULT OF THAT STUDY?

12 A THAT STUDY DID NOT INDICATE ANY ELEVATED  
13 RISK OF CHILDHOOD LEUKEMIA.

14 Q WHAT WAS THE NEXT STUDY THAT YOU CONSIDERED?

15 A THE CLAVEL 2005.

16 Q WHAT DID YOU FIND OF NOTE OR IMPORTANCE IN  
17 THAT STUDY?

18 A WELL, IN THIS STUDY, THERE IS -- THEY HAVE A  
19 SIGNIFICANT INCREASE AT THE HIGHEST AMOUNT OF MATERNAL  
20 CONSUMPTION. YOU HAVE A RISK OF 4.1. THERE IS ALSO A  
21 SIGNIFICANT DOSE-RESPONSE IN THIS STUDY.

22 SO, IN OTHER WORDS, IF YOU COMPARED MOTHERS  
23 WHO DRANK LESS THAN THREE CUPS, YOU SEE WHAT THE RISK IS.  
24 AND FOR THOSE WHO DRANK MORE THAN THREE CUPS, THE RISK  
25 GOES UP TO 4.1. SO THAT INDICATED A SIGNIFICANT INCREASE  
26 IN CHILDHOOD LEUKEMIA AND A SIGNIFICANT DOSE-RESPONSE,  
27 WHICH IS A POWERFUL OBSERVATION.

28 Q THERE WAS ALSO A 2005 STUDY BY MENEGAUX, IS

1 THAT RELATED TO THIS 2005 STUDY BY CLAVEL?

2 A YES. SOME OF THE CASES, QUITE A NUMBER OF  
3 THE CASES OVERLAP. IT IS ESSENTIALLY ABOUT THE SAME  
4 POPULATION, BUT IN ONE OF THEM, THEY PULLED OUT SOME OF  
5 THE CASES.

6 Q IN THE MENEGAUX STUDY, DID THEY LOOK AT THE  
7 SUBTYPES OF CHILDHOOD LEUKEMIA?

8 A YES.

9 Q WHAT, IF ANYTHING, DID YOU CONSIDER OF  
10 SIGNIFICANCE IN THE MENEGAUX 2005 STUDY?

11 A WELL, FOR CHILDHOOD LEUKEMIA, WHICH IN THIS  
12 STUDY WAS DEFINED AS CHILDREN 15 YEARS OF AGE OR YOUNGER,  
13 YOU SEE THAT THERE IS A DOSE-RESPONSE BY AMOUNT OF COFFEE  
14 CONSUMED BY THE MOTHER. IT GOES FROM 1.0 FOR LESS THAN  
15 THREE CUPS A DAY, TO 2.1 FOR FOUR TO EIGHT CUPS A DAY, TO  
16 2.8 FOR MOTHERS THAT CONSUMED MORE THAN EIGHT CUPS A DAY.

17 THE RESULT OF THAT ANALYSIS, THE TREND  
18 ANALYSIS IS STATISTICALLY SIGNIFICANT.

19 Q WHAT DID YOU CONCLUDE REGARDING THE RESULT  
20 OF THAT STUDY CONCERNING ACUTE LYMPHOID LEUKEMIA OR  
21 LYMPHATIC LEUKEMIA?

22 A WELL, I MEAN, YOU ESSENTIALLY SEE THE SAME  
23 TREND FOR ACUTE LYMPHATIC LEUKEMIA AND ACUTE MYELOID  
24 LEUKEMIA, BUT I DON'T RECALL IF THE TREND IS SIGNIFICANT  
25 OR NOT BECAUSE YOU HAVE GOT FEWER CASES. YOU ARE  
26 SPLITTING UP THE TOP ANALYSIS INTO FEWER CASES. BUT YOU  
27 ARE SEEING, ESSENTIALLY, A TREND OF AN INCREASED RISK  
28 WITH AN INCREASE OF BOTH A.L.L. AND A.M.L.

1           Q           HOW INCREASED WAS THE RISK OF A.L.L. FOR THE  
2 MOTHERS WHO CONSUMED LARGE AMOUNTS OF COFFEE DURING  
3 PREGNANCY IN THE MENEGAUX 2005 STUDY?

4           A           3.1.

5           Q           A THREE-FOLD RISK?

6           A           INCREASE, YES.

7           Q           WAS THAT STATISTICALLY SIGNIFICANT?

8           A           WELL, THAT DATA POINT IS BORDERLINE  
9 STATISTICALLY SIGNIFICANT, BUT THE DOSE-RESPONSE TREND  
10 FOR COMBINING BOTH IS STATISTICALLY SIGNIFICANT, WHICH IS  
11 ABOVE THAT. BUT IT IS CONSISTENT WITH BOTH SUBTYPES OF  
12 LEUKEMIA IN CHILDREN DATA.

13          Q           THE NEXT STUDY THAT YOU MENTIONED WAS THE  
14 MENEGAUX 2007 STUDY, AND WHAT DID YOU CONCLUDE FROM THIS  
15 STUDY?

16          A           WELL, I CONCLUDED FROM THIS STUDY THAT IT  
17 ALSO PROVIDED EVIDENCE FOR AN ASSOCIATION BETWEEN  
18 MATERNAL CONSUMPTION OF COFFEE AND LEUKEMIA. AND ALSO,  
19 WHEN YOU LOOK AT NON-SMOKERS, YOU ACTUALLY HAVE THE  
20 HIGHEST RISK.

21          Q           WHY WAS THAT OF SIGNIFICANCE TO YOU?

22          A           WELL, BECAUSE OF ANY POTENTIAL CONFOUNDING  
23 FROM SMOKING WOULD BE ELIMINATED WHEN YOU ARE ANALYZING  
24 THE DATA. SO I THINK THAT IS IMPORTANT IN THAT STUDY.

25          Q           ALL RIGHT. THE NEXT STUDY WAS BY MILNE FROM  
26 AUSTRALIA IN 2011. DID THAT STUDY PROVIDE INDEPENDENT  
27 DATA REGARDING THIS ISSUE?

28          A           YES.

1 Q DID THOSE AUTHORS ALSO INCLUDE IN THAT  
2 PUBLICATION A META-ANALYSIS?

3 A YES.

4 Q LET'S FIRST TALK ABOUT THE DATA THAT THEY  
5 COLLECTED.

6 WOULD YOU TELL THE COURT WHAT YOU FOUND OF  
7 NOTE IN THEIR DATA?

8 A IN THE MILNE ANALYSIS?

9 Q NOT IN THE META-ANALYSIS, BUT IN THE MILNE  
10 STUDY, THE CASE-CONTROL STUDY.

11 A IN THE STUDY?

12 Q YES.

13 A WELL, FOR ACUTE LEUKEMIA IN CHILDREN,  
14 THEY -- NONE OF THE RESULTS ARE STATISTICALLY SIGNIFICANT  
15 EVEN THOUGH THERE IS, YOU KNOW, A SLIGHT -- THERE IS  
16 SOMEWHAT OF A DOSE-RESPONSE. I GUESS THERE IS REALLY  
17 LIKE A 45 PERCENT DOSE-RESPONSE BETWEEN LESS THAN TWO  
18 CUPS A DAY TO MORE THAN TWO CUPS A DAY. THOSE INDIVIDUAL  
19 RESULTS AREN'T STATISTICALLY SIGNIFICANT.

20 BUT THEN WHEN YOU LOOK AT ACUTE LEUKEMIA IN  
21 NON-SMOKERS, YOU SEE A HIGHER RISK. THEN WHEN THEY  
22 ANALYZE THEIR DATA BY CHILDREN WITH LEUKEMIA WHO HAD  
23 SPECIFIC TRANSLOCATIONS --

24 Q STOP RIGHT THERE. WHAT IS A TRANSLOCATION?

25 A THESE ARE CHILDREN THAT ARE BORN WITH A  
26 LEUKEMIA THAT HAS GOT LIKE A GENETIC TRANSFORMATION TO  
27 IT. LIKE WHEN YOU -- CERTAINLY I KNOW LIKE IN ADULT, IT  
28 IS RELATED TO HOW YOU TREAT THE LEUKEMIA. WHAT THE

1 PROGNOSIS IS, HOW MANY CHROMOSOMAL TRANSLOCATIONS AND THE  
2 TYPES YOU MAY HAVE.

3 Q SO THESE ARE TRANSLOCATIONS OF CHROMOSOMES?

4 A YES.

5 Q I SEE. OKAY. ALL RIGHT. AND WHAT DID YOU  
6 CONSIDER TO BE IMPORTANT ABOUT THE FINDINGS REGARDING THE  
7 CHILDREN WHO WERE BORN, OR DEVELOPED, I SHOULD NOT SAY  
8 BORN, BUT DEVELOPED CHILDHOOD LEUKEMIA WITH TRANCE --  
9 CHROMOSOME TRANSLOCATIONS?

10 A THEY HAD THE HIGHEST RISK RELATED TO  
11 CIGARETTE SMOKING. AS YOU CAN SEE FROM -- IF THE MOTHER  
12 CONSUMED LESS THAN TWO CUPS A DAY, THE RISK IS 1.2. IF  
13 SHE CONSUMED MORE THAN TWO CUPS A DAY, THE RISK IS 2.5.

14 Q DID YOU SAY RELATED TO CIGARETTE SMOKING?

15 A IF I DID, I DID NOT MEAN TO SAY THAT. I AM  
16 TALKING ABOUT COFFEE CONSUMPTION. PARDON ME.

17 Q SO JUST SO WE ARE CLEAR, THE WOMEN WHO  
18 CONSUMED COFFEE DURING PREGNANCY MORE THAN TWO CUPS PER  
19 DAY WHO WERE NON-SMOKERS, THEY HAD -- THEIR CHILDREN HAD  
20 A TWO-AND-A-HALF-FOLD INCREASED RISK OF DEVELOPING  
21 CHILDHOOD LEUKEMIA WITH THESE CHROMOSOME TRANSLOCATIONS?

22 IS THAT --

23 A NO, THE MOTHER HAS A TWO-AND-A-HALF-FOLD  
24 INCREASED RISK OF HAVING HER CHILD THAT SHE BEARS DEVELOP  
25 LEUKEMIA WITH THESE TRANSLOCATIONS.

26 Q GOT IT. THANK YOU.

27 WHAT IS THE SIGNIFICANCE TO YOU THAT -- OF  
28 THAT, THAT THESE CHILDREN WERE BORN WITH A LEUKEMIA, I

1 SHOULD NOT SAY WERE BORN WITH, BUT THEY DEVELOPED  
2 LEUKEMIA WITH THESE CHROMOSOME TRANSLOCATIONS?

3 A WELL, I MEAN, IT IS -- YOU KNOW, IT IS  
4 ANOTHER TYPE OF ANALYSIS THAT IS DONE. IT IS SAYING,  
5 HEY, THERE IS THIS SEGMENT OF CHILDHOOD LEUKEMIA WHERE  
6 CHILDREN HAVE THESE TRANSLOCATIONS. IN THIS STUDY, YOU  
7 ARE SEEING, YOU KNOW, A HIGH RISK FROM, AND A  
8 DOSE-RESPONSE IN THE DATA FROM COFFEE CONSUMPTION.

9 Q GOT IT. THANK YOU.

10 NOW, WOULD YOU TELL US WHAT YOU GLEANED FROM  
11 THE MILNE AUTHORS' META-ANALYSIS THAT THEY ALSO REPORTED  
12 IN THIS PUBLICATION?

13 A YES, IN THEIR META-ANALYSIS, THEY  
14 DEMONSTRATE A SIGNIFICANT INCREASE IN CHILDHOOD ACUTE  
15 LEUKEMIA. THAT IS 1.67 FOR THOSE THAT CONSUME MORE THAN  
16 THREE CUPS A DAY. THEN WHEN YOU LOOK AT THE ACUTE  
17 LEUKEMIA IN NON-SMOKERS CONSUMING THE SAME AMOUNT, IT IS  
18 EVEN HIGHER. IT IS 2.3. THAT IS ALSO HIGHLY  
19 SIGNIFICANT.

20 Q ALL RIGHT. WHAT WAS THE NEXT STUDY THAT YOU  
21 CONSIDERED?

22 A THE BONAVENTURE 2013 STUDY.

23 Q OKAY. WOULD YOU TELL US, FIRST OF ALL,  
24 ABOUT THAT STUDY. WHAT YOU THOUGHT ABOUT THE QUALITY OF  
25 THAT STUDY.

26 A I MEAN, THIS IS A VERY WELL-CONTROLLED  
27 STUDY. IT WAS DONE -- IT ALSO HAS -- I THINK THERE WERE  
28 OVER 700 CHILDHOOD LEUKEMIA CASES INVOLVED IN IT. THE

1 STRONG ASPECTS OF THIS STUDY ARE THAT THERE WAS A HIGH  
2 PARTICIPATION RATE. IT WAS OVER 90 PERCENT FOR THE  
3 CASES, AND FOR THE CONTROLS, IT WAS OVER 70 PERCENT.  
4 THAT IS A PRETTY HIGH PARTICIPATION RATE FOR CONTROLS  
5 BECAUSE IT IS OFTEN DIFFICULT TO GET THEM TO PARTICIPATE.

6 THEY INSURED THAT THE CONTROLS WERE  
7 COMPARABLE TO THE FRENCH POPULATION IN TERMS OF REGION,  
8 BIRTH ORDER AND MATERNAL EDUCATION BY THE WAY THAT THEY  
9 SELECTED THE CONTROLS TO PUT INTO THEIR DATABASE. SO  
10 THAT WOULD, YOU KNOW, IN MY OPINION, INDICATE THAT  
11 SELECTION BIAS IS UNLIKELY FOR THE CONTROLS BECAUSE THEY  
12 ARE REPRESENTING THE FRENCH GENERAL POPULATION IN TERMS  
13 OF THE FACTORS THAT THEY EVALUATED FOR.

14 THE STUDY USED A STANDARD QUESTIONNAIRE AND  
15 THEY USED IDENTICAL INTERVIEW CONDITIONS. SO THAT SHOULD  
16 REDUCE THE RISK OF DIFFERENTIAL RECALL BIAS.

17 THEN THEY -- THEN ALSO, IF YOU LOOK AT IT,  
18 YOU COULD SAY, WELL, MAYBE WOMEN -- YOU KNOW, THIS CAN GO  
19 BOTH WAYS. YOU CAN TAKE THE ONE HAND AND SAY, WELL,  
20 MAYBE WOMEN THAT HAVE A CHILD WITH LEUKEMIA FEEL GUILTY  
21 AND THEY UNDER-REPORT THEIR COFFEE CONSUMPTION BECAUSE  
22 THEY ARE FEELING GUILTY THAT -- YOU KNOW, IF THEY KNEW  
23 THAT COFFEE CONSUMPTION WAS RELATED TO THE LEUKEMIA OR  
24 ADVERSE HEALTH EFFECTS, BUT I DON'T THINK THEY KNEW THAT.

25 SO THEN YOU CAN ALSO ENTERTAIN THE OPPOSITE  
26 AND SAY, WELL, MAYBE IF THEY FELT GUILTY BECAUSE THEIR  
27 CHILD, YOU KNOW, DEVELOPED LEUKEMIA, THEN THEY MIGHT  
28 REPORT MORE COFFEE CONSUMPTION.

1                   BUT YOU KNOW -- BUT THAT SEEMS UNLIKELY IN  
2 THE STUDY BECAUSE WHEN YOU LOOK AT THE ANALYSIS BY  
3 ALCOHOL INTAKE, WHICH MOTHERS AND PREGNANT MOTHERS KNOW  
4 SHE SHOULD NOT CONSUME, IF OUT OF GUILT THEY  
5 OVER-REPORTED FACTORS THAT THEY THOUGHT MIGHT BE RELATED  
6 TO CHILDHOOD LEUKEMIA, ONE WOULD THINK THEY CERTAINLY  
7 WOULD HAVE REPORTED ALCOHOL INTAKE, YET THERE IS NO  
8 ASSOCIATION BETWEEN CHILDHOOD LEUKEMIA AND ALCOHOL INTAKE  
9 IN THIS STUDY OR IN ANY OF THE STUDIES THAT THEY DID.

10                   THEN FURTHER ANALYSIS THAT THEY DID, AND  
11 THEY INDICATED THERE WAS NO MODIFYING EFFECTS ON THE RISK  
12 OF LEUKEMIA WHEN THE DATA WERE ANALYZED OR ADJUSTED FOR  
13 BIRTH ORDER, BREAST FEEDING, MATERNAL EDUCATION,  
14 SOCIO-PROFESSIONAL CATEGORY OF THE HOUSEHOLD. SO THEY  
15 HAVE, IN ESSENCE, ADJUSTED THE DATA FOR OTHER FACTORS  
16 THAT COULD POSSIBLY BE RELATED TO AN ELEVATED RISK OF  
17 LEUKEMIA. AND WHEN THEY DID THAT, IT DID NOT MODIFY  
18 THEIR FINDINGS.

19                   SO, IN MY OPINION, THIS IS A VERY STRONG  
20 STUDY.

21           Q           I WANT TO ASK YOU A QUESTION. NOW, DID YOU  
22 MAKE ANY EFFORTS TO DETERMINE WHETHER THE CASES IN THIS  
23 BONAVENTURE 2013 STUDY HAD BEEN INCLUDED IN ANY OF THE  
24 EARLIER FRENCH CASE-CONTROL STUDIES?

25           A           WELL, YOU CAN SEE FROM THE DATE OF WHEN THEY  
26 WERE DIAGNOSED THAT THERE IS NO OVERLAP.

27           Q           IS THAT IMPORTANT?

28           A           WELL, YOU WOULD NOT WANT TO BE -- WELL, IF

1 YOU ARE GOING TO INCLUDE THIS STUDY AND THEN INCLUDE  
2 ANOTHER STUDY, IF THERE IS SOME OVERLAP, THEN IT IS NOT  
3 REALLY TWO INDEPENDENT STUDIES. BUT IN THIS, THERE IS NO  
4 OVERLAP BETWEEN THIS AND THE EARLIER STUDIES IN THE  
5 CASES.

6 Q WAS THERE ANYTHING ELSE ABOUT THE WAY THAT  
7 THE BONAVENTURE STUDY WAS CONDUCTED OR ITS NATURE THAT  
8 YOU CONSIDERED IMPORTANT?

9 A WELL, I JUST WENT THROUGH QUITE A FEW.  
10 NOTHING THAT COMES TO MY HEAD. I GUESS IF I TOOK A LOOK  
11 AT THE STUDY RIGHT NOW, I MIGHT BE ABLE TO POINT SOME  
12 OTHER THINGS OUT TO YOU.

13 Q WELL, LET'S LOOK AT THE RESULTS AND TELL US  
14 WHAT YOU CONSIDERED TO BE IMPORTANT.

15 LET'S START WITH THE TOTAL CATEGORY OF ACUTE  
16 CHILDHOOD LEUKEMIA AND TELL US WHAT YOU FOUND TO BE  
17 IMPORTANT REGARDING THE RESULTS THAT THEY REPORTED IN  
18 BONAVENTURE 2013.

19 A WELL, YOU SEE A SIGNIFICANT DOSE-RESPONSE --  
20 YOU SEE A SIGNIFICANT TREND WITH AN INCREASE IN THE  
21 AMOUNT OF COFFEE CONSUMED PER DAY AND THE RISK OF  
22 CHILDHOOD LEUKEMIA. THEN WHEN THEY SEPARATED IT OUT, AND  
23 SAID, WELL, LET'S SEPARATE IT OUT INTO ACUTE  
24 LYMPHATIC --

25 Q LET ME INTERRUPT YOU JUST A MINUTE BEFORE WE  
26 GET TO THE SUBTYPES, I WOULD LIKE TO GO OVER THIS WITH  
27 YOU. WHEN YOU SAID THERE WAS A SIGNIFICANT TREND, ARE  
28 YOU REFERRING TO THE ODDS RATIO INCREASING FROM 1.0 TO

1 1.3 TO 1.6?

2 A YES, AND THE -- THAT TREND PIECE HAS LESS  
3 THAN .001.

4 Q WHICH MEANS?

5 A THAT WOULD ONLY OCCUR ONE TIME IN 1,000 DUE  
6 TO CHANCE ALONE.

7 Q DO YOU CONSIDER THAT TYPE OF A P-VALUE TO BE  
8 ROBUST?

9 A YES.

10 Q ALL RIGHT. I SEE THAT ON THE POWERPOINT THE  
11 ODDS RATIOS OF 1.3 AND 1.6 ARE BOLDED. WHY IS THAT?

12 A WELL, BECAUSE -- WELL, THE 1.3 IS BORDERLINE  
13 SIGNIFICANT AND THE 1.6, BY ITSELF, IS STATISTICALLY  
14 SIGNIFICANT, BUT I WOULD PUT MORE WEIGHT INTO THIS  
15 MONOTONIC DOSE-RESPONSE AND THE P-TREND THAT IS  
16 STATISTICALLY SIGNIFICANT BECAUSE IN THAT ANALYSIS, YOU  
17 ARE INCLUDING DATA FROM ALL THREE. YOU ARE COMBINING THE  
18 THREE DATA POINTS TO FACTOR IT INTO: IS THE RESULT  
19 SIGNIFICANT OR IS THERE A DOSE-RESPONSE OR NOT.

20 TO ME, THAT IS A MORE POWERFUL OBSERVATION  
21 THAN THE INDIVIDUAL DATA POINTS.

22 Q I UNDERSTAND. WOULD YOU NOW PROCEED TO THE  
23 DATA REGARDING THE ACUTE LYMPHATIC LEUKEMIA IN CHILDREN  
24 AND TELL US WHAT YOU FOUND TO BE NOTEWORTHY OF THAT DATA?

25 A YES. WELL, YOU CAN SEE THE ODDS RATIO THERE  
26 IS INCREASED WITH AN INCREASE IN MATERNAL CONSUMPTION.  
27 AGAIN, THE P-TREND IS HIGHLY SIGNIFICANT, .002.

28 Q AND THOSE WOMEN WHO CONSUMED GREATER THAN

1 TWO CUPS PER DAY HAD AN INCREASED RISK FOR THEIR CHILDREN  
2 TO DEVELOP ACUTE LYMPHOID LEUKEMIA OF A 2.4-FOLD  
3 INCREASED RISK?

4 MR. SCHURZ: OBJECTION; HEARSAY.

5 THE WITNESS: YES. WELL, IT IS 2.4 TO BE EXACT.

6 THE COURT: OVERRULED.

7 Q BY MR. METZGER: ALL RIGHT. AND WHAT  
8 SIGNIFICANCE DID YOU ATTRIBUTE TO THE DATA REGARDING  
9 ACUTE MYELOID LEUKEMIA IN THE CHILDREN?

10 A THAT IT SHOWS A SIGNIFICANT DOSE-RESPONSE IN  
11 RELATION TO MATERNAL COFFEE CONSUMPTION DURING PREGNANCY.

12 Q OKAY. AND WOULD YOU TELL US WHAT THE STUDY  
13 INDICATED TO YOU REGARDING THE RISK OF CHILDHOOD LEUKEMIA  
14 AMONG MOTHERS WHO WERE NON-SMOKERS BUT CONSUMED COFFEE  
15 DURING PREGNANCY?

16 A YES, YOU SEE THAT -- WELL, YOU SEE A  
17 MONOTONIC DOSE-RESPONSE FOR NONSMOKING MOTHERS ALSO,  
18 WHICH I THINK IS, YOU KNOW, EVEN A VERY POWERFUL  
19 OBSERVATION IN AND OF ITSELF BECAUSE NOW YOU -- YOU KNOW,  
20 THERE IS NO CONFOUNDING FROM CIGARETTE SMOKING.

21 Q WELL, HAS CIGARETTE SMOKING BEEN ASSOCIATED  
22 WITH LEUKEMIA?

23 A WITH MYELOGENOUS LEUKEMIA IN ADULTS. SO,  
24 YOU KNOW, I WOULD -- WELL, I WOULD NOT WANT A PREGNANT  
25 MOTHER SMOKING CIGARETTES. I WOULD HOPE THEY WOULD NOT.

26 Q WELL, FOR THE NONSMOKING MOTHERS WHOSE  
27 CHILDREN DEVELOPED ACUTE MYELOGENOUS -- THAT IS THE SAME  
28 THING, MYELOID AND MYELOGENOUS LEUKEMIA?

1           A           YES.

2           Q           FOR THOSE WOMEN, THEIR CHILDREN HAD -- WAS  
3 IT A GREATER THAN THREE-FOLD EXCESS RISK OF DEVELOPING  
4 THAT SUBTYPE OF LEUKEMIA?

5           A           YES.

6           Q           WAS THAT STATISTICALLY SIGNIFICANT?

7           A           YES, IT IS.

8           Q           ALL RIGHT. SO WHAT DID YOU CONCLUDE  
9 REGARDING THE BONAVENTURE 2013 STUDY?

10          A           I THINK IT IS A VERY WELL CONDUCTED STUDY OF  
11 A LARGE NUMBER OF CASES OF CHILDHOOD LEUKEMIA. IT  
12 DEMONSTRATES A SIGNIFICANT DOSE-RESPONSE BETWEEN MATERNAL  
13 ALCOHOL -- I MEAN MATERNAL COFFEE CONSUMPTION DURING  
14 PREGNANCY AND THE RISK OF HAVING A CHILD WITH LEUKEMIA.

15          Q           OKAY. GIVE ME ONE MOMENT.

16                    NOW, IN YOUR OPINION, IS IT FEASIBLE TO  
17 STUDY THE QUESTION OF WHETHER MATERNAL CONSUMPTION OF  
18 COFFEE DURING PREGNANCY INCREASES THE RISK OF CHILDHOOD  
19 LEUKEMIA IN A COHORT STUDY?

20          A           I THINK I HAD MENTIONED EARLIER THAT IT  
21 WOULD BE VIRTUALLY IMPOSSIBLE TO DO BECAUSE YOU WOULD  
22 NEED TO ENROLL TOO MANY PEOPLE IN THE STUDY. YOU COULD  
23 NOT POSSIBLY EVER GET ENOUGH CASES FROM WHAT I THINK I  
24 ESTIMATED 1,500,000 JUST TO LIKE PRODUCE ONE CASE OF  
25 CHILDHOOD LEUKEMIA. YOU KNOW, IN THESE STUDIES, THIS ONE  
26 HAD OVER 700 CASES. SO THE CASE-CONTROL STUDIES ARE MORE  
27 POWERFUL.

28          Q           OKAY. WHEN YOU SAY "MORE POWERFUL," DO YOU

1 MEAN IN TERMS OF STATISTICAL --

2 A STATISTICAL POWER, YES.

3 Q GO IT.

4 A IT IS THE ONLY WAY I KNOW THAT YOU COULD  
5 STUDY CHILDHOOD LEUKEMIA.

6 Q NOW, WE HAVE HEARD ABOUT CASE-CONTROL  
7 STUDIES HAVING THE POTENTIAL FOR RECALL BIAS. I THINK  
8 YOU MENTIONED THAT. WHAT EFFORTS DID THE INVESTIGATORS  
9 IN THE BONAVENTURE STUDY UNDERTAKE OR WHAT DATA IS THERE  
10 THAT BEARS UPON THE ISSUE OF WHETHER THIS STUDY IS  
11 CONFOUNDED BY RECALL BIAS?

12 A WELL, YOU KNOW, THERE IS A POTENTIAL FOR  
13 RECALL BIAS IN ANY RETROSPECTIVE STUDY THAT YOU DO, BUT I  
14 DON'T SEE EVIDENCE OF ANY RECALL BIAS IN THIS STUDY. I  
15 MEAN, IT IS POSSIBLE THAT MOTHERS, AS I MENTIONED  
16 EARLIER, THAT HAVE A CHILD WITH LEUKEMIA, YOU KNOW, OUT  
17 OF GUILT MIGHT OVER-REPORT HAZARDOUS THINGS THEY PUT INTO  
18 THEIR BODY DURING PREGNANCY. AS I SAID, THERE IS SOME  
19 INDIRECT EVIDENCE THAT WOULD CONTRADICT THAT BASED ON  
20 THAT THERE IS NO INCREASED RISK RELATED TO ALCOHOL  
21 CONSUMPTION DURING PREGNANCY.

22 ON THE OTHER HAND, IT COULD BE THAT OUT OF  
23 GUILT, YOU KNOW, THEY UNDER-REPORT IT. SO MAYBE THE RISK  
24 COULD BE HIGHER AND YOU JUST DON'T KNOW.

25 Q WHAT DID THE DATA SHOW REGARDING ALCOHOL  
26 CONSUMPTION IN THIS STUDY?

27 A WELL, THERE IS NO ASSOCIATION. WITH AN  
28 INCREASE OF ALCOHOL CONSUMPTION DURING PREGNANCY, THERE

1 WAS NO RISK OF AN INCREASE OF CHILDHOOD LEUKEMIA.

2 Q DID THEY ALSO REPORT DATA IN THIS STUDY  
3 REGARDING SMOKING?

4 A YES.

5 Q WHAT DID THAT SHOW?

6 A WELL, THE NON-SMOKER DATA, IT GOT A  
7 MONOTONIC DOSE-RESPONSE BETWEEN -- I'M SORRY, THEY HAVE  
8 AN OVERALL FINDING HERE FOR NON-SMOKERS. THERE IS A  
9 SIGNIFICANT INCREASE OF ACUTE LEUKEMIA IN CHILDHOOD,  
10 SIGNIFICANT INCREASE IN A.L.L., AND SIGNIFICANT INCREASE  
11 IN A.M.L.

12 Q OKAY. WHAT DOES THAT INDICATE TO YOU ABOUT  
13 THE EFFECT OF SMOKING ON THESE RESULTS FOR COFFEE?

14 A WELL, THAT SMOKING CERTAINLY DID NOT  
15 CONFOUND THE FINDINGS.

16 Q NOW, YOU ALSO MENTIONED THE CHENG  
17 META-ANALYSIS, I BELIEVE; IS THAT CORRECT?

18 A YES.

19 Q AND WHAT DID THAT META-ANALYSIS ATTEMPT TO  
20 DO?

21 A WELL, THIS META-ANALYSIS INCLUDED THE  
22 STUDIES ON CHILDHOOD LEUKEMIA THAT HAD BEEN DONE THAT  
23 THEY IDENTIFIED, YOU KNOW, PRIOR TO 2014. THEY ARE  
24 ESSENTIALLY THE SAME STUDIES THAT I EVALUATED. SO THEY  
25 DID A META-ANALYSIS.

26 Q WAS THIS META-ANALYSIS ALL OF CASE-CONTROL  
27 STUDIES THAT EVALUATED THE MATERNAL CONSUMPTION OF COFFEE  
28 DURING PREGNANCY AND CHILDHOOD LEUKEMIA?

1           A           YES.

2           Q           ALL RIGHT.  IN DOING A META-ANALYSIS, IS IT  
3 IMPORTANT TO MAKE SURE THAT THE STUDIES THAT YOU ARE  
4 INCLUDING IN THE META-ANALYSIS ARE NOT DOUBLE COUNTED?

5           A           OF COURSE.  YES.

6           Q           WHY IS THAT?

7           A           BECAUSE YOU DON'T -- YOU WOULD NOT HAVE  
8 INDEPENDENCE IN TERMS OF YOUR ANALYSIS IF YOU ARE  
9 COUNTING SAY TWO DIFFERENT STUDIES THAT HAVE THE SAME  
10 CASES AND RESULTS.

11          Q           WHY IS IT IMPORTANT TO HAVE INDEPENDENCE IN  
12 A META-ANALYSIS?

13          A           WELL, IF YOU ARE REPORTING WHAT THE SUMMARY  
14 RISK IS, YOU DON'T WANT TO BE COUNTING -- YOU DON'T WANT  
15 TO BE COUNTING, YOU KNOW, TWO POPULATIONS RATHER THAN IF  
16 IT IS JUST ONE.

17          Q           GOT IT.  ALL RIGHT.

18                    NOW, WOULD YOU TELL US WHICH STUDIES WERE  
19 INCLUDED IN THE CHENG META-ANALYSIS?

20                    PERHAPS WE CAN --

21          A           YES, WELL, I HAVE A -- I THINK I TOOK SOME  
22 COPIES RIGHT OUT OF -- WELL, HERE THEY ARE.  YES.  THERE  
23 IS THE ROSS STUDY.

24          Q           SO THERE IS TABLE 1, REPRODUCED FROM THE  
25 CHENG META-ANALYSIS?

26          A           YES.

27          Q           WHICH OF THE STUDIES THAT YOU JUST  
28 IDENTIFIED ARE INCLUDED?

1           A           THE SAME ONES THAT I JUST IDENTIFIED.

2           Q           TO YOUR KNOWLEDGE, ARE THESE ALL OF THE  
3 STUDIES THAT SPECIFICALLY ADDRESS THE RISK OF CHILDHOOD  
4 LEUKEMIA IN RELATIONSHIP TO MATERNAL CONSUMPTION OF  
5 COFFEE DURING PREGNANCY?

6           A           THEY ARE ALL THAT ARE IN THE LITERATURE TO  
7 MY KNOWLEDGE.

8           Q           ALTHOUGH THE PETRIDOU STUDY DID NOT REPORT  
9 AN INCREASED RISK, WAS THAT STILL INCLUDED IN THE  
10 CALCULATION OF THE META-RISK?

11          A           I WOULD HOPE SO, YES.

12          Q           WAS IT?

13          A           YES.

14          MR. SCHURZ: I WILL OBJECT THAT IT MISSTATES THE  
15 DOCUMENT. IT IS QUITE CLEAR AS REFLECTED IN TABLE NO. 1  
16 THAT NOT ONLY DID PETRIDOU NOT INDICATE AN INCREASED  
17 RISK, NEITHER DID MENEGAUX 2007, NOR DID MILNE IN 2011  
18 INDICATE ANY INCREASED RISK, CONTRARY TO THE PRIOR  
19 TESTIMONY.

20          THE COURT: ALL RIGHT. YOU WILL ARGUE ABOUT THAT  
21 LATER.

22          Q           BY MR. METZGER: SO IS THERE ANYTHING ELSE  
23 THAT YOU FEEL IS SIGNIFICANT FOR WHAT WAS INCLUDED IN  
24 THIS TABLE 1 OF THE CHENG META-ANALYSIS?

25          A           WELL, THIS WAS THE UNIVERSE OF STUDIES THAT  
26 WAS INCLUDED IN THE META-ANALYSIS. HOWEVER, IN SOME  
27 META-ANALYSES, THERE MIGHT BE SAY ONE STUDY THAT IS  
28 EXCLUDED BECAUSE OF THE TYPE OF ANALYSIS THEY DID SO THAT

1     THEY DID NOT DOUBLE COUNT.   SO IT DEPENDS ON THE TYPE OF  
2     ANALYSIS THAT THEY ARE DOING.

3           Q           NOW, IF WE TAKE A LOOK AT THE CLAVEL 2004 --  
4     I THINK YOU IDENTIFIED IT AS 2005?

5           A           RIGHT.

6           Q           AND THE MENEGAUX 2005, I SEE THAT FOR THE  
7     CLAVEL, THERE ARE RESULTS FOR ACUTE LEUKEMIA AND FOR  
8     MENEGAUX, THEY HAVE THE RESULTS FOR THE TWO SUBTYPES.   IS  
9     THIS THE SAME STUDY WHERE THEY JUST DID DIFFERENT  
10    ANALYSES?

11          A           IT IS THE SAME POPULATION.   THE CLAVEL, WHAT  
12    THEY HAVE IS 2004 AND I INDICATE AS 2005, IT IS THE SAME,  
13    THAT STUDY AND THE MENEGAUX STUDY ARE THE -- THEY ARE  
14    IDENTICAL POPULATIONS.   BUT IN THE CLAVEL STUDY, THEY ARE  
15    ONLY LOOKING AT 219 OF THE ACUTE CHILDHOOD LEUKEMIAS OUT  
16    OF 280 THAT ARE IN THAT POPULATION, BECAUSE THEY ARE  
17    DOING A DIFFERENT KIND OF ANALYSIS.

18                    SO WHEN THIS META-ANALYSIS IS DONE BY CHENG,  
19    HE IS NOT DOUBLE COUNTING.

20          Q           HOW DO YOU KNOW THERE IS NOT DOUBLE  
21    COUNTING?

22          A           YOU CAN LOOK IN THE FIGURES AND SEE WHICH  
23    STUDIES ARE INCLUDED.

24          Q           OKAY.   ALL RIGHT.

25                    NOW, WOULD YOU TELL THE COURT WHAT A FOREST  
26    PLOT IS?

27          A           WHAT A FOREST PLOT IS?

28          Q           MAYBE I AM USING THE WRONG TERM.   TELL THE

1 COURT WHAT FIGURE 2 IN THE MENEGAUX -- I AM SORRY, WOULD  
2 YOU PLEASE TELL THE COURT WHAT FIGURE 2 IN THE CHENG  
3 META-ANALYSIS DESCRIBES?

4 A YES. THIS WAS, AS IT INDICATES, IT IS A  
5 SUMMARY OF THE ODDS RATIOS FOR TOTAL ACUTE LEUKEMIA FOR  
6 YOU KNOW, EVER, LOW TO MODERATE, AND HIGH LEVEL DRINKERS  
7 VERSUS NEVER AND LOWEST DRINKERS.

8 SO IN THIS FIRST ANALYSIS, BECAUSE THEY ARE  
9 LOOKING AT -- THIS IS TOTAL LEUKEMIA, WHICH MEANS IT IS  
10 COMBINING THE A.M.L.S AND THE A.L.L.S IN CHILDHOOD.

11 Q SO ALL CHILDHOOD LEUKEMIA?

12 A ALL CHILDHOOD LEUKEMIAS, YES.

13 Q I SEE IN THIS FIGURE THERE IS A LINE, A  
14 VERTICAL LINE IN THE MIDDLE WITH A 1.0 BELOW IT. WHAT IS  
15 THAT SIGNIFYING?

16 A WELL, THAT WOULD BE A RELATIVE -- THAT WOULD  
17 BE AN ODDS RATIO OF 1.0, WHICH MEANS THAT THAT LINE,  
18 THERE IS NO INCREASED RISK. SO ANYTHING TO THE LEFT OF  
19 THAT LINE WOULD SHOW A DECREASED RISK. ANYTHING TO THE  
20 RIGHT WOULD SHOW AN INCREASED RISK OF WHERE THE DOTS ARE.  
21 THEN THE LINES ARE THE 95 PERCENT CONFIDENCE INTERVALS.

22 Q SO WAS THERE ANY STUDY THAT REPORTED A  
23 DECREASED RISK?

24 A WELL, YES, THE PETRIDOU STUDY.

25 Q DID ALL OF THE OTHER STUDIES REPORT  
26 INCREASED RISKS?

27 A YES.

28 Q IS THAT GRAPHICALLY SHOWN ON FIGURE 2?

1           A           YES. THEN HE HAS THE SUMMARY FROM THAT  
2 FIRST ANALYSIS WHICH IS THE, YOU KNOW, HIGH CONSUMPTION  
3 VERSUS EVER.

4           Q           WOULD YOU TELL US WHAT THE RESULTS WERE FOR  
5 THAT?

6           A           I'M SORRY, VERSUS THE LOWEST.

7           Q           SO HIGHEST CONSUMPTION VERSUS LOWEST FOR  
8 TOTAL LEUKEMIA, CHILDHOOD LEUKEMIA; IS THAT CORRECT?

9           A           WELL, IT IS ACTUALLY NEVER/LOWEST. SO IN  
10 THE STUDY, IF THERE WAS NO EXPOSURE, THEY USED THAT. IF  
11 IN THE STUDY THEY DID NOT HAVE NO EXPOSURE, BUT HAD THE  
12 LOWEST EXPOSURE, THEN THEY USED THAT.

13                        SO IN THIS FIRST ANALYSIS FOR TOTAL  
14 CHILDHOOD LEUKEMIA, THEY ARE LOOKING AT, IT LOOKS LIKE,  
15 EVER EXPOSED VERSUS NEVER IN THE LOWEST EXPOSURE.

16          Q           WHAT WAS THE META-RISK FOR THAT ANALYSIS?

17          A           1.22.

18          Q           WAS THAT STATISTICALLY SIGNIFICANT?

19          A           YES.

20          Q           WHAT IS -- WHAT WERE THE RESULTS FOR THE LOW  
21 TO MODERATE CONSUMPTION VERSUS NEVER OR LOWEST EXPOSURE?

22          A           THE META-RISK IS 1.16.

23          Q           IS THAT STATISTICALLY SIGNIFICANT?

24          A           YES, IT IS.

25          Q           WHAT WAS THE RESULT FOR THE HIGHEST  
26 CONSUMPTION VERSUS NEVER AND LOWEST FOR THE META-RISK OF  
27 ALL THESE STUDIES?

28          A           1.72.

1 Q WAS THAT STATISTICALLY SIGNIFICANT?

2 A YES.

3 Q ALL RIGHT. NOW, I HAVE BEEN USING THE TERM  
4 "META-RISK." I DON'T KNOW THAT WE HAVE ACTUALLY DEFINED  
5 THAT. WOULD YOU TELL THE COURT WHAT THAT MEANS?

6 A JUST SIMPLY THE OVERALL RISK FROM YOUR  
7 META-ANALYSIS.

8 Q HOW IS THAT DETERMINED?

9 A IT IS DETERMINED FROM POOLING THE DATA IN  
10 ALL OF THE STUDIES THAT YOU HAVE, INCLUDING IN YOUR META-  
11 ANALYSIS.

12 Q SO ALL THE DATA IS POOLED AND ESSENTIALLY  
13 THE RISK IS CALCULATED FROM THE POOLED DATA?

14 A YES.

15 Q ALL RIGHT. WHAT ARE THE ADVANTAGES OF DOING  
16 THAT?

17 A WELL, IF YOU HAVE, YOU KNOW, A NUMBER OF  
18 STUDIES THAT HAVE -- THAT ARE SMALL, YOU CAN INCREASE THE  
19 STATISTICAL POWER BY INCREASING THE NUMBER OF CASES.  
20 THAT IS A GOOD REASON TO DO IT. IF YOU JUST WANT TO LOOK  
21 AT AN OVERALL SUMMARY RISK OF LEUKEMIA RELATED TO, YOU  
22 KNOW, THE LITERATURE ON MATERNAL COFFEE CONSUMPTION, JUST  
23 POOLING ALL THE DATA, YOU CAN DO IT THAT WAY. THEY WOULD  
24 CALL THAT THE META-RISK.

25 Q DOES THAT HELP ASSESS WHETHER A STUDY THAT  
26 IS AN OUTLIER IS AFFECTING THE RESULT?

27 A WELL, I DON'T KNOW THAT IT INDICATES THE  
28 STUDY IS AFFECTING THE RESULTS. I MEAN, IF THERE IS A

1 STUDY THAT IS LOW OR HIGH IN THERE, THERE COULD BE AN  
2 OUTLIER, IT WOULD BE INCLUDED IN THE RESULTS. SO IT IS  
3 GOING TO LIKE PULL YOU BACK TOWARD THE MEAN.

4 Q OKAY. SO THE DATA -- THE RESULTS FROM ALL  
5 THE STUDIES END UP BEING INCLUDED IN THE CALCULATION OF  
6 THE META-RISK; IS THAT IT?

7 A YES.

8 Q EVEN THE NEGATIVE STUDY, THE PETRIDOU STUDY?

9 A YES.

10 Q DID THE CHENG -- AUTHORS OF THE CHENG  
11 META-ANALYSIS ALSO DO META-RISK CALCULATIONS FOR THE  
12 MAJOR CHILDHOOD LEUKEMIA SUBTYPE, ACUTE LYMPHATIC  
13 LEUKEMIA?

14 A YES, THAT IS IN FIGURE 4.

15 Q WHAT DID YOU NOTE FROM THIS ANALYSIS?

16 A WELL, IN THIS ANALYSIS, YOU LOOK AT THE  
17 FIRST RESULT, THE ODDS RATIO FROM THE POOLED DATA IS  
18 1.26. THAT IS FOR EVER VERSUS NEVER OR LOWEST DRINKERS.  
19 SO EVER IS LIKE MORE THAN LOWEST AND IT COULD BE THE  
20 HIGHEST. SO THAT IS THE COMBINED GROUP IN THIS ONE.

21 SO WHEN YOU LOOK AT IF YOU EVER CONSUMED  
22 COFFEE DURING PREGNANCY, COMPARED TO THE LOWEST, OR  
23 NEVER, YOU HAVE AN ODDS RATIO OF 1.26 THAT IS  
24 STATISTICALLY SIGNIFICANT.

25 NOW, THERE IS ONE THING, SINCE THIS IS ACUTE  
26 LYMPHATIC LEUKEMIA, YOU DON'T SEE THE GREEK STUDY IN HERE  
27 BECAUSE THE GREEK STUDY DID NOT PRESENT DATA BY ACUTE  
28 LYMPHATIC LEUKEMIA. IT JUST SAID "ACUTE LEUKEMIA." SO

1 YOU COULD INCLUDE IT IN THE FIRST ANALYSIS, BUT YOU CAN'T  
2 INCLUDE IT IN THE SECOND ANALYSIS.

3 Q I UNDERSTAND. WHAT ABOUT THE DATA THAT THEY  
4 CONCLUDED FOR LOW TO MODERATE CONSUMPTION OF COFFEE  
5 VERSUS NEVER OR LOWEST CONSUMPTION?

6 A FOR LOW EXPOSURE, THE RISK IS 1.09 AND THAT  
7 IS NOT -- THAT IS NOT STATISTICALLY SIGNIFICANT.

8 Q WHAT ABOUT THE HIGHEST CONSUMPTION OF COFFEE  
9 VERSUS NEVER OR LOWEST CONSUMPTION IN RELATIONSHIP TO  
10 CHILDHOOD ACUTE LYMPHATIC LEUKEMIA?

11 A THAT RISK IS 1.6 AND THAT IS HIGHLY  
12 SIGNIFICANT.

13 Q WHAT DO YOU MEAN BY "HIGHLY SIGNIFICANT"?

14 A WELL, THE LOWER BOUND OF THE CONFIDENCE  
15 INTERVAL IS 1.28 AND THE UPPER BOUND IS 2.12. SO, YOU  
16 KNOW, THAT IS A PRETTY ROBUST FINDING.

17 Q IS THERE ANYTHING ELSE OF SIGNIFICANCE TO  
18 YOU IN THIS ANALYSIS OF THE META-RISK FOR A.L.L.?

19 A WELL, I DON'T KNOW. IF YOU HAD ANOTHER  
20 QUESTION TO ASK ME ABOUT IT, I DON'T KNOW WHAT YOU ARE  
21 THINKING, BUT IT SHOWS THAT WHEN YOU POOL ALL OF THE DATA  
22 FROM THESE -- ALL OF THE STUDIES THAT HAD BEEN DONE TO  
23 DATE, YOU FIND THAT, YOU KNOW, FROM THE HIGHEST MATERNAL  
24 CONSUMPTION OF COFFEE, YOU HAVE THE HIGHEST ODDS RATIO  
25 FOR ACUTE LYMPHATIC LEUKEMIA AMONG MOTHERS OF THE HIGHEST  
26 COFFEE CONSUMERS.

27 Q VERY GOOD. DID YOU ALSO DO A REVIEW OF THE  
28 ANALYSIS FOR CHILDHOOD ACUTE MYELOGENOUS LEUKEMIA?

1 A YES.

2 Q IS THAT CONTAINED IN FIGURE 5?

3 A YES.

4 Q WOULD YOU TELL US WHAT YOU FOUND SIGNIFICANT  
5 ABOUT THAT ANALYSIS OR CALCULATION?

6 A WELL, AGAIN, WHEN YOU LOOK AT THE EVER  
7 CONSUMING COFFEE VERSUS NEVER OR LOWEST DRINKERS IN THE  
8 STUDY, THE ODDS RATIO IS 1.35, AND THAT IS STATISTICALLY  
9 SIGNIFICANT. AND IN THE SECOND GROUPING, WHEN YOU LOOK  
10 AT -- I THINK IT IS -- MY COPY IS BLURRED, I THINK IT IS  
11 LOW TO MODERATE EXPOSURE VERSUS NEVER TO LOWEST, THE RISK  
12 IS 1.18. THAT IS STATISTICALLY SIGNIFICANT.

13 THEN WHEN YOU GO TO THE HIGH COFFEE  
14 CONSUMERS VERSUS NEVER OR LOWEST COFFEE CONSUMERS, THE  
15 RISK IS -- IT LOOKS LIKE 1.68 ON MY COPY AND THAT RESULT  
16 IS STATISTICALLY SIGNIFICANT.

17 SO YOU HAVE A SIGNIFICANT INCREASE IN RISK  
18 IN THE META-ANALYSIS, WHETHER IT IS TOTAL CHILDHOOD  
19 LEUKEMIA, A.L.L. OR A.M.L. SEPARATELY.

20 Q OKAY. SO WHAT DO YOU CONCLUDE REGARDING THE  
21 CHENG META-ANALYSIS OF THE CASE-CONTROL STUDIES OF  
22 MATERNAL CONSUMPTION OF COFFEE DURING PREGNANCY AND THE  
23 DEVELOPMENT OF CHILDHOOD LEUKEMIA?

24 A I THINK IT PROVIDES VERY STRONG EVIDENCE  
25 THAT THERE IS A SIGNIFICANT ASSOCIATION BETWEEN MATERNAL  
26 COFFEE CONSUMPTION DURING PREGNANCY AND CHILDHOOD  
27 LEUKEMIA.

28 Q NOW, I THINK WE HAVE HEARD ABOUT PUBLICATION

1 BIAS. DID YOU ASSESS THAT ISSUE WITH REGARD TO THIS  
2 META-ANALYSIS?

3 A WELL, I DON'T THINK THERE IS ANY PUBLICATION  
4 BIAS IN THE ANALYSIS BECAUSE HE HAS INCLUDED EVERY -- HE  
5 DID NOT EXCLUDE ANY STUDIES FOR, YOU KNOW, FOR WHATEVER  
6 REASON. LIKE HE COULD, IN A META-ANALYSIS, EXCLUDE  
7 STUDY X OR STUDY Y BECAUSE OF DEFICIENCIES IN IT OR IF  
8 THE EXPOSURE WASN'T -- YOU HAD PROBLEMS WITH THE  
9 EXPOSURE. BUT IN THIS ANALYSIS, HE INCLUDED EVERY STUDY  
10 IN THE LITERATURE.

11 Q WERE THERE ANY OTHER FEATURES OF THIS STUDY  
12 THAT YOU CONSIDERED TO BE IMPORTANT?

13 A WELL, HE SAYS THAT THEY EVALUATED  
14 PUBLICATION BIAS AND THEY DID NOT FIND THAT THAT AFFECTED  
15 THE RESULTS. SO, I MEAN, I THINK IT IS A VERY SOLID  
16 STUDY. IT IS A VERY GOOD STUDY. A VERY STRONG STUDY.

17 Q HAVE YOU SEEN ANY PUBLISHED CRITICISMS IN  
18 THE PEER-REVIEWED LITERATURE OF THE CHENG META-ANALYSIS?

19 A I HAVE NOT.

20 Q HAVE YOU SEEN ANY PUBLISHED CRITICISMS IN  
21 THE PEER-REVIEWED LITERATURE OF THE BONAVENTURE  
22 CASE-CONTROL STUDY FROM 2013?

23 A I HAVE NOT.

24 Q OKAY. NOW, THERE HAS BEEN A CLAIM MADE  
25 THAT -- OR I WOULD LIKE YOU TO ASSUME THAT A CLAIM HAS  
26 BEEN MADE THAT COFFEE CONSUMPTION DURING PREGNANCY IS NOT  
27 A RISK FACTOR FOR CHILDHOOD LEUKEMIA BECAUSE WEBSITES OF  
28 ORGANIZATIONS LIKE THE AMERICAN CANCER SOCIETY AND OTHER

1 ORGANIZATIONS HAVE NOT PUT IT UP AS A RISK FACTOR.

2 DO YOU AGREE WITH THAT CONTENTION?

3 MR. SCHURZ: OBJECTION; MISSTATES EVIDENCE AND IS  
4 ARGUMENTATIVE.

5 THE COURT: THE OBJECTION IS SUSTAINED.  
6 ARGUMENTATIVE. NO FOUNDATION.

7 MR. METZGER: I WILL ASK IT THIS WAY:

8 Q ASSUMING, DR. INFANTE, THAT ORGANIZATIONS  
9 LIKE THE AMERICAN CANCER SOCIETY, THE NATIONAL CANCER  
10 INSTITUTE AND OTHERS HAVE NOT LISTED CHILDHOOD -- HAVE  
11 NOT LISTED MATERNAL CONSUMPTION OF COFFEE DURING  
12 PREGNANCY AS A RISK FACTOR FOR CHILDHOOD LEUKEMIA. WHAT  
13 SIGNIFICANCE WOULD YOU ATTRIBUTE TO THAT?

14 A WELL, I WOULD NOT ATTRIBUTE ANY SIGNIFICANCE  
15 TO IT. I MEAN, THERE IS USUALLY A LONG LAG TIME BETWEEN  
16 WHEN KNOWLEDGE BECOMES AVAILABLE AND WHEN INSTITUTIONS  
17 MAKE, YOU KNOW, PRONOUNCEMENTS ABOUT THOSE ASSOCIATIONS.  
18 PEOPLE DON'T SIT ON THE EDGE OF THEIR CHAIRS AND WAIT FOR  
19 A NEW STUDY, AND THEN ALL OF A SUDDEN INCORPORATE IT INTO  
20 SOME EVALUATION. EVERYBODY IS BUSY DOING THEIR OWN  
21 THING. BUT -- SO I DON'T -- I MEAN, THIS IS A FAIRLY NEW  
22 META-ANALYSIS. THE BONAVENTURE STUDY HAS JUST BEEN DONE  
23 IN 2013, WHICH IS A VERY STRONG STUDY. AND  
24 ORGANIZATIONS, AMERICAN CANCER SOCIETY, WHOEVER, JUST  
25 DOESN'T ACT THAT FAST.

26 THE COURT: WE ARE GOING TO RECESS AT THIS TIME.

27 HOW MUCH LONGER ARE YOU GOING TO BE WITH  
28 THIS WITNESS, MR. METZGER?

1 MR. METZGER: I THINK I AM CLOSE TO BEING DONE.  
2 JUST A FEW MORE MINUTES TOMORROW. I SHOULD WRAP IT UP.

3 THE COURT: ALL RIGHT. MR. SCHURZ, HOW MUCH TIME  
4 ON CROSS?

5 MR. SCHURZ: I WILL BE CONCLUDED TOMORROW FOR SURE,  
6 YOUR HONOR.

7 THE COURT: ALL RIGHT. WE WILL BE IN RECESS UNTIL  
8 TOMORROW AT 9:00 O'CLOCK A.M.

9 MR. METZGER: THANK YOU.

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11 (THE MATTER WAS ADJOURNED AT 4:24 P.M.)

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SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

DEPARTMENT 323

HON. ELIHU M. BERLE, JUDGE

COUNCIL FOR EDUCATION AND RESEARCH ON )  
TOXICS, A CALIFORNIA CORPORATION, )

PLAINTIFF, )

VS. )

CASE NO.  
BC435759

STARBUCKS CORPORATION, A CALIFORNIA )  
CORPORATION, ET AL., )

DEFENDANTS. )

\_\_\_\_\_  
AND CONSOLIDATED ACTION. )

I, KAREN VILICICH, CSR NO. 7634, OFFICIAL  
COURT REPORTER OF THE SUPERIOR COURT OF THE STATE OF  
CALIFORNIA, FOR THE COUNTY OF LOS ANGELES, DO HEREBY  
CERTIFY THAT THE FOREGOING PAGES 151 THROUGH 237 COMPRISE  
A FULL, TRUE AND CORRECT TRANSCRIPT OF THE TESTIMONY AND  
PROCEEDINGS HELD IN THE ABOVE-ENTITLED MATTER ON MONDAY,  
OCTOBER 20, 2014.

DATED THIS 20TH DAY OF OCTOBER, 2014.

\_\_\_\_\_  
KAREN VILICICH, CSR NO. 7634  
OFFICIAL REPORTER PRO TEMPORE

# **EXHIBIT “E”**

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

DEPARTMENT NO. 323

HON. ELIHU M. BERLE, JUDGE

COUNCIL FOR EDUCATION AND )  
RESEARCH ON TOXICS, )

PLAINTIFF, )

VS. )

NO. BC435759

STARBUCKS CORPORATION, )  
ET AL., )

DEFENDANTS. )

AND CONSOLIDATED ACTION. )

REPORTER'S TRANSCRIPT OF TRIAL PROCEEDINGS

TUESDAY, OCTOBER 21, 2014

MORNING SESSION

APPEARANCES:

FOR THE PLAINTIFF:

METZGER LAW GROUP  
BY: RAPHAEL METZGER  
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CCROLA JOB  
NO. 114674

DANA L. SHELLEY, RPR, CSR #10177  
OFFICIAL REPORTER PRO TEM

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1 CASE NUMBER: BC435759  
2 CASE NAME: CERT VS. STARBUCKS  
3 DEPARTMENT: 323 HON. ELIHU M. BERLE  
4 REPORTER: DANA SHELLEY, RPR, CSR #10177  
5 LOS ANGELES, CALIFORNIA TUESDAY, OCTOBER 21, 2014  
6 TIME: 9:21 A.M.  
7 APPEARANCES: (AS HERETOFORE NOTED.)  
8

9 THE COURT: ON THE TRIAL, CERT VS. STARBUCKS, ALL  
10 COUNSEL ARE PRESENT. DR. INFANTE IS ON THE STAND. AND  
11 MR. METZGER SAID THERE ARE ONLY A FEW QUESTIONS LEFT.  
12

13 PETER FRANCIS INFANTE,  
14 CALLED AS A WITNESS BY THE PLAINTIFF, HAVING BEEN  
15 PREVIOUSLY SWORN, TESTIFIED FURTHER AS FOLLOWS:

16 THE COURT: DR. INFANTE, YOU UNDERSTAND YOU'RE  
17 STILL UNDER OATH?

18 THE WITNESS: YES, SIR.

19 THE COURT: PLEASE RESTATE YOUR NAME FOR THE  
20 RECORD.

21 THE WITNESS: PETER FRANCIS INFANTE.

22 THE COURT: MR. METZGER, DO YOU HAVE ANY  
23 QUESTIONS?

24 MR. METZGER: YES, YOUR HONOR.

25 THE COURT: OKAY.

26 MR. METZGER: THANK YOU.  
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DIRECT EXAMINATION (RESUMED)

BY MR. METZGER:

Q DR. INFANTE, YESTERDAY YOU DISCUSSED THREE TYPES OF EPIDEMIOLOGIC STUDIES THAT BEAR ON THE HUMAN CARCINOGENICITY OF ACRYLAMIDE. THE FIRST TYPE OF STUDY THAT YOU DISCUSSED WERE THE OCCUPATIONAL EPIDEMIOLOGY STUDIES OF ACRYLAMIDE PRODUCTION WORKERS EXPOSED TO ACRYLAMIDE.

WHAT DO YOU CONCLUDE REGARDING THE HUMAN CARCINOGENICITY OF ACRYLAMIDE, BASED UPON THAT BODY OF EPIDEMIOLOGIC LITERATURE?

MR. SCHURZ: ASKED AND ANSWERED.

THE COURT: OVERRULED.

THE WITNESS: MY CONCLUSION ABOUT THE OCCUPATIONAL STUDIES RELATED TO ACRYLAMIDE EXPOSURE IS THAT THEY DEMONSTRATE A SIGNIFICANT INCREASE IN MORTALITY FROM PANCREATIC CANCER AND THAT THE -- THERE ARE TWO STUDIES THAT DEMONSTRATE DOSE RESPONSE BY FOUR MODES OF EXPOSURE TO ACRYLAMIDE, SHOWING AN INCREASED RISK OF PANCREATIC CANCER.

SO BASED UPON THAT INFORMATION, IT'S MY OPINION THAT THE OCCUPATIONAL STUDIES DEMONSTRATE A SIGNIFICANT INCREASED RISK OF PANCREATIC CANCER.

Q BY MR. METZGER: OKAY. THE SECOND TYPE OF STUDY THAT YOU DISCUSSED WERE CASE-CONTROL STUDIES OF VARIOUS CANCERS IN RELATIONSHIP TO CONSUMPTION OF COOKED POTATOES. WHAT DO YOU CONCLUDE REGARDING THE HUMAN CARCINOGENICITY OF ACRYLAMIDE BASED UPON THAT BODY OF

1 EPIDEMIOLOGIC LITERATURE?

2 A WELL, THE POTATO STUDIES DEMONSTRATE  
3 SIGNIFICANTLY ELEVATED RISKS OF VARIOUS TYPES OF CANCERS  
4 AT A NUMBER OF SITES. AND THE STUDIES ALSO --  
5 SEVERAL -- OR MORE THAN SEVERAL OF THESE STUDIES ALSO  
6 DEMONSTRATED DOSE-RESPONSE RELATIONSHIP.

7 SO IN MY OPINION, THERE'S SOME EVIDENCE  
8 RELATED TO POTATO CONSUMPTION AND CANCER.

9 Q OKAY. AND LASTLY, REGARDING THE ACRYLAMIDE  
10 STUDIES, THE THIRD TYPE OF STUDY THAT YOU DISCUSSED WERE  
11 THE EPIDEMIOLOGIC STUDIES OF DIETARY ACRYLAMIDE  
12 EXPOSURE. AND WHAT DO YOU CONCLUDE REGARDING THE HUMAN  
13 CARCINOGENICITY OF ACRYLAMIDE BASED UPON THAT BODY OF  
14 EPIDEMIOLOGIC LITERATURE?

15 A WELL, THE DIETARY ACRYLAMIDE STUDIES  
16 DEMONSTRATE THAT THERE ARE SOME CANCERS THAT SHOW  
17 SIGNIFICANTLY ELEVATED RISKS.

18 AND I NOTE THAT PARTICULARLY THE OVARIAN AND  
19 THE BREAST CANCER FINDINGS ARE, I THINK, IMPORTANT  
20 BECAUSE OF THE EXPERIMENTAL STUDIES DEMONSTRATING A HIGH  
21 FREQUENCY OF THESE TUMORS IN EXPERIMENTAL ANIMALS.

22 SO MY CONCLUSION ABOUT IT ALL IS THAT, YOU  
23 KNOW, THERE'S SOME EVIDENCE.

24 Q ALL RIGHT. WELL, NOW TAKING ALL OF THE  
25 EPIDEMIOLOGIC STUDIES FOR THE THREE BODIES OF  
26 EPIDEMIOLOGIC LITERATURE THAT YOU'VE ASSESSED REGARDING  
27 THE HUMAN CARCINOGENICITY OF ACRYLAMIDE, WHAT IS YOUR  
28 OVERALL CONCLUSION REGARDING THE HUMAN CARCINOGENICITY

1 OF ACRYLAMIDE, BASED UPON THESE EPIDEMIOLOGIC STUDIES?

2 A WELL, THERE'S CERTAINLY SOME -- I THINK THE  
3 STRONGEST EVIDENCE IS IN THE OCCUPATIONAL SETTING  
4 BECAUSE THAT DEMONSTRATES A MONOTONIC DOSE RESPONSE.  
5 AND THE OTHER DATA SETS, I THINK THEY CONTRIBUTE SOME  
6 EVIDENCE.

7 Q ALL RIGHT. YESTERDAY YOU ALSO DISCUSSED  
8 EPIDEMIOLOGIC STUDIES THAT EVALUATED CONSUMPTION OF  
9 COFFEE IN RELATION TO THREE TYPES OF HUMAN CANCER.

10 THE FIRST BODY OF EPIDEMIOLOGIC LITERATURE  
11 THAT YOU DISCUSSED CONCERNED CONSUMPTION OF COFFEE AND  
12 BLADDER CANCER. WHAT DO YOU CONCLUDE REGARDING THE RISK  
13 OF BLADDER CANCER FROM CONSUMPTION OF COFFEE BASED UPON  
14 YOUR REVIEW OF THOSE EPIDEMIOLOGIC STUDIES?

15 A THERE ARE A LARGE NUMBER OF STUDIES THAT  
16 DEMONSTRATE A SIGNIFICANTLY INCREASED RISK OF BLADDER  
17 CANCER IN RELATION TO COFFEE CONSUMPTION. AND A NUMBER  
18 OF THEM DEMONSTRATE SIGNIFICANT DOSE RESPONSES.

19 AND WHEN YOU ADD THIS INFORMATION TO WHAT  
20 IARC HAD CONCLUDED IN 1990, THAT THERE WAS LIMITED  
21 EVIDENCE FOR THE CARCINOGEN RELATED TO -- LIMITED  
22 EVIDENCE FOR BLADDER CANCER, I THINK THIS ADDS TO THAT  
23 EVIDENCE.

24 Q OKAY. AND YOU ALSO DISCUSSED THE  
25 EPIDEMIOLOGIC STUDIES REGARDING COFFEE CONSUMPTION AND  
26 PANCREATIC CANCER. WHAT DO YOU CONCLUDE REGARDING THE  
27 RISK OF PANCREATIC CANCER FROM CONSUMPTION OF COFFEE,  
28 BASED UPON THOSE EPIDEMIOLOGIC STUDIES?

1           A           WELL, THAT THERE ARE A LARGE NUMBER OF  
2           STUDIES THAT DEMONSTRATE SIGNIFICANTLY INCREASED RISKS  
3           OF PANCREATIC CANCER, INCLUDING SOME THAT DEMONSTRATED  
4           DOSE RESPONSE.   AND --

5           MR. SCHURZ:   YOUR HONOR, WE WOULD OBJECT.   IT  
6           APPEARS AS THOUGH DR. INFANTE IS JUST READING FROM A  
7           TABLET IN FRONT OF HIM AS OPPOSED TO ANSWERING  
8           QUESTIONS.   WE'VE BEEN NOT PROVIDED THE NOTES THAT HE'S  
9           READING FROM.

10                    AND WE WOULD MOVE TO STRIKE THE PRIOR  
11           ANSWERS THAT HE'S BEEN READING FROM HIS TABLET AND ASK  
12           TO SEE IT.

13           THE COURT:   HAVE YOU BEEN READING FROM A TABLET,  
14           DR. INFANTE?

15           THE WITNESS:   YES.   I'M MAKING NOTES AS WE SPEAK,  
16           LIKE -- IF YOU'D LIKE -- YOUR HONOR, IF YOU'D LIKE TO  
17           SEE IT?

18           THE COURT:   ALL RIGHT.   WELL, LET'S --

19           THE WITNESS:   THIS IS MY SUMMARY.

20           THE COURT:   ALL RIGHT.   SO DURING THE BREAK, ANY  
21           PROBLEM PRODUCING THAT FOR COUNSEL FOR THE DEFENDANT?

22           MR. METZGER:   NO, YOUR HONOR.

23           THE COURT:   OKAY.   DO THAT DURING THE BREAK.

24                    SO LET'S TRY TO WRAP UP HIS TESTIMONY.   THIS  
25           IS JUST RETREADING THE SAME GROUND.

26           Q           BY MR. METZGER:   DR. INFANTE, TURN OVER YOUR  
27           TABLET, PLEASE.

28           A           OKAY.

1 Q SO WE WERE ON THE -- I THINK YOU JUST  
2 QUITE -- I DON'T KNOW IF YOU QUITE FINISHED YOUR ANSWER  
3 REGARDING PANCREATIC CANCER.

4 WHAT IS YOUR CONCLUSION REGARDING THE --  
5 YOU'RE REVIEW OF THE EPIDEMIOLOGIC STUDIES REGARDING  
6 COFFEE CONSUMPTION AND PANCREATIC CANCER?

7 A MY CONCLUSION IS, THERE ARE A LARGE NUMBER  
8 OF STUDIES THAT DEMONSTRATE A SIGNIFICANTLY INCREASED  
9 RISK OF PANCREATIC CANCER, AND SEVERAL OF WHICH  
10 DEMONSTRATE A DOSE RESPONSE.

11 AND IN MY OPINION, THAT ADDS TO THE IARC  
12 EVALUATION IN THE EARLY '90S. SO IN MY OPINION, THEY  
13 CONTRIBUTE SOME EVIDENCE TO THE CARCINOGENICITY OF  
14 COFFEE IN HUMANS.

15 Q THE LAST BODY OF LITERATURE THAT YOU  
16 DISCUSSED WAS THE EPIDEMIOLOGIC STUDIES REGARDING  
17 MATERNAL CONSUMPTION OF COFFEE AND CHILDHOOD LEUKEMIA.  
18 WHAT DO YOU CONCLUDE REGARDING THE HUMAN CARCINOGENICITY  
19 OF COFFEE, BASED UPON THAT BODY OF EPIDEMIOLOGIC  
20 LITERATURE?

21 A THE LITERATURE RELATED TO MATERNAL COFFEE  
22 CONSUMPTION AND LEUKEMIA IN THEIR CHILDREN, I THINK, IS  
23 VERY STRONG EVIDENCE OF A CARCINOGENIC EFFECT FROM  
24 COFFEE CONSUMPTION TO PREGNANT WOMEN AND THE RISK TO  
25 THEIR CHILDREN.

26 AND THE STUDIES DEMONSTRATE A DOSE RESPONSE  
27 FOR TOTAL LEUKEMIA, FOR ACUTE LYMPHATIC LEUKEMIA, AND  
28 ALSO FOR ACUTE MYELOGENOUS LEUKEMIA.

1 Q OKAY. SO REGARDING THESE THREE TYPES OF  
2 CANCER FOR WHICH YOU HAVE ASSESSED THE BODY OF  
3 EPIDEMIOLOGIC LITERATURE -- NAMELY, BLADDER CANCER,  
4 PANCREATIC CANCER, AND CHILDHOOD LEUKEMIA -- WHAT IS  
5 YOUR OVERALL CONCLUSION REGARDING THE CARCINOGENICITY OF  
6 COFFEE, BASED UPON THOSE DATA SETS?

7 A THAT CONSUMPTION OF COFFEE CARRIES WITH IT  
8 A -- THERE'S EVIDENCE OF AN INCREASED RISK OF CANCER IN  
9 HUMANS, WITH THE STRONGEST DATA BEING FOR CHILDHOOD  
10 LEUKEMIA.

11 Q OKAY. NOW, DO ANY OF THE EPIDEMIOLOGIC  
12 STUDIES REGARDING CONSUMPTION OF COFFEE AND CANCER THAT  
13 YOU READ ASSESS THE IMPACT OF ACRYLAMIDE IN COFFEE ON  
14 HUMAN CANCER?

15 A IN NONE OF THE STUDIES THAT I READ DID  
16 ANYONE MEASURE THE AMOUNT OF THE ACRYLAMIDE IN THE  
17 COFFEE.

18 Q HAVE YOU FORMED ANY CONCLUSION REGARDING THE  
19 RISK OF CANCER SPECIFICALLY FROM ACRYLAMIDE IN COFFEE?

20 A I DON'T THINK IT'S POSSIBLE TO DRAW ANY  
21 CONCLUSION FROM THE EPIDEMIOLOGICAL DATA BECAUSE THE  
22 ACRYLAMIDE WASN'T MEASURED IN THE COFFEE.

23 Q OKAY. HOW COULD ONE ASSESS THE HUMAN  
24 CARCINOGENICITY OF ACRYLAMIDE IN COFFEE IF NOT FROM THE  
25 EPIDEMIOLOGIC LITERATURE?

26 MR. SCHURZ: OBJECTION; LACKS FOUNDATION, CALLS  
27 FOR SPECULATION FROM THIS WITNESS.

28 THE COURT: OVERRULED.

1 THE WITNESS: WELL, YOU WOULD HAVE TO DO A  
2 QUANTITATIVE RISK ASSESSMENT BASED ON EXPERIMENTAL DATA.

3 MR. METZGER: OKAY. THANK YOU VERY MUCH, DR.  
4 INFANTE. I HAVE NO FURTHER QUESTIONS.

5 THE COURT: ALL RIGHT. MR. SCHURZ?

6 MR. SCHURZ: THANK YOU, YOUR HONOR.

7  
8 CROSS-EXAMINATION

9 BY MR. SCHURZ:

10 Q GOOD MORNING, DR. INFANTE.

11 A GOOD MORNING.

12 Q I SEE YOU'VE GOT SOME NOTES THERE. DO YOU  
13 HAVE ANY NOTES THAT YOU'RE USING TO RESPOND TO QUESTIONS  
14 THAT I'LL BE ASKING?

15 A NO, BUT I'M GOING TO MAKE NOTES AS YOU ASK  
16 ME QUESTIONS. I USUALLY DO THAT.

17 Q LET'S BEGIN WITH SOME OF THE OPINIONS YOU  
18 DISCUSSED WITH MR. METZGER RELATING TO THE COFFEE  
19 EPIDEMIOLOGY. AND I'D LIKE TO START WITH THE OPINIONS  
20 YOU'VE OFFERED, DR. INFANTE, WITH RESPECT TO PANCREATIC  
21 CANCER.

22 SHOWING YOU THE PAGE 121 OF YOUR  
23 DEMONSTRATIVE -- AND YOU WILL SEE THIS ON YOUR SCREEN --  
24 YOU IDENTIFY FIVE META-ANALYSES ON COFFEE AND PANCREATIC  
25 CANCER; IS THAT CORRECT?

26 A 121 -- LET ME GET IT.

27 META-ANALYSES, PANCREATIC CANCER. YES.

28 Q AND INCLUDED AMONG THOSE FIVE IS THE NISHI

1 META-ANALYSIS, WHICH WAS SIX CASE CONTROLS, PUBLISHED IN  
2 1996; CORRECT?

3 A YES.

4 Q AND ALL OF THOSE CASE CONTROLS WERE INCLUDED  
5 IN THE SUBSEQUENT TURATI 2011 META-ANALYSIS; CORRECT?

6 A I WOULD HAVE TO -- I'M NOT SURE, AS I SIT  
7 HERE. I DON'T RECALL. I'D HAVE TO LOOK BACK AND  
8 COMPARE THE TWO STUDIES.

9 Q ALL RIGHT. SO I'D LIKE TO FOCUS OUR  
10 ATTENTION ON THE FOUR MORE RECENT ONES.

11 NOW, SPECIFICALLY WITH RESPECT TO THE  
12 PANCREATIC CANCER META-ANALYSES THAT YOU HAVE IDENTIFIED  
13 AND THE VALUES THAT YOU HAVE SET FORTH, NONE OF THE  
14 META-ANALYSES REPORT A STATISTICALLY SIGNIFICANT  
15 POSITIVE ASSOCIATION BETWEEN COFFEE AND PANCREATIC  
16 CANCER, DO THEY?

17 A THAT'S CORRECT, YES. AND THEY --

18 Q AND THE META-ANALYSES --

19 MR. METZGER: EXCUSE ME. I DON'T THINK DR.  
20 INFANTE HAD FINISHED.

21 THE COURT: DO YOU WISH TO COMPLETE YOUR ANSWER?

22 THE WITNESS: WELL, THERE ARE SOME THAT SHOW THE P  
23 TREND, BUT IT'S NOT SIGNIFICANT AT THE 05 LEVEL. IT'S  
24 SIGNIFICANT AT THE .11 LEVEL.

25 THE COURT: CAN YOU SPEAK UP LOUDER, PLEASE.

26 THE WITNESS: YES. SO THAT DOES NOT MEET THE 05  
27 LEVEL OF STATISTICAL SIGNIFICANCE. I THINK THAT'S  
28 INDICATED IN THE SLIDE.

1 Q BY MR. SCHURZ: OKAY. NOW, THE  
2 META-ANALYSES SUMMARIZED HERE REFLECT THE COMBINED  
3 ANALYSIS OF SOME 34 CASE-CONTROL STUDIES AND A TOTAL OF  
4 15 COHORT STUDIES; CORRECT?

5 A 34 CASE-CONTROL STUDIES AND 15 COHORT  
6 STUDIES, YES.

7 Q AND AMONG THOSE COHORT STUDIES ARE A NUMBER  
8 OF LARGE, PUBLICLY FINANCED STUDIES, INCLUDING THE  
9 HARVARD NURSES STUDY, THE EPIC STUDY, AND OTHERS;  
10 CORRECT?

11 A YOU KNOW, I DON'T KNOW THEM BY THOSE NAMES.  
12 ARE YOU REFERRING TO SOME OF THE STUDIES THAT ARE ON  
13 THIS SLIDE?

14 Q I'M REFERRING TO THE COHORT STUDIES THAT  
15 WERE PART OF YOUR REVIEW.

16 A OKAY. I'M ONLY SAYING, I DON'T RECALL THEM  
17 BY WHO FUNDED THEM BUT BY THE AUTHORS. SO MAYBE IF YOU  
18 COULD REFER TO THEM, I'LL KNOW WHICH ONES YOU'RE  
19 SPEAKING ABOUT.

20 Q OKAY. WELL, WE'LL TALK ABOUT THEM  
21 INDIVIDUALLY.

22 WOULD YOU AGREE WITH ME, DR. INFANTE, THAT  
23 THE RANGE OF STUDIES THAT ARE ENCOMPASSED WITHIN THE  
24 META-ANALYSES FOR COFFEE AND PANCREATIC CANCER  
25 CONSTITUTE A LARGE BODY OF EPIDEMIOLOGIC LITERATURE?

26 A THE META-ANALYSES? YES.

27 Q AND THE STUDIES INVOLVE A BROAD RANGE OF  
28 DIFFERENT POPULATIONS, DO THEY NOT?

1           A       YES.

2           Q       IN FACT, POPULATIONS FROM THREE DIFFERENT  
3 CONTINENTS; ISN'T THAT CORRECT?

4           A       WELL, YOU KNOW, I DIDN'T -- I GUESS I  
5 LOOKED -- I INDICATED WHERE THEY WERE FROM. I DON'T  
6 KNOW HOW MANY CONTINENTS THAT COULD BE.

7           Q       OKAY. DOES IT SOUND ACCURATE TO SAY THAT  
8 THERE ARE STUDIES EVALUATING COFFEE CONSUMPTION AND  
9 PANCREATIC CANCER INVOLVING POPULATIONS FROM EUROPE,  
10 ASIA, AND THE UNITED STATES, NORTH AMERICA?

11          A       YOU LEFT OUT -- I DON'T KNOW IF THERE WERE  
12 SOUTH AMERICA IN THOSE OR NOT, SOME OF THE STUDIES I  
13 REVIEWED FROM SOUTH AMERICA.

14                    BUT WHATEVER THEY ARE, I WOULDN'T ARGUE WITH  
15 THAT, BECAUSE I HAVE THEM BY INDIVIDUAL COUNTRY, I  
16 THINK, ON SOME OF THE OTHER SLIDES.

17          Q       ALL RIGHT. AND THE PUBLICATIONS RELATING TO  
18 COFFEE CONSUMPTION AND PANCREATIC CANCER COVER AN  
19 EXTENDED PERIOD OF TIME, MORE THAN 30 YEARS OF  
20 PUBLICATIONS FROM 1980 THROUGH 2013; CORRECT?

21          A       WHATEVER IS ON THE SLIDES, I WOULDN'T ARGUE  
22 WITH YOU ABOUT THAT. TO GIVE YOU THE CORRECT ANSWER,  
23 I'D HAVE TO GO BACK AT THE SLIDES AND SEE WHEN THEY  
24 STARTED, BUT THAT COULD BE CORRECT.

25          Q       OKAY. AS YOU SIT HERE TODAY, YOU DON'T  
26 KNOW?

27          A       WELL, NO, I CAN -- WELL, I'M SAYING I WOULD  
28 HAVE TO REFER TO MY SLIDES TO ANSWER YOUR QUESTION

1 ACCURATELY.

2 Q OKAY. SO LET'S TALK ABOUT SOME OF THE  
3 INDIVIDUAL META-ANALYSES YOU IDENTIFIED AND REVIEWED AS  
4 PART OF YOUR WORK IN THIS CASE. AND LET ME START WITH  
5 THE TURATI 2011 META-ANALYSES, WHICH IS EXHIBIT 2083.  
6 AND YOU'LL SEE IT ON YOUR SCREEN, AND WE'LL GET YOU A  
7 HARD COPY, AS WELL.

8 AND DO YOU RECOGNIZE THIS TURATI  
9 META-ANALYSIS OF COFFEE CONSUMPTION AND PANCREATIC  
10 CANCER, DR. INFANTE?

11 A YES.

12 (EXHIBIT 2083 MARKED FOR  
13 IDENTIFICATION.)

14 Q BY MR. SCHURZ: AND YOU REVIEWED THIS AS  
15 PART OF YOUR WORK IN THIS CASE; CORRECT?

16 A I'M LOOKING AT MY -- I MADE NOTES ON ALL OF  
17 THEM THAT I REVIEWED. SO I'M JUST GOING TO REFER TO MY  
18 NOTES, TO FAMILIARIZE MYSELF WITH IT, IF YOU DON'T MIND.

19 Q ARE THESE NOTES THAT HAVE BEEN PROVIDED TO  
20 US, DR. INFANTE?

21 A YES. THEY'RE EXHIBIT 222.

22 Q ALL RIGHT.

23 A (REVIEWS DOCUMENT.)

24 WHOOPS, SORRY. THAT'S BLADDER CANCER. I  
25 PULLED THE WRONG ONES. IT'S EXHIBIT 227.

26 (REVIEWS DOCUMENT.)

27 Q AND DR. INFANTE, THE QUESTION THAT I ASKED  
28 IS: DID YOU RELY ON THIS STUDY IN FORMING YOUR

1 OPINIONS?

2 A YES. I MEAN, I RELIED ON ALL OF THE  
3 INFORMATION THAT I READ --

4 Q ALL RIGHT.

5 A -- IN THE LITERATURE. AND SOME SHOWED MORE  
6 POSITIVE EFFECTS THAN OTHERS.

7 Q AND LET'S DISCUSS THE OPINIONS -- OR EXCUSE  
8 ME. LET'S DISCUSS THE FINDINGS OF THE TURATI  
9 META-ANALYSIS THAT ARE SET FORTH IN EXHIBIT 2083.

10 NOW, AS REFLECTED IN THE ABSTRACT, THIS  
11 META-ANALYSIS COVERS 37 CASE CONTROLS AND 17 COHORTS;  
12 CORRECT?

13 A NO -- WELL, I THINK, 34 CASE-CONTROL STUDIES  
14 AND 17 COHORT STUDIES.

15 Q AND INVOLVED OVER 10,000 CASES OF PANCREATIC  
16 CANCER; CORRECT?

17 A YES.

18 Q ALL RIGHT. AND LET ME FOCUS YOUR ATTENTION  
19 TO PAGE 1 OF THE EXHIBIT 2083, WHERE THE AUTHORS OFFER  
20 THEIR CONCLUSIONS IN THE ABSTRACT. AND THE TURATI  
21 AUTHORS CONCLUDE:

22 "THIS META-ANALYSIS PROVIDES  
23 QUANTITATIVE EVIDENCE THAT COFFEE CONSUMPTION  
24 IS NOT APPRECIABLY RELATED TO PANCREATIC  
25 CANCER RISK, EVEN AT HIGH INTAKES."

26 CORRECT?

27 A YES. WELL, YOU'LL NOTE IT SAYS  
28 "APPRECIABLY," BECAUSE THE LOWER BOUND OF THE CONFIDENCE

1 INTERVAL IS .99. IF THAT WERE 1.01, TWO HUNDREDTHS  
2 MORE, THE RESULT WOULD BE STATISTICALLY SIGNIFICANT. SO  
3 I THINK THAT'S WHY THEY USED THE WORDS "APPRECIABLY  
4 RELATED."

5 Q LET'S TAKE A LOOK AT FIGURE NO. 2 AT PAGE  
6 003 OF THE TURATI PAPER, WHICH SETS FORTH --

7 DO YOU HAVE THAT IN FRONT OF YOU?

8 A I'M SORRY. WHAT PAGE ARE YOU ON?

9 Q IT'S PAGE 3.

10 A OKAY.

11 Q AND THIS FIGURE SETS OUT THE RELATIVE RISKS  
12 AND CONFIDENCE INTERVALS OF THE PANCREATIC CANCER FOR  
13 HIGH -- HIGHEST VERSUS LOWEST COFFEE-DRINKING  
14 CATEGORIES; CORRECT?

15 A ARE YOU TALKING ABOUT THE TOP ENTRY? IT  
16 SAYS "CASE-CONTROL STUDIES WITHOUT SMOKING ADJUSTMENT."

17 Q YES.

18 A IS THAT THE SECTION YOU'RE SPEAKING OF?

19 Q YES -- WELL, I'M LOOKING AT THE ENTIRE  
20 FIGURE, WHICH YOU CAN SEE AT THE BOTTOM OF PAGE 3 IS  
21 IDENTIFIED AS FIGURE 2. DO YOU SEE THAT?

22 A NO. I THINK WE'RE ON THE SAME PAGE, BUT I  
23 JUST DON'T KNOW WHICH YOU'RE REFERRING TO.

24 Q SURE, I APPRECIATE THAT. IF YOU LOOK AT THE  
25 BOTTOM OF THE PAGE, YOU CAN SEE WHERE IT READS "FIGURE  
26 NO. 2, RELATIVE RISKS." DO YOU SEE THAT? AND 95  
27 PERCENTAGE CONFIDENCE INTERVALS.

28 DO YOU SEE THAT?

1 A YES.

2 Q ALL RIGHT. THIS IS ALL JUST BY WAY OF  
3 ORIENTATION.

4 NOW LET'S LOOK AT THE VALUES THAT THE TURATI  
5 AUTHORS CAPTURED HERE. AND YOU CAN SEE THAT THEY'VE  
6 SEGREGATED THOSE STUDIES THAT ADDRESS THE RISK OF  
7 PANCREATIC CANCER WHERE THERE WAS AN ADJUSTMENT FOR  
8 SMOKING AND WHERE THERE WAS NO ADJUSTMENT FOR SMOKING;  
9 CORRECT?

10 A YES.

11 Q AND LOOKING AT THE TOP ONE, AND DIRECTING  
12 YOUR ATTENTION TO THE TOP OF FIGURE 2, THEY REPORT A  
13 VALUE FOR ALL STUDIES WITHOUT SMOKING ADJUSTMENT. AND  
14 THEY INCLUDE A RELATIVE RISK VALUE OF 1.25, WITH A  
15 CONFIDENCE -- 95TH PERCENT CONFIDENCE INTERVAL OF 0.96  
16 TO 1.63; CORRECT?

17 A YES.

18 Q SO THIS IS NOT STATISTICALLY SIGNIFICANT;  
19 CORRECT?

20 A CORRECT. BUT I MEAN, IT'S CLOSE TO BEING.

21 Q YEAH.

22 A IT PROVIDES SOME EVIDENCE OF AN ELEVATED  
23 RISK.

24 Q AND THESE ARE STUDIES THAT SHOW THAT THERE  
25 WAS NO ADJUSTMENT FOR SMOKING; CORRECT?

26 A CORRECT.

27 Q AND YESTERDAY YOU TESTIFIED THAT SMOKING IS  
28 A RISK FACTOR FOR PANCREATIC CANCER; CORRECT?

1 A YES.

2 Q SO THESE STUDIES DO NOT CONTROL FOR THE  
3 POTENTIAL CONFOUNDING THAT WOULD RESULT FROM CIGARETTE  
4 SMOKING; CORRECT?

5 A YOU MEAN, THAT ANALYSIS?

6 Q YES.

7 A CORRECT.

8 Q ALL RIGHT. SO IF WE CONTINUE ON --

9 A BUT SOME OF THE STUDIES THAT ARE -- I'LL  
10 JUST MAKE A POINT. SOME OF THE STUDIES INCLUDED IN THIS  
11 META-ANALYSIS HAVE VERY POOR METHODOLOGY. LIKE JUST FOR  
12 EXAMPLE, THE FIRST ONE, JICK. I MEAN THAT WAS TERRIBLE  
13 METHODOLOGY IN THAT.

14 SO I DON'T KNOW THAT THEY SEPARATED THESE  
15 STUDIES THAT THEY'RE INCLUDING IN THEIR META-ANALYSIS --  
16 THAT THEY DID ANY CRITICAL EVALUATION OF THEM. LOOKS TO  
17 ME LIKE THEY JUST THREW EVERYTHING IN.

18 Q ALL RIGHT. AND WE'LL DISCUSS A NUMBER OF  
19 THESE INDIVIDUAL STUDIES THAT YOU'VE INCLUDED ON YOUR  
20 TABLES.

21 BUT LET'S STAY HERE FOR THE MOMENT WITH  
22 FIGURE NO. 2. AND WOULD YOU AGREE THAT AS WE LOOK AT  
23 STUDIES WITH THE SMOKING ADJUSTMENT -- AND WE'RE NOW  
24 MOVING DOWN IN FIGURE 2 TO THE NEXT CATEGORY OF DATA.

25 AND WE SEE A SEPARATE CALCULATION FOR  
26 STUDIES WITH SMOKING. AND WE SEE A -- FOR THE  
27 CASE-CONTROL STUDIES, WE SEE A VALUE OF 1.10 AND A  
28 RELATIVE -- WITH A CONFIDENCE INTERVAL OF 0.92 TO 1.31;

1 CORRECT?

2 A I'M TRYING TO SEE WHICH ONE FROM THE CHART.  
3 I'VE REDONE THIS, AND I'M TRYING TO SEE WHICH ONE THIS  
4 IS FROM THE ACTUAL PUBLICATION.

5 WHAT'S THE -- ARE YOU TALKING ABOUT ALL  
6 STUDIES WITHOUT ADJUSTMENT NOW? WHICH ONES?

7 Q I'M LOOKING AT STUDIES WITH ADJUSTMENT FOR  
8 SMOKING. STUDIES WITH SMOKING ADJUSTMENT, CASE-CONTROL  
9 STUDIES. THE QUESTION --

10 A WELL, THEY HAVE TWO SETS OF STUDIES WITH  
11 SMOKING ADJUSTMENT. THAT'S WHY I'M WONDERING WHICH  
12 ONE -- WHICH GROUP YOU'RE SPEAKING OF.

13 Q AND AS REFLECTED HERE ON THE SCREEN, DR.  
14 INFANTE, WE'RE LOOKING AT THE CASE-CONTROL STUDIES. AND  
15 DO YOU SEE THAT?

16 A YES.

17 Q OKAY. AND HERE, AGAIN, THE TURATI AUTHORS  
18 OBSERVED THAT THERE IS A NON-STATISTICALLY SIGNIFICANT  
19 RISK ASSOCIATED WITH THE CASE-CONTROL STUDIES FOR  
20 PANCREATIC CANCER WHERE THERE HAS BEEN AN ADJUSTMENT FOR  
21 SMOKING; CORRECT?

22 A CORRECT.

23 Q AND AS WE CAN SEE HERE, WHEN WE COMPARE IT,  
24 THE VALUES GO DOWN. THERE'S A DIFFERENCE BETWEEN  
25 STUDIES WITHOUT THE SMOKING ADJUSTMENT AND THOSE WITH  
26 IT; CORRECT?

27 A YES.

28 Q ALL RIGHT. NOW, WOULD YOU AGREE, DR.

1 INFANTE, THAT IN EVALUATING THE INCIDENCE OF PANCREATIC  
2 CANCER AND COFFEE CONSUMPTION, ADJUSTING FOR TOBACCO USE  
3 IS IMPORTANT?

4 A YES.

5 Q ALL RIGHT. SO LET'S TALK A LITTLE BIT ABOUT  
6 THE CONCLUSIONS THAT THE TURATI AUTHORS REPORT. AND IF  
7 I COULD DIRECT YOUR ATTENTION TO PAGE 6 OF EXHIBIT 2083.  
8 LET ME KNOW WHEN YOU'RE THERE.

9 A 6. OKAY.

10 I'M THERE.

11 Q OKAY. AND YOU RECALL -- AND DIRECTING YOUR  
12 ATTENTION TO THE LEFT-HAND COLUMN AT THE TOP. AND THE  
13 TURATI AUTHORS OBSERVE:

14 "BESIDES THE ORIGINAL HYPOTHESIS-  
15 GENERATING ARTICLE, AMONG THE 37 SMOKING-  
16 ADJUSTING STUDIES, ONLY 5 FOUND SIGNIFICANT  
17 INCREASED RISKS."

18 DO YOU SEE THAT?

19 A YES.

20 Q NOW, YOU -- IN YOUR SLIDES THAT YOU PROVIDED  
21 TO US YESTERDAY, YOU IDENTIFIED 14 CASE-CONTROL STUDIES  
22 THAT REPORT SIGNIFICANTLY INCREASED RISKS OF PANCREATIC  
23 CANCER; CORRECT?

24 A YES.

25 Q ALL RIGHT. NOW, LET'S TAKE A LOOK AT PAGE  
26 NO. 5 OF THE TURATI ARTICLE. AND I'M RIGHT NOW AT THE  
27 SECTION RIGHT UNDER THE HEADER "DISCUSSION." DO YOU SEE  
28 THAT?

1 A OKAY.

2 Q AND THE TURATI AUTHORS BEGIN THEIR  
3 DISCUSSION WITH THE STATEMENT:

4 "THE PRESENT META-ANALYSES, CARRIED OUT  
5 ON 54 STUDIES AND 10,594 CASES, FOUND NO  
6 APPRECIABLE OVERALL ASSOCIATION BETWEEN COFFEE  
7 CONSUMPTION AND PANCREATIC CANCER RISK.  
8 RESULTS WERE CONSISTENT FOR CASE-CONTROL AND  
9 COHORT STUDIES THAT INCLUDED ADJUSTMENT FOR  
10 SMOKING CONSUMPTION IN MULTIPLE REGRESSION  
11 MODELS."

12 DO YOU SEE THAT?

13 A YES.

14 Q WOULD YOU AGREE, DR. INFANTE, THAT THE CASE  
15 CONTROLS AND COHORT STUDIES THAT ARE ADJUSTED FOR  
16 SMOKING ARE CONSISTENT?

17 A IN THEIR META-ANALYSES, THAT'S WHAT THEY'RE  
18 SAYING.

19 Q ALL RIGHT. AND THE AUTHORS CONCLUDE -- THE  
20 AUTHORS CONTINUE TO OBSERVE:

21 "WE OBSERVED A WEAK ASSOCIATION IN  
22 CASE-CONTROL STUDIES NOT ADJUSTED FOR TOBACCO,  
23 WHICH CAN BE ATTRIBUTED TO RESIDUAL  
24 CONFOUNDING BY SMOKING."

25 DO YOU SEE THAT, DR. INFANTE?

26 A YES.

27 Q AND WOULD YOU AGREE THAT THE WEAK  
28 ASSOCIATION THAT IS FOUND IN SOME OF THE CASE-CONTROL

1 STUDIES THAT ARE NOT ADJUSTED FOR TOBACCO CAN BE  
2 ATTRIBUTED TO RESIDUAL CONFOUNDING BY SMOKING?

3 A WELL, THAT'S WHAT THEY'RE SAYING HERE.

4 Q AND MY QUESTION TO YOU, DR. INFANTE, IS:  
5 WOULD YOU AGREE THAT THE OBSERVED WEAK ASSOCIATION IN  
6 THE CASE-CONTROL STUDIES THAT YOU REVIEWED THAT ARE NOT  
7 ADJUSTED FOR TOBACCO CAN BE ATTRIBUTED TO RESIDUAL  
8 CONFOUNDING BY SMOKING?

9 A CAN BE, BUT YOU DON'T KNOW THAT THEY WERE.

10 Q OKAY. NOW, YOU INCLUDED A RANGE OF  
11 CASE-CONTROL STUDIES THAT WERE NOT ADJUSTED FOR SMOKING;  
12 IS THAT CORRECT?

13 A YES. I PRESENTED THE RESULTS THAT THE  
14 AUTHORS PRESENTED.

15 Q AND HOW MANY OF THE CASE-CONTROL STUDIES  
16 THAT YOU PRESENTED IN YOUR TABLES RELATING TO PANCREATIC  
17 CANCER WERE NOT ADJUSTED FOR SMOKING?

18 A I DON'T KNOW THAT NUMBER OFFHAND. I  
19 REVIEWED --

20 Q OKAY. LET'S TALK, IF I MAY -- IF I COULD  
21 DIRECT YOUR ATTENTION TO PAGE 4 OF EXHIBIT 2083, IT'S  
22 FIGURE NO. 4. AND IT APPEARS JUST ABOVE THE MATERIAL  
23 THAT WE WERE LOOKING AT TOGETHER.

24 A WAIT A MINUTE. IS THIS A DIFFERENT -- ARE  
25 WE ON THE SAME -- WHAT PAGE, PLEASE?

26 Q SAME PAGE, PAGE 4.

27 MR. METZGER: PAGE 5, I THINK.

28 THE WITNESS: PAGE 4?

1 Q BY MR. SCHURZ: EXCUSE ME, PAGE 5 -- THANK  
2 YOU -- OF EXHIBIT 2083. AND YOU SEE A FIGURE NO. 4?

3 A YES.

4 Q OKAY. NOW, THIS GRAPH SHOWS THE CUMULATIVE  
5 RELATIVE RISKS FOR ALL OF THE STUDIES WITH SMOKING  
6 ADJUSTED; IS THAT CORRECT?

7 A YES.

8 Q AND WHAT THIS GRAPH SHOWS OVER TIME IS THAT  
9 THE NUMBER OF STUDIES THAT HAVE BEEN PUBLISHED PROVIDING  
10 INFORMATION WITH RESPECT TO HIGHEST VERSUS LOWEST  
11 COFFEE-DRINKING IN THE SMOKING-ADJUSTED STUDIES FOR  
12 PANCREATIC CANCER; CORRECT?

13 A YES.

14 Q AND IF WE TAKE A LOOK AT THE LEFT-HAND SIDE  
15 OF THE CHART THAT WE'RE LOOKING AT HERE, WE SEE A SINGLE  
16 STUDY -- OR A PAIR OF STUDIES FROM 1981 THAT WERE THE  
17 FIRST STUDIES RELATING TO PANCREATIC CANCER AND COFFEE  
18 CONSUMPTION; CORRECT?

19 A YES.

20 Q AND THAT STUDY THAT INCLUDES THE MC MAHON  
21 STUDY, DOES IT NOT?

22 A YES.

23 Q AND THAT STUDY SHOWS A RELATIVE RISK OF  
24 ROUGHLY 2.7; CORRECT?

25 A YES.

26 Q WITH VERY WIDE CONFIDENCE INTERVALS;  
27 CORRECT?

28 A YES.

1 Q AND THEN OVER TIME WHAT WE SEE IS THE  
2 ADDITION OF ADDITIONAL STUDIES THAT ARE PUBLISHED IN THE  
3 PEER-REVIEWED ARTICLE, ANALYZING PANCREATIC CANCER AND  
4 COFFEE CONSUMPTION; CORRECT?

5 A YES.

6 Q SO IF WE LOOK AT THE BOTTOM OF THE GRAPH, WE  
7 SEE ON THE -- WHAT I GUESS IS THE X AXIS, WE SEE A YEAR  
8 AND NUMBER OF STUDIES; CORRECT?

9 A YES.

10 Q AND WHAT THE AUTHORS ARE REFLECTING HERE IS  
11 THE CUMULATIVE GROWTH OF STUDIES OVER TIME AND THE  
12 CORRESPONDING RELATIVE RISK ASSOCIATED WITH COFFEE  
13 CONSUMPTION AT THE HIGHEST VERSUS LOWEST LEVELS;  
14 CORRECT?

15 A YES.

16 Q ALL RIGHT. NOW, AND WHAT WE SEE, AS THIS  
17 GRAPH INDICATES, IS THAT OVER TIME THE RELATIVE RISK  
18 VALUES DROP; CORRECT?

19 A YES, EXCEPT FOR THE LAST INTERVAL, WHERE  
20 THEY RISE AGAIN.

21 Q AND WHAT WE SEE IN THE CONTEXT OF THE DROP  
22 IN THE GRAPH IS THAT BEGINNING IN 1984 -- STRIKE THAT --  
23 BEGINNING IN 1983, THE VALUES THAT ARE BEING REPORTED  
24 FOR PANCREATIC CANCER AND COFFEE CONSUMPTION ARE NO  
25 LONGER STATISTICALLY SIGNIFICANT; CORRECT?

26 A WELL, EXCEPT THE 1990 -- IT'S HARD TO SEE  
27 WITH THAT BAR, AS TO HOW -- IF THAT'S ABOVE OR WHERE --  
28 IT LOOKS LIKE IT'S EITHER ON THE LINE OR SOMEWHERE. SO

1 THAT ONE COULD BE STATISTICALLY SIGNIFICANT.

2 Q AND CERTAINLY, BY 1995, WE ARE -- WHEN WE  
3 HIT THE RANGE OF 25 STUDIES EVALUATING THE HIGHEST  
4 VERSUS LOWEST COFFEE-DRINKING, THE VALUES HOVER AROUND 1  
5 AND ARE NO LONGER STATISTICALLY SIGNIFICANT; CORRECT?

6 A CORRECT.

7 Q AND AS THOSE VALUES AND THE NUMBER OF  
8 STUDIES ACCUMULATES, THE CONFIDENCE INTERVAL GETS  
9 TIGHTER AND TIGHTER; CORRECT?

10 A YES.

11 Q AND SINCE 1995, NONE OF THE VALUES THAT HAVE  
12 BEEN REPORTED IN THIS CUMULATIVE META-ANALYSIS REFLECT A  
13 STATISTICALLY SIGNIFICANT INCREASED RISK FROM COFFEE  
14 CONSUMPTION AND PANCREATIC CANCER IN THE HIGHEST VERSUS  
15 LOWEST; CORRECT?

16 A YES, EXCEPT FOR THE FINAL CUMULATIVE  
17 ANALYSIS, THE LOWER BOUND IS .99. AND I'M JUST SAYING,  
18 IF THAT WERE ANOTHER ONE-HUNDREDTH, THAT WOULD BE  
19 STATISTICALLY SIGNIFICANT. AND THAT'S WHY THE AUTHOR  
20 SAID THERE'S NO "APPRECIABLE." IT STILL DOESN'T MEAN  
21 THERE'S NOT SOME SLIGHT RISK.

22 Q AND SO LET'S SEE WHAT THE TURATI AUTHORS HAD  
23 TO SAY WITH RESPECT TO THEIR OWN DATA. AND AGAIN, LET'S  
24 STAY ON PAGE NO. 5.

25 AND RETURNING TO THE DISCUSSION, AT THE SAME  
26 PARAGRAPH THAT WE WERE LOOKING AT, DIRECTING YOUR  
27 ATTENTION, DR. INFANTE, TO THAT PARAGRAPH THAT WE WERE  
28 DISCUSSING EARLIER, HERE THE TURATI AUTHORS OBSERVE:

1 "THE PATTERN OBSERVED IN THE CUMULATIVE  
2 META-ANALYSIS, WITH THE DECREASE OF THE POOLED  
3 RELATIVE RISK OVER TIME TO APPROACH UNITY  
4 SINCE THE MID 1990S, IS LIKELY DUE TO FALSE  
5 POSITIVE RESULTS IN EARLIER STUDIES."

6 DO YOU SEE THAT?

7 A YES.

8 Q AND THE --

9 A BUT I MEAN, THAT'S SPECULATION.

10 Q WELL, IT'S --

11 A THEY DON'T HAVE AN ANALYSIS TO SHOW THAT.  
12 THAT'S THEIR INTERPRETATION OF IT.

13 Q IT IS THEIR INTERPRETATION OF THE DATA THEY  
14 ANALYZED; CORRECT?

15 A YES.

16 Q YES. ALL RIGHT.

17 LET'S TAKE A LOOK AT SOME OF THE OTHER  
18 META-ANALYSES THAT YOU HAVE RELIED ON AND REVIEWED IN  
19 THE CONTEXT OF PANCREATIC CANCER. AND LET ME START WITH  
20 THE GENKINGER META-ANALYSIS, WHICH IS EXHIBIT 1072.

21 A ALL RIGHT.

22 Q AND WE'LL GET YOU A HARD COPY OF THIS.

23 BUT DO YOU -- CAN YOU IDENTIFY THIS DOCUMENT  
24 FOR US, EXHIBIT 1072, DR. INFANTE?

25 A (REVIEWS DOCUMENT.)

26 YES. THIS IS THE GENKINGER STUDY OF -- IT  
27 SAYS "2011" ON IT. SO I DON'T THINK -- IN 2011 OR '12,  
28 IT WAS PUBLISHED.

1 (EXHIBIT 1072 MARKED FOR  
2 IDENTIFICATION.)

3 Q BY MR. SCHURZ: AND YOU REVIEWED THIS IN  
4 DEVELOPING YOUR OPINIONS IN THIS CASE; CORRECT?

5 A YES.

6 Q YOU RELIED ON THIS IN DEVELOPING YOUR  
7 OPINIONS; CORRECT?

8 A WELL, IT'S ONE DOCUMENT I RELIED ON, YES.

9 Q AND THIS IS A POOLED ANALYSIS OF THE DATA  
10 CONCERNING THE COHORT STUDIES RELATING TO COFFEE  
11 CONSUMPTION AND PANCREATIC CANCER; CORRECT?

12 A YES.

13 Q ALL RIGHT. NOW, LET ME DIRECT YOUR  
14 ATTENTION TO PAGE 11 OF EXHIBIT 1072.

15 A IS THERE A PAGE NUMBER ON THIS ONE? MY COPY  
16 STARTS AT 305.

17 Q IF YOU LOOK AT THE BOTTOM, YOU'LL SEE IN  
18 HANDWRITING A BATES NUMBER WITH A -- A NUMBER THERE.

19 A ALL RIGHT.

20 Q AND DO YOU HAVE PAGE 11 IN FRONT OF YOU?

21 A YES.

22 Q AND DIRECTING YOUR ATTENTION TO THE AUTHORS'  
23 CONCLUSION, WHICH APPEARS AT THE RIGHT-HAND COLUMN AT  
24 THE BOTTOM. AND DO YOU SEE THAT, WHERE IT BEGINS "IN  
25 SUMMARY"?

26 A YES.

27 Q AND GENKINGER AUTHORS CONCLUDE:

28 "IN SUMMARY, WE FOUND NO ASSOCIATION

1           BETWEEN INTAKES OF TEA AND COFFEE DURING  
2           ADULTHOOD AND PANCREATIC CANCER RISK IN THIS  
3           POOLED ANALYSIS."

4           DO YOU SEE THAT?

5           A        YES.

6           Q        ALL RIGHT. LET'S TAKE A LOOK AT THE THIRD  
7           META-ANALYSIS THAT YOU REVIEWED AND RELIED UPON IN  
8           DEVELOPING YOUR OPINIONS RELATING TO PANCREATIC CANCER.  
9           AND THAT'S THE DONG 2011, AT EXHIBIT 908.

10          A        ALL RIGHT. I MEAN, IN MY SLIDE, I HAVE THE  
11          IDENTICAL DATA THAT THEY HAVE IN THESE PAPERS.

12                   (EXHIBIT 908 MARKED FOR IDENTIFICATION.)

13          Q        BY MR. SCHURZ: AND YOU REVIEWED THE DONG  
14          ARTICLE, WHICH IS IDENTIFIED HERE AT 908; CORRECT?

15          A        YES.

16          Q        AND YOU RELIED ON IT IN DEVELOPING YOUR  
17          OPINIONS; CORRECT?

18          A        YES. IT DOESN'T SHOW A POSITIVE  
19          ASSOCIATION, BUT I REVIEWED IT. SO WHEN YOU SAY I  
20          RELIED UPON IT, I REVIEWED ALL OF THE LITERATURE. I  
21          DIDN'T RELY; I TOOK IT INTO CONSIDERATION. IT DOESN'T  
22          MEAN THAT THIS IS A STUDY THAT SHOWED POSITIVE EVIDENCE  
23          BECAUSE VERY CLEARLY, IN MY SLIDE, IT DOESN'T SHOW THAT.

24          Q        IN FACT, NONE OF THE META-ANALYSES YOU  
25          RELIED ON SHOWED ANY POSITIVE EVIDENCE OF AN INCREASED  
26          STATISTICALLY SIGNIFICANT RISK ASSOCIATED WITH  
27          PANCREATIC CANCER; CORRECT?

28          A        WELL, NOT A STATISTICALLY SIGNIFICANT

1 INCREASED RISK, BUT THE TURATI STUDY THAT WE JUST  
2 DISCUSSED AND WHERE THEY SAID "NO APPRECIABLE INCREASED  
3 RISK," YOU'VE GOT A 13 PERCENT INCREASE, AND IT'S  
4 ONE-HUNDREDTH AWAY FROM BEING STATISTICALLY SIGNIFICANT.

5 Q ALL RIGHT. LET'S TAKE A LOOK AT WHAT THE  
6 DONG AUTHORS CONCLUDE AT EXHIBIT 908. AND LET ME DIRECT  
7 YOUR ATTENTION TO 006. AND WE'RE IN THE LAST PARAGRAPH  
8 ON PAGE 006 ON EXHIBIT 908.

9 AND DO YOU HAVE THAT IN FRONT OF YOU?

10 A I'M GETTING IT. ALL RIGHT.

11 Q AND HERE THE DONG AUTHORS OBSERVE:

12 "IN SUMMARY, THERE IS SUBSTANTIAL  
13 EVIDENCE FROM BOTH LABORATORY AND ANIMAL  
14 STUDIES ON THE FAVORABLE INFLUENCE OF COFFEE  
15 ON THE RISK OF PANCREATIC CANCER."

16 DO YOU SEE THAT?

17 A YES.

18 Q YOU DID NOT REVIEW THE ANIMAL DATA RELATING  
19 TO COFFEE IN THIS CASE; CORRECT?

20 A CORRECT.

21 Q AND YOU DID NOT REVIEW THE EXPERIMENTAL DATA  
22 ON COFFEE AS PART OF YOUR WORK IN THIS CASE; CORRECT?

23 A CORRECT.

24 Q SO CONTINUING ON, THE AUTHORS CONCLUDE --  
25 AND THIS IS THE LAST SENTENCE OF DONG, 908 --

26 MR. METZGER: COULD WE HAVE THE COMPLETE SENTENCE  
27 READ, NOT JUST A FRAGMENT, YOUR HONOR? IF HE'S GOING TO  
28 READ FROM THE ARTICLE, I'D LIKE THE COMPLETE SENTENCE

1 READ.

2 THE COURT: ALL RIGHT. GO AHEAD. COMPLETE  
3 SENTENCE. IT'S IN FRONT OF EVERYBODY. GO AHEAD, READ  
4 IT, THE COMPLETE SENTENCE.

5 MR. SCHURZ: IF YOUR HONOR WOULD LIKE, I'M HAPPY  
6 TO READ THE WHOLE THING.

7 THE COURT: ALL RIGHT.

8 Q BY MR. SCHURZ: (READING:)

9 "ALTHOUGH WELL-DESIGNED STUDIES -- IN  
10 PARTICULAR, RANDOMIZED CLINICAL STUDIES AMONG  
11 HIGH-RISK POPULATIONS -- ARE NEEDED TO PROVIDE  
12 VALUABLE INSIGHTS INTO COFFEE CONSUMPTION AND  
13 THE RISK OF PANCREATIC CANCER, OUR META-  
14 ANALYSIS, WHICH INCLUDED 14 PROSPECTIVE COHORT  
15 STUDIES, CONFIRMED THAT COFFEE CONSUMPTION IS  
16 INVERSELY ASSOCIATED WITH THE RISK OF  
17 PANCREATIC CANCER."

18 CORRECT?

19 A YES. AND THAT'S WHAT THEIR STUDY SHOWS, AND  
20 THAT'S WHAT I'VE INDICATED IN MY SLIDE, THAT -- AND I'LL  
21 ALSO DRAW YOUR ATTENTION, THEY SAID THAT RANDOMIZED  
22 CLINICAL TRIALS ARE NEEDED TO REALLY ANSWER THE  
23 QUESTION. AND THAT IS A POINT THAT I MADE YESTERDAY.

24 Q AND WHAT THE AUTHORS ARE INTERESTED IN HERE  
25 IS WHETHER THOSE RANDOMIZED TRIALS WOULD CONFIRM THAT  
26 COFFEE EXERTS A PROTECTIVE EFFECT ON THE RISK OF  
27 PANCREATIC CANCER, WHICH IS --

28 MR. METZGER: OBJECTION --

1 Q BY MR. SCHURZ: -- WHY THEY STATE:

2 "OUR META-ANALYSIS CONFIRMED THAT COFFEE  
3 CONSUMPTION IS INVERSELY ASSOCIATED WITH THE  
4 RISK OF PANCREATIC CANCER."

5 CORRECT?

6 MR. METZGER: OBJECTION; ARGUMENTATIVE.

7 THE COURT: OVERRULED.

8 THE WITNESS: I THINK YOU'RE SAYING THIS IS WHAT  
9 THE AUTHORS THOUGHT. I DON'T SEE -- I DON'T GET THIS IS  
10 WHAT THE AUTHORS THOUGHT FROM WHAT'S IN THIS PARAGRAPH.

11 THEY'RE SAYING THAT THE WAY TO REALLY ANSWER  
12 THE QUESTION IS THROUGH RANDOMIZED CLINICAL TRIALS, AND  
13 I AGREE WITH THAT.

14 Q BY MR. SCHURZ: AND THEIR DATA, ANALYZED  
15 HERE, SHOWED AND DEMONSTRATED THAT COFFEE CONSUMPTION IS  
16 INVERSELY ASSOCIATED WITH THE RISK OF PANCREATIC CANCER;  
17 CORRECT?

18 MR. METZGER: OBJECTION; ASKED AND ANSWERED.

19 THE WITNESS: YES, AND --

20 THE COURT: OVERRULED.

21 THE WITNESS: -- THAT'S WHAT I INDICATED IN MY  
22 SLIDE TOO. I'M NOT DISAGREEING WITH IT, THEIR  
23 CONCLUSION.

24 Q BY MR. SCHURZ: OKAY.

25 A THAT INCLUDES ALL OF IT.

26 Q OKAY.

27 A ALL RIGHT.

28 Q LET'S TURN TO THE NEXT META-ANALYSIS THAT

1 YOU RELIED ON, WHICH IS THE YU ANALYSIS, AT EXHIBIT  
2 10998.

3 AND DO YOU HAVE EXHIBIT 10998 IN FRONT OF  
4 YOU, DR. INFANTE?

5 A YES, I DO.

6 (EXHIBIT 10998 MARKED FOR  
7 IDENTIFICATION.)

8 Q BY MR. SCHURZ: AND THIS IS THE FOURTH  
9 META-ANALYSIS THAT YOU RELIED ON IN EVALUATING  
10 PANCREATIC CANCER AND COFFEE CONSUMPTION; CORRECT?

11 A WELL, IT'S ONE OF THEM THAT I PRESENTED,  
12 YES. AGAIN, WHEN YOU SAY "RELIED UPON," I PRESENTED  
13 THEM SO I WOULD PRESENT ALL THE DATA.

14 AND THIS STUDY DOES NOT SHOW -- YU DOES NOT  
15 SHOW AN INCREASED RISK. IN FACT, THERE'S A SIGNIFICANT  
16 REDUCTION. THAT'S INDICATED IN MY SLIDE. I'M NOT  
17 DISAGREEING WITH THAT AT ALL.

18 Q YOU'RE NOT DISAGREEING WITH THE YU AUTHORS'  
19 CONCLUSION THAT COFFEE EXERTS A PROTECTIVE EFFECT WITH  
20 RESPECT TO COFFEE AND PANCREATIC CANCER?

21 MR. METZGER: OBJECTION; ARGUMENTATIVE. THAT'S A  
22 DIFFERENT --

23 THE COURT: OVERRULED.

24 THE WITNESS: WELL, I WOULD DISAGREE WITH THAT,  
25 YES.

26 Q BY MR. SCHURZ: OKAY. ALL RIGHT.

27 A I'M SAYING THERE'S A SIGNIFICANT REDUCTION.  
28 I WOULDN'T SAY THAT THAT INDICATES A PROTECTIVE EFFECT,

1 IN MY OPINION, BECAUSE YOU CAN'T DETERMINE THAT FROM AN  
2 OBSERVATIONAL STUDY.

3 Q AND WHAT THE YU AUTHORS CONCLUDED, BASED  
4 UPON THEIR REVIEW OF THE COHORT STUDIES RELATED TO  
5 PANCREATIC CANCER, IS THAT THERE WAS A STATISTICALLY  
6 SIGNIFICANT DECREASED RISK ASSOCIATED WITH COFFEE  
7 CONSUMPTION AND PANCREATIC CANCER; CORRECT?

8 A YES. AND THAT'S -- AGAIN, THAT'S WHAT I  
9 HAVE IN MY SLIDE. THAT'S WHAT I'VE INDICATED.

10 Q BUT YOU WOULD DISAGREE, ONCE AGAIN, WITH THE  
11 YU AUTHORS' CONCLUSION THAT COFFEE APPEARS TO BE  
12 ASSOCIATED WITH AN INVERSE ASSOCIATION WITH PANCREATIC  
13 CANCER; CORRECT?

14 A WELL, I DON'T KNOW IF THAT'S A CONCLUSION  
15 FROM THEIR DATA. THAT'S AN INTERPRETATION OF IT. AND  
16 I'M SAYING YOU CAN'T MAKE THAT DETERMINATION FROM AN  
17 OBSERVATIONAL STUDY.

18 Q ALL RIGHT. NOW, YOU MENTIONED IARC AND  
19 IARC'S EARLIER REVIEW OF PANCREATIC CANCER. AND IF I  
20 COULD SHOW YOU IN YOUR DEMONSTRATIVE, WHICH WAS AT SLIDE  
21 95, IARC DID HAVE AN ULTIMATE CONCLUSION WITH RESPECT TO  
22 PANCREATIC CANCER, DID THEY NOT?

23 A YES.

24 Q AND THE CONCLUSION THAT IARC REPORTED WITH  
25 RESPECT TO PANCREATIC CANCER IS THAT:

26 "THERE IS INADEQUATE EVIDENCE IN HUMANS  
27 THAT COFFEE-DRINKING IS CARCINOGENIC IN THE  
28 PANCREAS."

1 CORRECT?

2 A WELL, I DON'T -- RIGHT. YES, THAT'S WHAT  
3 THAT SAYS.

4 Q OKAY. LET'S TALK A LITTLE BIT ABOUT THE  
5 COHORT STUDIES THAT YOU REVIEWED RELATING TO PANCREATIC  
6 CANCER AND COFFEE CONSUMPTION.

7 NOW, DR. INFANTE, WOULD YOU AGREE THAT THE  
8 GREAT MAJORITY OF COHORT STUDIES ON COFFEE CONSUMPTION  
9 AND PANCREATIC CANCER DO NOT REPORT AN ELEVATED RISK OF  
10 PANCREATIC CANCER ASSOCIATED WITH COFFEE CONSUMPTION?

11 A YES. THE COHORT STUDIES, YOU'RE REFERRING  
12 TO?

13 Q YES.

14 A YES.

15 Q SHOWING YOU EXHIBIT 00663. THIS IS THE  
16 BHOO-PATHY 2013 STUDY FROM THE EUROPEAN PROSPECTIVE  
17 INVESTIGATION INTO NUTRITION AND CANCER, OR ALSO  
18 REFERRED TO AS THE EPIC STUDY.

19 AND DR. INFANTE, THIS STUDY WAS INCLUDED  
20 AMONG YOUR RELIANCE MATERIALS IN THIS CASE?

21 A YOU KNOW, I DON'T -- I DON'T RECALL THAT  
22 BEING IN ONE OF MY SLIDES. SO LET ME TRY TO REFER TO  
23 THE SLIDES.

24 (REVIEWS DOCUMENTS.)

25 (EXHIBIT 663 MARKED FOR IDENTIFICATION.)

26 MR. METZGER: YOUR HONOR, I WOULD LIKE THE  
27 PREDICATE QUESTION: HAS HE SEEN THIS STUDY? HAS HE  
28 READ, REVIEWED, OR CONSIDERED IT?

1 THE COURT: WHAT DID --

2 MR. METZGER: PARDON?

3 THE COURT: WHAT'S YOUR -- WHAT DID YOU SAY,  
4 "PREDICATE QUESTION"?

5 MR. METZGER: YEAH, THE FOUNDATIONAL QUESTION:  
6 HAS HE READ, REVIEWED, OR CONSIDERED THE STUDY? IT  
7 APPEARS TO HAVE BEEN ADVANCE-PUBLISHED. IT'S NOT A  
8 FINAL DOCUMENT, AND IT WASN'T IN THE SLIDES. I HAVE A  
9 FEELING THAT HE HASN'T SEEN THIS. SO I'D LIKE --

10 THE COURT: AND THAT WAS THE QUESTION, WHETHER HE  
11 HAD CONSIDERED IT OR RELIED ON IT.

12 MR. METZGER: WELL, THAT WASN'T THE QUESTION.  
13 THAT'S WHAT I'M ASKING THE INITIAL QUESTION BE.

14 MR. SCHURZ: I'M WELL AWARE OF HOW TO LAY A  
15 FOUNDATION.

16 THE WITNESS: WELL, I'M REVIEWING MY SLIDES TO SEE  
17 IF IT WAS INCLUDED.

18 Q BY MR. SCHURZ: RIGHT.

19 A I DON'T SEE IT ON THERE, NO.

20 Q OKAY. DID YOU REVIEW THIS STUDY?

21 A NO.

22 Q OKAY. I'LL REPRESENT TO YOU THAT THIS IS  
23 THE LARGEST STUDY ON PANCREATIC CANCER, IN TERMS OF THE  
24 NUMBER OF CASES --

25 MR. METZGER: OBJECTION, YOUR HONOR. 721, VAGUE.  
26 HE HASN'T REVIEWED IT; HE CAN'T EXAMINE HIM ABOUT IT.

27 THE COURT: WELL, WE'RE WAITING FOR A QUESTION.

28 MR. METZGER: WELL, HE'S MAKING A REPRESENTATION.

1 I'D LIKE A QUESTION, NOT A REPRESENTATION.

2 MR. SCHURZ: THE FOUNDATION, YOUR HONOR, IS, HERE  
3 IS THE LARGEST COHORT STUDY --

4 MR. METZGER: OBJECTION --

5 MR. SCHURZ: -- RELATING TO PANCREATIC CANCER.

6 THE COURT: ALL RIGHT. ASK A QUESTION.

7 Q BY MR. SCHURZ: THIS IS THE LARGEST STUDY  
8 RELATING TO PANCREATIC CANCER THAT'S BEEN PUBLISHED;  
9 CORRECT?

10 MR. METZGER: OBJECTION; 721(B) --

11 THE WITNESS: I DON'T KNOW. I'D HAVE TO REVIEW --

12 MR. METZGER: HOLD IT; HOLD IT.

13 OBJECTION; 721(B).

14 THE COURT: OVERRULED.

15 MR. METZGER: WHAT? I'M SORRY, YOUR HONOR.

16 THE COURT: THE WITNESS SAID HE DOESN'T KNOW.  
17 NEXT QUESTION.

18 Q BY MR. SCHURZ: YOU DID NOT PERFORM A  
19 SYSTEMATIC REVIEW OF THE COHORT STUDIES, DID YOU, DR.  
20 INFANTE?

21 MR. METZGER: OBJECTION. AS TO PANCREATIC CANCER  
22 OR AS TO ALL COHORT STUDIES? WHAT'S THE QUESTION?

23 OBJECTION; VAGUE.

24 THE COURT: ALL RIGHT. THE OBJECTION IS  
25 SUSTAINED. REPHRASE YOUR QUESTION, PLEASE.

26 MR. SCHURZ: I'D BE HAPPY TO, YOUR HONOR.

27 Q DR. INFANTE, DID YOU PERFORM A SYSTEMATIC  
28 REVIEW OF ALL OF THE COHORT STUDIES RELATING TO COFFEE

1 CONSUMPTION AND PANCREATIC CANCER?

2 A WELL, I'M LOOKING AT -- I BELIEVE THAT I  
3 DID.

4 (REVIEWS DOCUMENTS.)

5 LET ME LOOK.

6 (REVIEWS DOCUMENTS.)

7 WELL, IN THE COHORT STUDIES, IF YOU LOOK AT  
8 MY SLIDE 119, IT STARTS WITH NOMURA 1981. SO YES, I  
9 DID. LOOKS LIKE I MISSED THIS ONE, BUT I -- ONE, TWO,  
10 THREE, FOUR...

11 I REVIEWED 21 STUDIES THAT I IDENTIFIED.

12 Q ON THE COHORT STUDIES RELATING TO COFFEE AND  
13 PANCREATIC CANCER, YOU DID NOT REVIEW THE BHOO-PATHY  
14 POOLED ANALYSIS; CORRECT?

15 MR. METZGER: OBJECTION; ASKED AND ANSWERED.

16 THE WITNESS: CORRECT.

17 MR. SCHURZ: OKAY.

18 THE COURT: OBJECTION OVERRULED.

19 Q BY MR. SCHURZ: SO THIS WAS INCLUDED IN YOUR  
20 RELIANCE MATERIALS --

21 MR. METZGER: OBJECTION; LACKING IN FOUNDATION.  
22 HE DOESN'T KNOW THAT.

23 THE COURT: OVERRULED.

24 Q BY MR. SCHURZ: CORRECT?

25 MR. METZGER: OBJECTION; LACKING IN FOUNDATION,  
26 CALLING FOR SPECULATION.

27 THE COURT: OVERRULED.

28 THE WITNESS: ARE YOU TALKING ABOUT THE BHOO-PATHY

1 STUDY?

2 Q BY MR. SCHURZ: YES.

3 A NO, I DIDN'T REVIEW IT. I APPARENTLY MISSED  
4 IT.

5 Q SO THIS WAS PRODUCED TO YOU BY COUNSEL AS  
6 PART OF YOUR PREPARATION, AND YOU CHOSE NOT TO REVIEW  
7 THIS; CORRECT?

8 MR. METZGER: OBJECTION; LACKING FOUNDATION.

9 THE WITNESS: I DON'T RECALL SEEING THIS. IF I  
10 HAD, I WOULD HAVE REVIEWED IT.

11 Q BY MR. SCHURZ: ALL RIGHT. SO YOU'RE NOT --

12 A IF THEY DID PRODUCE IT TO ME, I -- SOMEHOW I  
13 OVERLOOKED IT OR MISSED IT. I DIDN'T --

14 THE COURT: ALL RIGHT. THE WITNESS DIDN'T SEE IT  
15 OR REVIEW IT. NEXT QUESTION.

16 MR. SCHURZ: OKAY.

17 Q IN FACT, AT THE TIME YOU FORMED YOUR  
18 OPINIONS AT YOUR DEPOSITION, YOU'D ONLY REVIEWED IN  
19 THEIR ENTIRETY THREE COHORT STUDIES ON COFFEE AND  
20 PANCREATIC CANCER; IS THAT CORRECT?

21 A NO, I DON'T -- I DON'T RECALL.

22 Q ALL RIGHT. LET'S TALK --

23 A WELL, WAIT A SECOND. LET ME LOOK. I DON'T  
24 THINK THAT'S CORRECT. WELL, WAIT A MINUTE.

25 (REVIEWS DOCUMENTS.)

26 AS OF THE TIME OF MY DEPOSITION, THAT'S  
27 CORRECT.

28 Q BY MR. SCHURZ: ALL RIGHT. AT THE TIME YOU

1 FORMED YOUR INITIAL OPINIONS THAT YOU COMMUNICATED AT  
2 YOUR DEPOSITION, YOU'D READ THREE OF THE COHORT STUDIES  
3 RELATING TO COFFEE CONSUMPTION AND PANCREATIC CANCER IN  
4 THEIR ENTIRETY; CORRECT?

5 MR. METZGER: DID I HEAR "IN ENTIRETY" AT THE END?

6 THE COURT: ARE YOU TALKING ABOUT IN REFERENCE TO  
7 THIS CASE?

8 MR. SCHURZ: YES.

9 THE WITNESS: WELL, MAYBE I REVIEWED MORE THAN  
10 THAT, BUT I HAD DATA IN THE CHART, IN EXHIBIT 227, ON  
11 THREE COHORT STUDY RESULTS THAT DEMONSTRATED SIGNIFICANT  
12 INCREASES.

13 Q BY MR. SCHURZ: OKAY.

14 A SO SINCE I -- SINCE I HAD LOOKED  
15 PRELIMINARILY AT THE DATA AND I HADN'T COMPLETED ALL THE  
16 DATA ON THE COHORT STUDIES, I PUT DOWN SOME OF THE  
17 RESULTS THAT WERE -- THAT SHOWED SIGNIFICANTLY ELEVATED  
18 RISKS, WITH THE INTENTION THEN TO COMPLETE THE REVIEW,  
19 WHICH I DID.

20 Q RIGHT. OKAY.

21 A SO HOW MANY I HAD ACTUALLY -- I CERTAINLY  
22 HAD LOOKED AT THEM, OR I WOULDN'T HAVE BEEN ABLE TO  
23 IDENTIFY THEM THREE OF THEM THAT SHOWED POSITIVE  
24 FINDINGS.

25 Q OKAY. LET'S TALK ABOUT THOSE THREE THAT YOU  
26 DID REVIEW PRIOR TO YOUR DEPOSITION. AND LET'S START  
27 WITH THE HARNACK COHORT STUDY, AT EXHIBIT 1158.

28 AND IF YOU'D LOOK AT THE SCREEN, DR.

1 INFANTE, CAN YOU IDENTIFY THIS DOCUMENT AS THE HARNACK  
2 STUDY OF 1997?

3 A YES.

4 (EXHIBIT 1158 MARKED FOR  
5 IDENTIFICATION.)

6 Q BY MR. SCHURZ: AND YOU REVIEWED THIS STUDY  
7 AS PART OF YOUR WORK IN THIS CASE?

8 A YES.

9 Q AND YOU RELIED ON IT IN FORMING YOUR  
10 OPINIONS; CORRECT?

11 A YES.

12 EXCUSE ME, YOUR HONOR. I WONDER IF -- COULD  
13 I HAVE A BATHROOM BREAK?

14 THE COURT: DO YOU WANT TO TAKE A RECESS?

15 THE WITNESS: YES.

16 THE COURT: ALL RIGHT. WE'LL TAKE A FIVE-MINUTE  
17 RECESS.

18 (RECESS.)

19 THE COURT: BACK ON THE RECORD IN CERT VS.  
20 STARBUCKS. COUNSEL ARE PRESENT. DR. INFANTE IS ON THE  
21 STAND. MR. SCHURZ WAS INQUIRING.

22 COUNSEL, YOU MAY PROCEED.

23 MR. SCHURZ: THANK YOU, YOUR HONOR.

24 Q BEFORE THE BREAK, DR. INFANTE, WE WERE JUST  
25 ABOUT TO DISCUSS THE HARNACK ARTICLE, WHICH IS EXHIBIT  
26 1158. DO YOU HAVE THAT IN FRONT OF YOU?

27 A YES.

28 Q AND THIS IS ONE OF THE DOCUMENTS OR ARTICLES

1 YOU RELIED UPON IN FORMING YOUR OPINIONS; CORRECT?

2 A YES.

3 Q AND IF WE TAKE A LOOK AT EXHIBIT 1158, AND  
4 GO TO TABLE NO. 4 AT PAGE 0004, WE CAN SEE THE DATA THAT  
5 YOU HAVE IDENTIFIED AS INDICATING A STATISTICALLY  
6 SIGNIFICANT INCREASE IN RISK FOR CONSUMERS OF OVER 17.5  
7 CUPS OF COFFEE PER WEEK.

8 DO YOU HAVE WHAT IS IDENTIFIED AS TABLE  
9 NO. 4 ON PAGE 4 OF THE HARNACK ARTICLE IN FRONT OF YOU?

10 A TABLE 4. YES, I DO.

11 Q NOW, IF WE LOOK IMMEDIATELY TO THE RIGHT OF  
12 THE VALUES THAT YOU CHOSE TO IDENTIFY, WE SEE A CATEGORY  
13 OF "NEVER-SMOKERS"; CORRECT?

14 A YES.

15 Q AND HERE THE HARNACK INVESTIGATORS ANALYZE  
16 THE RELATIVE RISK FOR NEVER-SMOKERS IN THE IOWA WOMEN'S  
17 HEALTH STUDY; CORRECT?

18 A THEY DID THAT ANALYSIS, YES. AND THEY ALSO  
19 DID AN ANALYSIS THAT I RELIED ON THAT SAYS IT'S ADJUSTED  
20 FOR CIGARETTE SMOKING, AMONG OTHER FACTORS. BUT THIS IS  
21 A DIFFERENT ANALYSIS, AMONG THE NEVER-SMOKERS.

22 Q AND IN THE NEVER-SMOKERS, THE AUTHORS REPORT  
23 THAT THERE IS NO STATISTICALLY SIGNIFICANT INCREASE  
24 ASSOCIATED WITH COFFEE CONSUMPTION AT THIS LEVEL;  
25 CORRECT?

26 A WELL, THEY SHOW A RELATIVE RISK OF 1.74.  
27 AND THE LOWER BOUND, AT THE 95 CONFIDENCE INTERVAL, IS  
28 .8. SO THAT IS NOT STATISTICALLY SIGNIFICANT.

1                   BUT THEN YOU'RE ALSO REDUCING THE NUMBER OF  
2                   CASES IN HALF IN THAT ANALYSIS. IF YOU LOOK AT THE  
3                   ANALYSIS THAT I RELIED UPON, YOU'VE GOT 35 CASES. AND  
4                   IN THAT ANALYSIS, THERE IS AN ADJUSTMENT FOR AGE AND  
5                   SMOKING STATUS AND PACK-YEARS OF SMOKING.

6                   Q           AND SMOKING IS A RISK FACTOR FOR PANCREATIC  
7                   CANCER; CORRECT?

8                   A           CORRECT. AND THEY'VE ADJUSTED FOR SMOKING  
9                   IN THE FIRST ANALYSIS. THAT'S A SEPARATE GROUP OF  
10                  INDIVIDUALS WHO ARE NONSMOKERS.

11                  Q           AND AS A GENERAL RULE --

12                  A           IT'S STILL SHOWING AN ELEVATED RISK, EVEN  
13                  THOUGH IT'S NOT SIGNIFICANT, BUT THAT COULD BE A  
14                  DIFFERENT POPULATION TOO.

15                  Q           NOW, DR. INFANTE, YOU INDICATED THAT THE  
16                  TOTAL COHORT INVOLVES A LARGER GROUP OF CASES; CORRECT?

17                  A           YES.

18                  Q           AND --

19                  A           WELL, IT'S TWICE AS MANY. YOU'VE GOT 35  
20                  VERSUS 17 AMONG THE NONSMOKERS.

21                  Q           RIGHT. AND THE FACT THAT IT HAS MORE CASES  
22                  GIVES THE UNDERLYING VALUES GREATER STABILITY AND LOWER  
23                  CONFIDENCE INTERVALS; CORRECT -- OR NARROWER CONFIDENCE  
24                  INTERVALS; CORRECT?

25                  A           WELL, THAT'S A CONSEQUENCE OF THE LARGER  
26                  NUMBERS.

27                  Q           RIGHT. AND SINCE THE HARNACK 1997 ARTICLE,  
28                  THERE'S BEEN A FURTHER ANALYSIS, AN UPDATE OF THE IOWA

1 WOMEN'S HEALTH STUDY, AS IT RELATES TO COFFEE  
2 CONSUMPTION AND PANCREATIC CANCER, HASN'T THERE?

3 A WELL, I DON'T KNOW -- I DON'T RECALL. IS IT  
4 ONE OF THE -- IS THERE ONE OF THE OTHERS THAT I REVIEWED  
5 THAT IS AN UPDATE?

6 Q DO YOU KNOW?

7 A I DON'T RECALL.

8 Q OKAY. TAKE A LOOK, IF YOU WOULD, AT THE  
9 GENKINGER ANALYSIS, WHICH WE WERE DISCUSSING EARLIER --  
10 AT EXHIBIT 1072, WHICH YOU HAVE IN FRONT OF YOU.

11 A (ATTEMPTS TO LOCATE DOCUMENT.)

12 Q AND DO YOU HAVE EXHIBIT 1072 IN FRONT OF  
13 YOU?

14 A THAT'S WHAT I'M LOOKING TO SEE. YES, I DO.

15 Q OKAY. TAKE A LOOK AT TABLE NO. 1 OF EXHIBIT  
16 1072, AT PAGE 003.

17 A WHAT PAGE, ZERO --

18 Q 03.

19 A 03.

20 Q AND I'M LOOKING AT TABLE NO. 1. AND DO YOU  
21 HAVE THAT IN FRONT OF YOU?

22 A YES.

23 Q AND DIRECTING YOUR ATTENTION TO THE TABLE  
24 WHICH LISTS -- IN THE COLUMN THAT LISTS COHORTS, DO YOU  
25 SEE THE INITIALS OR THE ACRONYM FOR THE IOWA WOMEN'S  
26 HEALTH STUDY THERE, THAT APPEARS AS THE FIFTH ROW?

27 A YES.

28 Q AND DID YOU REVIEW, DR. INFANTE, THE

1 GENKINGER UPDATED ANALYSIS WITH RESPECT TO THE DATA OF  
2 THE IOWA WOMEN'S HEALTH STUDY IN TERMS OF PANCREATIC  
3 CANCER AND COFFEE CONSUMPTION?

4 A NO. I THINK I HAVE IT IN THE META-ANALYSIS  
5 SECTION.

6 Q AND AT THE TIME THAT THE GENKINGER ANALYSIS  
7 WAS PERFORMED IN 2012, THERE WERE, IN FACT, 166 CASES  
8 THAT ARE REPORTED OUT OF THE IOWA WOMEN'S HEALTH STUDY;  
9 CORRECT?

10 A YES.

11 Q AND WITH RESPECT TO THE VALUES THAT ARE  
12 REPORTED HERE -- AND I'LL DIRECT YOUR ATTENTION TO PAGE  
13 7 OF THE STUDY, AND FIGURE NO. 1. AND HERE WE'RE GOING  
14 TO LOOK SPECIFICALLY AT THE TOP, WHICH IS RELATING TO  
15 COFFEE, WHICH IS AT A.

16 AND DO YOU HAVE TABLE 1?

17 A FIGURE 1?

18 Q EXCUSE ME. DO YOU HAVE FIGURE 1, SECTION A,  
19 IN FRONT OF YOU?

20 A RIGHT.

21 Q AND HERE THE GENKINGER INVESTIGATORS REPORT  
22 THE RELATIVE RISK AND CONFIDENCE INTERVALS FOR THE IOWA  
23 WOMEN'S HEALTH STUDY OF THE 166 CASES THAT WERE  
24 ANALYZED; CORRECT?

25 A THAT'S WHAT I'M LOOKING FOR. WHERE IS IT  
26 UNDER -- A, B, OR C?

27 Q IT'S A, AND IT'S -- A RELATES TO COFFEE.

28 A (REVIEWS DOCUMENT.)

1                   THIS RELATES TO COFFEE? WHERE DOES IT SAY  
2 THAT?

3           Q       AT THE BOTTOM.

4           A       OKAY.

5                   (REVIEWS DOCUMENT.)

6           Q       SO WOULD YOU AGREE, DR. INFANTE, THAT THE  
7 UPDATED REVIEW OF THE IOWA WOMEN'S HEALTH STUDY  
8 PERFORMED BY GENKINGER SHOWED A STATISTICALLY  
9 SIGNIFICANT DECREASED RISK OF PANCREATIC CANCER BEING  
10 REPORTED OUT OF THE IOWA WOMEN'S HEALTH STUDY, BASED ON  
11 166 CASES?

12           A       WELL, I CAN'T TELL FROM THAT FIGURE. I  
13 CAN'T TELL WHERE THE BAR STOPS. MAYBE WE COULD LOOK  
14 AT -- ARE THESE DATA REPRESENTED IN A TABLE?

15           Q       WELL, WOULD YOU AGREE WITH ME --  
16 UNDERSTANDING THAT IT'S DIFFICULT TO DISCERN EXACTLY  
17 WHERE THAT CONFIDENCE INTERVAL IS -- THAT IT REFLECTS A  
18 SUBSTANTIALLY REDUCED RISK OF PANCREATIC CANCER IN  
19 COFFEE CONSUMPTION BEING REPORTED OUT OF THE IOWA  
20 WOMEN'S HEALTH STUDY FOR 166 CASES?

21           A       WELL, THE DATA THAT I REPORTED WAS AMONG  
22 POSTMENOPAUSAL WOMEN. ARE THESE POSTMENOPAUSAL WOMEN,  
23 OR ARE THESE MORE WOMEN FROM THE IOWA STUDY? IT COULD  
24 BE A DIFFERENT POPULATION.

25           Q       THIS IS THE ENTIRE POPULATION OF THE IOWA  
26 WOMEN'S HEALTH STUDY.

27           A       WELL, IF IT'S THE ENTIRE POPULATION, THEN IT  
28 DOESN'T CONTRADICT WHAT I HAVE IN MY SLIDE, BECAUSE THE

1 DATA I PRESENTED WAS FOR POSTMENOPAUSAL WOMEN.

2 Q YOU CHOSE A SUBGROUP ANALYSIS OF A MUCH  
3 SMALLER GROUP OF CASES; CORRECT?

4 A I WAS SHOWING WHAT THE RISK WAS AMONG  
5 POSTMENOPAUSAL WOMEN. AND IN FACT, IT SHOWS A  
6 SIGNIFICANT DOSE RESPONSE IN A '97 STUDY. I DON'T SEE  
7 THAT THEY EVALUATED THESE DATA FOR DOSE RESPONSE, AND I  
8 DON'T SEE AN EVALUATION FOR POSTMENOPAUSAL WOMEN.

9 SO THEY'RE DIFFERENT ANALYSES, AND IT'S A --  
10 THEY DON'T INCLUDE A SEPARATE ANALYSIS FOR  
11 POSTMENOPAUSAL WOMEN, WHICH IS WHAT I CITED ON SLIDE  
12 119.

13 Q MY QUESTION, DR. INFANTE: WOULD YOU AGREE  
14 THAT THE REPORT OUT FROM GENKINGER OF THE IOWA WOMEN'S  
15 HEALTH STUDY THAT'S INCLUDED IN THE 2012 ANALYSIS  
16 REFLECTS A DECREASED RISK ASSOCIATED WITH COFFEE  
17 CONSUMPTION AND PANCREATIC CANCER?

18 A AMONG ALL WOMEN, YES. BUT IT DOESN'T ANSWER  
19 THE QUESTION ABOUT POSTMENOPAUSAL WOMEN, WHAT THEIR RISK  
20 IS --

21 Q OKAY.

22 A -- WHICH IS WHAT I CITED IN MY SLIDE 119.

23 Q LET'S TALK ABOUT SOME OF THE OTHER COHORT  
24 STUDIES, THE TWO OTHER COHORT STUDIES THAT YOU REVIEWED  
25 IN THEIR ENTIRETY PRIOR TO YOUR DEPOSITION.

26 AND LET'S START WITH THE NILSSON STUDY.  
27 IT'S EXHIBIT 1644. AND WE'LL GET YOU A HARD COPY. BUT  
28 BASED UPON WHAT YOU SEE IN FRONT OF THE SCREEN, DO YOU

1 RECOGNIZE THIS AS THE NILSSON 2010 STUDY?

2 A YES.

3 (EXHIBIT 1644 MARKED FOR  
4 IDENTIFICATION.)

5 Q BY MR. SCHURZ: AND YOU REVIEWED THIS STUDY  
6 AS PART OF YOUR WORK IN THIS CASE?

7 A YES.

8 Q AND YOU RELIED ON THIS STUDY IN FORMING YOUR  
9 OPINIONS WITH RESPECT TO PANCREATIC CANCER AND COFFEE  
10 CONSUMPTION; CORRECT?

11 A YES. I MEAN, WHEN YOU ASK ME IF I RELY ON  
12 THE STUDY, I DON'T KNOW EXACTLY WHAT YOU MEAN WHEN YOU  
13 SAY "RELY" ON IT, BECAUSE I PRESENTED STUDIES THAT HAD  
14 NEGATIVE FINDINGS TOO.

15 SO YOU WANT TO SAY, "WELL, YOU RELIED ON A  
16 STUDY THAT SHOWS -- THAT DOESN'T SHOW ANY INCREASED  
17 RISK." I REVIEWED ALL OF THE INFORMATION. I CONSIDERED  
18 BOTH POSITIVE AND NEGATIVE STUDIES IN DRAWING MY  
19 CONCLUSION.

20 SO I WOULDN'T SAY THAT I DREW AN  
21 INTERPRETATION OF THE DATA --

22 THE COURT: ALL RIGHT. THAT'S ENOUGH. WE DON'T  
23 NEED A LONG FILIBUSTER.

24 DID YOU CONSIDER THE STUDY?

25 THE WITNESS: YES.

26 THE COURT: ALL RIGHT. LET'S PROCEED.

27 MR. SCHURZ: I'LL USE THAT TERMINOLOGY SINCE  
28 "RELY" SEEMS TO BE CAUSING PROBLEMS.

1 Q LET ME DIRECT YOU IN EXHIBIT 1644 TO TABLE  
2 NO. 3, AT PAGE 0006.

3 A (ATTEMPTS TO LOCATE DOCUMENT.)

4 Q AND DO YOU HAVE TABLE 3 IN FRONT OF YOU?

5 A 06?

6 Q YES.

7 A TABLE 3. YES, I DO.

8 Q OKAY. AND IF WE LOOK AT THE RESULTS FOR  
9 PANCREATIC CANCER IN THIS TABLE, WHICH APPEARS TOWARDS  
10 THE BOTTOM, THERE IS NO STATISTICALLY SIGNIFICANT  
11 ASSOCIATION BETWEEN TOTAL COFFEE CONSUMPTION AND  
12 PANCREATIC CANCER; CORRECT?

13 A YES. THE MULTIVARIANT ANALYSIS SHOWS 1.5,  
14 AND THE CONFIDENCE INTERVAL IS BETWEEN .57 AND 3.92.

15 Q OKAY.

16 A AND I HAVE THOSE DATA IN MY SLIDES.

17 Q AND LET'S TAKE A LOOK AT TABLE NO. 5, WHICH  
18 IS AT PAGE 10.

19 A (REVIEWS DOCUMENT.)

20 Q AND HERE WE SEE THE DATA THAT'S PROVIDED FOR  
21 BOILED COFFEE. DO YOU SEE THAT?

22 A YES.

23 Q AND THIS IS WHERE THE AUTHORS FOUND SOME  
24 POSITIVE STATISTICALLY SIGNIFICANT ASSOCIATION; CORRECT?

25 A YES, THEY DID.

26 Q SO THEY'VE REPORTED SIGNIFICANT ASSOCIATION  
27 BETWEEN COFFEE CONSUMPTION AND PANCREATIC CANCER, WAS  
28 WITH BOILED COFFEE; CORRECT?

1           A           YES, AND THAT'S WHAT'S INDICATED IN MY  
2 SLIDE. I HAVE THE RESULTS FOR TOTAL COFFEE AND BOILED  
3 COFFEE.

4           Q           WHAT IS BOILED COFFEE, AS IT'S ANALYZED HERE  
5 IN THE NILSSON STUDY?

6           A           I ASSUME IT'S COFFEE THAT WAS BOILED,  
7 WHEREAS THE TOTAL COFFEE WOULD BE COFFEE CONSUMPTION  
8 REGARDLESS OF HOW IT WAS PREPARED.

9           THE COURT: IS THERE A DISTINCTION BETWEEN BOILED  
10 COFFEE AND BREWED COFFEE?

11          MR. SCHURZ: YES, THERE IS, YOUR HONOR. AS IT'S  
12 ANALYZED BY THESE AUTHORS, THERE IS A DISTINCTION.

13          THE COURT: OKAY.

14          Q           BY MR. SCHURZ: DIRECTING YOUR ATTENTION TO  
15 PAGE 2 OF EXHIBIT 1644. AND IF I COULD DIRECT YOUR  
16 ATTENTION TO -- IT'S THE THIRD PARAGRAPH ON THE RIGHT --  
17 EXCUSE ME, LEFT-HAND SIDE. DO YOU SEE THAT?

18          A           YES.

19          Q           AND THE AUTHORS HERE DESCRIBE WHAT THEY'RE  
20 REFERRING TO AS "SCANDINAVIAN BOILED COFFEE." DO YOU  
21 SEE THAT?

22          A           YES.

23          Q           AND THE AUTHORS REPORT:

24                       "SCANDINAVIAN BOILED COFFEE -- ONCE VERY  
25 COMMON ACROSS SWEDEN, BUT NOW LIMITED  
26 PRIMARILY TO THE LARGE RURAL AREAS OF NORTHERN  
27 SWEDEN -- IS PREPARED BY HEATING A MIXTURE OF  
28 COARSELY GROUND COFFEE BEANS AND WATER TO A

1 BOIL, WHICH RESULTS IN HIGH DITERPENE  
2 CONCENTRATION."

3 DO YOU SEE THAT?

4 A YES.

5 Q OKAY. SO YOUR OBSERVATIONS WITH RESPECT TO  
6 THE POSITIVE ASSOCIATION ARE PREDICATED ON THE  
7 SCANDINAVIAN BOILED COFFEE AS OPPOSED TO THE BREWED  
8 COFFEE VALUES THAT THE NILSSON INVESTIGATORS REPORTED;  
9 CORRECT?

10 A I REPORTED THE RESULTS OF BOTH.

11 Q NOW, LET'S TAKE A LOOK AT THE THIRD COHORT  
12 STUDY THAT YOU REVIEWED PRIOR TO YOUR DEPOSITION, AND  
13 THAT WAS THE LIN COHORT STUDY, COMING OUT OF JAPAN. AND  
14 SHOWING YOU NOW WHAT IS EXHIBIT 1446.

15 AND DO YOU HAVE EXHIBIT 1446 IN FRONT OF  
16 YOU?

17 A YES, I DO.

18 (EXHIBIT 1446 MARKED FOR  
19 IDENTIFICATION.)

20 Q BY MR. SCHURZ: DID YOU CONSIDER THIS  
21 DOCUMENT?

22 A YES.

23 Q OKAY. AND LET'S LOOK AT THE DATA THAT THE  
24 AUTHORS REPORT. AND IF I COULD DIRECT YOUR ATTENTION TO  
25 PAGE 3 OF EXHIBIT 1446. WE'RE GOING TO TAKE A LOOK AT  
26 TABLE ROMAN NUMERAL II. AND DO YOU HAVE THAT IN FRONT  
27 OF YOU?

28 A YES.

1 Q OKAY. NOW, LET ME DIRECT YOUR ATTENTION  
2 FIRST TO THE RIGHT-HAND SIDE OF TABLE NO. II OF EXHIBIT  
3 1446, WHICH PROVIDES THE VALUES FOR FEMALES. DO YOU SEE  
4 THAT?

5 A YES.

6 Q AND THE LIN INVESTIGATORS REPORT THERE IS NO  
7 STATISTICALLY SIGNIFICANT ASSOCIATION BETWEEN COFFEE  
8 CONSUMPTION AT ANY AMOUNT AND PANCREATIC CANCER IN  
9 FEMALES; CORRECT?

10 A YEAH, AND THAT'S WHAT I REPORTED IN MY  
11 SLIDE.

12 Q AND TURNING TO THE MALES ON THE -- NOW ON  
13 THE LEFT-HAND SIDE OF THE TABLE, THERE IS NO  
14 STATISTICALLY SIGNIFICANT ASSOCIATION BETWEEN PANCREATIC  
15 CANCER IN MALES AND COFFEE CONSUMPTION AT ANYWHERE  
16 BETWEEN ONE TO TWO CUPS PER MONTH AND TWO TO THREE CUPS  
17 PER DAY; CORRECT?

18 A YES. THAT'S MORE THAN FOUR CUPS PER DAY.

19 Q RIGHT. AND SO LIN SHOWS A STATISTICALLY  
20 SIGNIFICANT POSITIVE ASSOCIATION BETWEEN COFFEE  
21 CONSUMPTION AND PANCREATIC CANCER IN ONE OUT OF THE TEN  
22 CATEGORIES OF CONSUMPTION INVESTIGATED; CORRECT?

23 A WHAT WAS THE LAST PHRASE YOU ADDED ON? I  
24 DIDN'T FOLLOW, WITH THE --

25 Q SURE. THE LIN ANALYSIS SHOWS A  
26 STATISTICALLY SIGNIFICANT POSITIVE ASSOCIATION BETWEEN  
27 COFFEE CONSUMPTION AND PANCREATIC CANCER IN ONLY ONE OUT  
28 OF THE TEN EXPOSURE CATEGORIES EVALUATED BY THESE

1       AUTHORS; CORRECT?

2               A           WELL, I DIDN'T COUNT THE NUMBER OF EXPOSURE  
3       CATEGORIES, BUT IN THE HIGHEST EXPOSURE CATEGORY, THEY  
4       HAVE A SIGNIFICANTLY INCREASED RISK OF PANCREATIC  
5       CANCER.  AND THAT'S ADJUSTED FOR CIGARETTE SMOKING ALSO.

6               Q           IN MEN AND NOT IN WOMEN; CORRECT?

7               A           CORRECT.  YES.

8               Q           YES.  AND THERE WAS NO DOSE RESPONSE IN  
9       EITHER MALES OR FEMALES OBSERVED IN THE LIN 2002 STUDY;  
10       CORRECT?

11              A           WHERE -- YOU KNOW, I DON'T -- I'M GOING TO  
12       HAVE TO LOOK AT THE DATA THERE, ANALYSES AND DOSE  
13       RESPONSE.

14              Q           OKAY.  I DON'T WANT TO TAKE THE TIME TO DO  
15       THAT.  IF YOU DON'T KNOW, WE'LL MOVE ON.

16                           I'D LIKE TO TURN, THEN, TO A NEW CATEGORY OF  
17       THE MATERIALS YOU ANALYZED WITH RESPECT TO COFFEE  
18       CONSUMPTION AND PANCREATIC CANCER AND SPECIFICALLY TALK  
19       ABOUT THE CASE CONTROLS THAT YOU LOOKED AT.

20              A           THE CASE-CONTROL STUDIES?

21              Q           YES.

22              A           OKAY.

23              Q           NOW, I'D LIKE TO DISCUSS SOME OF THE  
24       SPECIFIC CASES YOU IDENTIFIED IN YOUR ANALYSIS.

25                           BUT AS A THRESHOLD MATTER, YOU DID NOT  
26       SEGREGATE OUT, IN YOUR ANALYSIS OF THE CASE-CONTROL  
27       STUDIES, THOSE STUDIES THAT FAILED TO ADJUST FOR TOBACCO  
28       USE; CORRECT?

1           A           (REVIEWS DOCUMENT.)

2                       I DON'T HAVE THEM ON MY SLIDE. I'D HAVE TO  
3 LOOK THROUGH MY NOTES TO SEE WHICH ONES INDICATE THAT,  
4 IF I INDICATED IT --

5           Q           ALL RIGHT.

6           A           -- WHICH IS EXHIBIT 227.

7           Q           AND AS WE TALKED ABOUT BEFORE, TOBACCO AND  
8 SMOKING IS A RISK FACTOR FOR PANCREATIC CANCER; CORRECT?

9           A           YES.

10          Q           SO AS A GENERAL RULE, YOU WOULD WANT TO  
11 FOCUS ON THOSE STUDIES THAT HAVE MADE AN ADJUSTMENT FOR  
12 SMOKING IN THEIR ANALYSIS OF PANCREATIC CANCER AND  
13 COFFEE CONSUMPTION; CORRECT?

14          A           YEAH, OR NEVER-SMOKERS.

15          Q           OKAY. ALL RIGHT.

16          A           YEAH, THEY'RE TWO DIFFERENT GROUPS.

17          Q           ALL RIGHT. SO LET'S TALK ABOUT A COUPLE  
18 OF -- JUST A COUPLE OF EXAMPLES.

19                       LET ME FIRST ASK YOU TO TAKE A LOOK AT THE  
20 WYNDER STUDY FROM 1986, WHICH IS EXHIBIT 10983. AND YOU  
21 CONSIDERED THIS STUDY IN FORMING YOUR OPINIONS, DR.  
22 INFANTE?

23          A           YES. I CONSIDERED ALL THE STUDIES IN THESE  
24 SLIDES IN FORMING MY OPINIONS.

25                       (EXHIBIT 10983 MARKED FOR  
26 IDENTIFICATION.)

27          Q           BY MR. SCHURZ: OKAY. AND YOU CITE THIS  
28 STUDY AS EVIDENCE OF AN ASSOCIATION BETWEEN COFFEE

1 CONSUMPTION AND PANCREATIC CANCER; CORRECT?

2 A YES. IN FEMALES.

3 Q ALL RIGHT. NOW, LET ME DIRECT YOUR  
4 ATTENTION TO THE AUTHORS' CONCLUSIONS; AND SPECIFICALLY,  
5 AT PAGE 0004 OF EXHIBIT 10983.

6 A (REVIEWS DOCUMENT.)

7 Q AND IT'S THE FIRST FULL PARAGRAPH THAT  
8 APPEARS ON THE LEFT-HAND SIDE, LEFT-HAND COLUMN. DO YOU  
9 HAVE THAT IN FRONT OF YOU?

10 A YES.

11 Q AND THE AUTHORS OF THE WYNDER STUDY OBSERVE:

12 "THE FINDINGS OF THE PRESENT STUDY  
13 SUGGEST THAT DECAFFEINATED COFFEE CONSUMPTION  
14 IS NOT A FACTOR IN THE ETIOLOGY OF PANCREATIC  
15 CANCER IN HUMANS."

16 DO YOU SEE THAT?

17 A THAT'S WHAT THEY'RE SAYING THERE, YES.

18 Q AND THE AUTHORS FIND THAT THERE'S NO  
19 EVIDENCE OF A DOSE RESPONSE; CORRECT?

20 A WELL, LET ME READ IT.

21 (REVIEWS DOCUMENT.)

22 YES. AND THEY'RE SAYING THAT BECAUSE THEY  
23 DIDN'T FIND IT IN MEN, THEY ONLY FOUND IT IN WOMEN, THAT  
24 THE TWO RESULTS CANCEL EACH OTHER OUT.

25 Q AND THE ABSENCE OF A DOSE RESPONSE AND THE  
26 FAILURE TO REPLICATE IN MEN AND WOMEN LEADS THEM TO  
27 CONCLUDE THAT:

28 "THE ELEVATED RISK FOUND IN THE SUBGROUP

1 OF WOMEN ARGUES AGAINST A CAUSATIVE  
2 RELATIONSHIP BETWEEN DECAFFEINATED COFFEE-  
3 DRINKING AND PANCREATIC CANCER."

4 CORRECT?

5 A WELL, THAT'S THEIR INTERPRETATION OF IT, BUT  
6 I DON'T RECALL THAT THEY DID AN ANALYSIS TO SHOW THAT.  
7 I MEAN, THEY HAVE DIFFERENT RESULTS FOR MEN AND WOMEN.  
8 SO SINCE THEY DID, THEY SAID, "WELL, ONE CANCELS THE  
9 OTHER OUT." SO I DON'T AGREE.

10 THE COURT: IS THERE A COMPARABLE STUDY WITH  
11 REGARD TO CAFFEINATED COFFEE?

12 MR. SCHURZ: THERE ARE A NUMBER OF THEM.

13 THE COURT: I MEAN, BY THE SAME --

14 MR. SCHURZ: OH, BY THE WYNDER INVESTIGATORS? NO,  
15 NOT THAT I'M AWARE OF, YOUR HONOR.

16 THE COURT: ALL RIGHT.

17 Q BY MR. SCHURZ: ALL RIGHT. LET'S TAKE A  
18 LOOK AT ANOTHER OF THE CASE-CONTROL STUDIES THAT YOU  
19 IDENTIFIED; AND SPECIFICALLY, THE GHADIRIAN 1990  
20 ARTICLE, AT EXHIBIT 1082.

21 AND DO YOU SEE THE GHADIRIAN ARTICLE,  
22 EXHIBIT 1082, IN FRONT OF YOU?

23 A YES.

24 (EXHIBIT 1082 MARKED FOR  
25 IDENTIFICATION.)

26 Q BY MR. SCHURZ: AND DID YOU CONSIDER THE  
27 GHADIRIAN ARTICLE IN DEVELOPING YOUR OPINIONS IN THIS  
28 CASE?

1 A YES.

2 Q ALL RIGHT. DIRECTING YOUR ATTENTION TO PAGE  
3 1, AND JUST FOCUSING ON THE ABSTRACT OF THE GHADIRIAN  
4 PAPER, EXHIBIT 1082; AND SPECIFICALLY, THE LAST  
5 SENTENCE, WHERE THE AUTHORS OBSERVE:

6 "COFFEE DRINKERS WERE COLLECTIVELY AT  
7 LOWER RISK THAN NONDRINKERS, PARTICULARLY WHEN  
8 COFFEE WAS CONSUMED WITH MEALS, NOT ON AN  
9 EMPTY STOMACH."

10 DO YOU SEE THAT?

11 A YES.

12 Q YOU RELY ON THIS STUDY AS EVIDENCE OF AN  
13 ASSOCIATION BETWEEN COFFEE CONSUMPTION AND AN INCREASED  
14 RISK OF PANCREATIC CANCER; CORRECT?

15 A FOR DECAFFEINATED COFFEE ONLY.

16 Q OKAY.

17 A I HAVE THE RESULTS FOR THE REGULAR COFFEE  
18 AND TOTAL COFFEE IN MY SLIDE, AND I INDICATE WHAT THEY  
19 ARE.

20 Q ALL RIGHT. AND DID YOU CONSIDER THE  
21 AUTHORS' CONCLUSIONS AS YOU INTERPRETED THEIR DATA?

22 A NO, I DON'T CONSIDER CONCLUSIONS WHEN I  
23 INTERPRET THE DATA. I EVALUATE THE DATA -- OR I  
24 INTERPRET THE DATA.

25 Q LET'S TURN --

26 A THE INTERPRETATION IS A MATTER OF THEIR  
27 PERSONAL INTERPRETATION.

28 Q OKAY. LET'S TURN TO ANOTHER CASE-CONTROL

1 STUDY YOU REVIEWED AND INCLUDED AMONG YOUR MATERIALS.  
2 AND THAT'S THE SILVERMAN STUDY, EXHIBIT 1949.

3 A WHAT YEAR?

4 Q AND THIS IS AN ARTICLE FROM 1998.

5 AND DID YOU CONSIDER THIS ARTICLE IN FORMING  
6 YOUR OPINIONS IN THIS MATTER?

7 A YES. I CONSIDERED ALL OF THE LITERATURE.

8 (EXHIBIT 1949 MARKED FOR  
9 IDENTIFICATION.)

10 Q BY MR. SCHURZ: AND YOU -- SPECIFICALLY, YOU  
11 RELY ON IT AS EVIDENCE OF A STATISTICALLY SIGNIFICANT  
12 ELEVATED RISK AMONG AFRICAN-AMERICANS, COFFEE DRINKERS,  
13 AND PANCREATIC CANCER; CORRECT?

14 A YES.

15 Q ARE YOU FAMILIAR WITH HOW THE SILVERMAN  
16 AUTHORS INTERPRET THEIR OWN DATA?

17 A WELL, I HAVEN'T READ THEIR INTERPRETATION,  
18 BUT I PRESENT -- IN MY SLIDE, I PRESENT THE DATA FOR  
19 MALES AND FEMALES, WHITES AND BLACKS.

20 Q NOW, LET ME DIRECT YOU TO PAGE 8 OF THE  
21 EXHIBIT 1949. ON THE LEFT-HAND COLUMN, IT'S THE SECOND  
22 FULL PARAGRAPH. AND DO YOU HAVE THAT IN FRONT OF YOU?

23 A YES.

24 Q ALL RIGHT. AND THE SILVERMAN AUTHORS  
25 OBSERVE:

26 "NUMEROUS STUDIES OF PANCREATIC CANCER  
27 HAVE EXAMINED THE RELATIONSHIP BETWEEN COFFEE-  
28 DRINKING AND PANCREATIC CANCER RISK. ALTHOUGH

1 RESULTS OF MOST STUDIES DO NOT SUPPORT AN  
2 ASSOCIATION, POSITIVE FINDINGS FROM A SMALL  
3 NUMBER OF STUDIES HAVE RAISED THE POSSIBILITY  
4 OF A WEAK ASSOCIATION FOR HEAVY COFFEE  
5 DRINKING.

6 "HOWEVER, THERE IS A GENERAL CONSENSUS  
7 THAT ANY WEAK EFFECT IS LIKELY TO BE A RESULT  
8 OF RESIDUAL CONFOUNDING BY SMOKING OR OTHER  
9 SOURCES OF CONFOUNDING OR BIAS. OUR RESULTS  
10 ARE CONSISTENT WITH THIS VIEW."

11 DO YOU SEE THAT?

12 A YES.

13 Q AND I TAKE IT THAT YOU DO NOT CONCUR WITH  
14 THE SILVERMAN AUTHORS' OBSERVATION THAT THE WEAK  
15 ASSOCIATION IS ATTRIBUTABLE TO RESIDUAL CONFOUNDING FROM  
16 TOBACCO; CORRECT?

17 A WELL, THAT'S THEIR INTERPRETATION. I MEAN,  
18 THEY CITE TWO SOURCES FOR THAT.

19 Q ALL RIGHT. NOW, LET'S TAKE A LOOK AT THEIR  
20 ANALYSIS OF THE -- THAT YOU HAVE RELIED ON IN THIS CASE,  
21 WHICH WE CAN FIND AT PAGE 7. AND IT'S TABLE NO. 6. I'M  
22 SORRY, IT'S PAGE -- STRIKE THAT. IT'S NOT -- IT'S PAGE  
23 6.

24 A ARE WE STILL ON SILVERMAN?

25 Q WE ARE, AND PAGE 6 OF THAT STUDY. LET ME  
26 KNOW WHEN YOU'RE THERE.

27 A OKAY.

28 Q NOW, YOU'VE INDICATED AND REPORTED DATA WITH

1 RESPECT TO THE -- WITH RESPECT TO AFRICAN-AMERICAN  
2 COFFEE DRINKERS; CORRECT?

3 A THAT'S INCORRECT. I PRESENTED THE DATA FOR  
4 WHITES AND AFRICAN-AMERICANS AND MALES AND FEMALES.

5 Q AND YOU CITE THE EVIDENCE WITH RESPECT TO  
6 AFRICAN-AMERICANS AS PART OF YOUR EVIDENCE OF A  
7 STATISTICALLY SIGNIFICANT ELEVATED RISK; CORRECT?

8 A IT WAS BORDERLINE.

9 Q OKAY. AND WHEN THE SILVERMAN AUTHORS  
10 PERFORMED AN ANALYSIS AMONG AFRICAN-AMERICAN NONSMOKERS,  
11 THE ODDS RATIO AS REPORTED IN THIS ARTICLE WAS 1.0, WITH  
12 A CONFIDENCE INTERVAL OF 0.4 TO 2.6; CORRECT?

13 A YES. AMONG NONSMOKERS; CORRECT.

14 Q ALL RIGHT. SO UNDER THE -- THE SILVERMAN  
15 DATA SHOWS NO INCREASED RISK WHATSOEVER FOR AFRICAN-  
16 AMERICAN NONSMOKERS, AS REPORTED BY THE AUTHORS;  
17 CORRECT?

18 A YES, AMONG NONSMOKERS. BECAUSE YOU HAVE TO  
19 LOOK AND SEE IF THE OTHER ANALYSES WERE ADJUSTED FOR  
20 SMOKING. BECAUSE, I MEAN, QUITE A LARGE PORTION OF THE  
21 POPULATION SMOKES.

22 SO IF YOU HAVE A POSITIVE FINDING IN  
23 NONSMOKERS, THAT ADDS CONSIDERABLE EVIDENCE; BUT IF YOU  
24 DON'T, THAT ADDS SOME EVIDENCE. BUT ON THE OTHER HAND,  
25 A LARGE PORTION OF THE POPULATION SMOKES, SO THERE'S  
26 SOME INTERACTION WITH THAT.

27 AND THE QUESTION IS, WHO IS THE BEST GROUP  
28 TO STUDY? AND A LOT OF THESE STUDIES, THEY ADJUST FOR

1 CIGARETTE SMOKING AND FIND SIGNIFICANT ASSOCIATIONS.

2 AND THEN YOU POINTED OUT, WELL, THERE WERE  
3 SOME OF NONSMOKERS THAT THEY DIDN'T FIND AN ASSOCIATION,  
4 AND THAT'S IMPORTANT ALSO.

5 AND THEN IT'S A QUESTION OF, WELL, WHICH IS  
6 THE CORRECT ANALYSIS TO LOOK AT, IF YOU'RE LOOKING AT  
7 RISK FROM COFFEE CONSUMPTION TO THE GENERAL POPULATION?  
8 IS IT THAT THERE'S NO RISK FOR NONSMOKERS, SO YOU  
9 SHOULDN'T SMOKE IF YOU'RE GOING TO DRINK COFFEE?

10 IN OTHER WORDS, IT'S A QUESTION OF WHAT'S  
11 THE -- WHAT'S THE APPROPRIATE ANALYSIS TO LOOK AT COFFEE  
12 RISK FOR THIS CANCER IN THE GENERAL POPULATION.

13 Q AND WOULD YOU AGREE, DR. INFANTE, THAT IN  
14 LOOKING AT THE PANCREATIC CANCER EPIDEMIOLOGY, IT'S  
15 IMPORTANT TO LOOK AT THOSE STUDIES THAT HAVE MADE  
16 ADJUSTMENTS FOR SMOKING AND TOBACCO USE?

17 A YES.

18 Q OKAY. LET'S TURN NOW AND TALK TO SOME OF  
19 YOUR OPINIONS AS IT RELATES TO BLADDER CANCER.

20 THE COURT: IF YOU'RE GOING TO SWITCH TO ANOTHER  
21 SUBJECT, LET ME JUST INTERRUPT FOR A MOMENT. PLEASE  
22 STAY IN YOUR SEATS.

23 (OTHER MATTER HEARD.)

24 THE COURT: BACK ON THE RECORD IN CERT VS.  
25 STARBUCKS.

26 MR. SCHURZ.

27 MR. SCHURZ: THANK YOU, YOUR HONOR.

28 Q DR. INFANTE, I'D LIKE TO NOW TURN TO THE

1 OPINIONS THAT YOU HAVE OFFERED WITH RESPECT TO BLADDER  
2 CANCER. AND SPECIFICALLY, LET'S START WITH THE  
3 META-ANALYSES THAT YOU SUMMARIZED IN YOUR DEMONSTRATIVE  
4 AT 106, AND THEN IT CONTINUES ON AT 107. WE'LL TAKE A  
5 LOOK AT BOTH.

6 NOW, THE META-ANALYSES THAT YOU REVIEWED  
7 INCLUDE THE SALA, ZEEGERS, YU, ZHOU, AND BAI  
8 META-ANALYSES; CORRECT?

9 A YES.

10 Q LET'S START WITH THE SALA ARTICLE, WHICH IS  
11 EXHIBIT 10816.

12 AND JUST TAKING A LOOK AT THE MONITOR, DO  
13 YOU RECOGNIZE THE SALA ARTICLE, EXHIBIT 10816?

14 A YES.

15 (EXHIBIT 10816 MARKED FOR  
16 IDENTIFICATION.)

17 Q BY MR. SCHURZ: AND DID YOU CONSIDER THIS  
18 STUDY IN FORMING YOUR OPINIONS IN THIS MATTER?

19 A YES.

20 Q NOW, DIRECTING YOUR ATTENTION TO PAGE 005 OF  
21 EXHIBIT 10816. AND SPECIFICALLY, TO TABLE NO. 3. DO  
22 YOU HAVE THAT IN FRONT OF YOU?

23 A TABLE 3. YES.

24 Q AND WE'VE ALSO GOT IT ON THE MONITOR, IF  
25 THAT'S EASIER TO READ.

26 A (REVIEWS DOCUMENT.)

27 Q DR. INFANTE, ARE YOU FAMILIAR WITH TABLE  
28 NO. 3?

1 A WELL, I REVIEWED IT, YES.

2 Q OKAY. AND THIS PROVIDES THE RISK OF BLADDER  
3 CANCER FOR NUMBER OF CUPS OF COFFEE PER DAY IN  
4 NONSMOKERS; CORRECT?

5 A YES.

6 Q AND LOOKING AT NONSMOKERS OR NEVER-SMOKERS  
7 IS APPROPRIATE HERE, AS WELL, BECAUSE SMOKING IS A  
8 CONFOUNDER, IS IT NOT, FOR BLADDER CANCER?

9 A YES.

10 Q ALL RIGHT. AND THE RELATIVE RISK FOR EVER-  
11 COFFEE DRINKERS TO NEVER-COFFEE DRINKERS, AS REPORTED IN  
12 SALA, IS 1.0; CORRECT?

13 A I'M SORRY. WHERE ARE YOU?

14 Q I'M SORRY. IF YOU TAKE A LOOK AT TABLE 3 --

15 A YES.

16 Q -- ON THE LEFT-HAND SIDE, WE SEE THE COLUMN  
17 WHERE IT IDENTIFIES EVER-COFFEE DRINKERS. AND THE VALUE  
18 THAT IS REPORTED BY THE SALA INVESTIGATORS IS 1.0;  
19 CORRECT?

20 A YES.

21 Q ALL RIGHT. SO WITH RESPECT TO COMPARING  
22 NEVER-COFFEE DRINKERS WITH EVER-COFFEE DRINKERS, THE  
23 SALA INVESTIGATORS DO NOT REPORT ANY INCREASED RISK OR  
24 DECREASED RISK; CORRECT?

25 A CORRECT.

26 Q ALL RIGHT. AND NOW WE SEE THE EXPOSURE  
27 CATEGORIES THAT ARE IDENTIFIED BY THE SALA  
28 INVESTIGATORS. AND WE SEE THAT FOR ONE TO TWO CUPS PER

1 DAY, AGAIN, THE ODDS RATIO IS 1.0. AND FOR THREE TO  
2 FIVE CUPS PER DAY, IT REMAINS AT 1.0. AND AT SIX TO  
3 NINE CUPS PER DAY, IT REMAINS AT 1.0. CORRECT?

4 A YES.

5 Q SO AT EACH OF THESE LEVELS OF CONSUMPTION,  
6 THE SALA INVESTIGATORS FAIL TO FIND ANY ASSOCIATION AT  
7 ALL WITH RESPECT TO INCREASED CONSUMPTION OF COFFEE AND  
8 BLADDER CANCER; CORRECT?

9 A YES.

10 Q ALL RIGHT. NOW, YOU HAVE --

11 A BUT AT THE HIGHEST DOSE, THEY DID.

12 Q AND THAT'S THE VALUE THAT YOU'VE INCLUDED IN  
13 YOUR CHART, OR HIGHLIGHTED IN YOUR CHART, IS IT NOT:  
14 THE TEN CUPS PER DAY, OF 1.8; CORRECT?

15 A YEAH, BECAUSE THE HIGHEST EXPOSED GROUP  
16 SHOWS THE HIGHEST RISK.

17 Q RIGHT. AND SO FROM -- AND IT JUMPS FROM NO  
18 ASSOCIATION WHATSOEVER, AT SIX TO NINE CUPS PER DAY, TO  
19 A RELATIVE -- OR AN ODDS RATIO OF 1.8 AT TEN CUPS PER  
20 DAY; CORRECT?

21 A CORRECT.

22 Q RIGHT. AND THE P TREND THAT IS REFLECTED --  
23 OR THE DOSE RESPONSE TREND HERE IS NOT STATISTICALLY  
24 SIGNIFICANT; CORRECT?

25 A CORRECT.

26 Q ALL RIGHT. NOW --

27 A .15, TO BE SPECIFIC.

28 Q YEAH. NOW, THE SALA META-ANALYSIS WAS ONE

1 OF THE STUDIES YOU CRITICIZED DR. BOFFETTA FOR FAILING  
2 TO CONSIDER, WAS IT NOT?

3 A YES.

4 Q AND IT WAS INCLUDED IN HIS RELIANCE  
5 MATERIALS, WAS IT NOT?

6 A IT WAS INCLUDED IN WHOSE RELIANCE MATERIALS?

7 Q DR. BOFFETTA'S.

8 A I DON'T KNOW WHAT HIS RELIANCE MATERIALS  
9 WERE.

10 Q HAVE YOU REVIEWED THE AUTHORS OF THE SALA  
11 STUDY?

12 A HAVE I REVIEWED THE AUTHORS?

13 Q DO YOU KNOW WHO THE AUTHORS OF THE SALA  
14 STUDY ARE?

15 A I DON'T RECALL, AS I SIT HERE.

16 Q SO DIRECTING YOUR ATTENTION TO PAGE 1 OF  
17 EXHIBIT 10816. AND I DIRECT YOUR ATTENTION SPECIFICALLY  
18 TO THE NAME OF PAOLO BOFFETTA, AS A CO-AUTHOR OF THE  
19 SALA STUDY. DO YOU SEE THAT?

20 A WELL, YES.

21 Q DID YOU KNOW WHETHER DR. BOFFETTA WAS ONE OF  
22 THE LISTED AUTHORS OF THE SALA STUDY?

23 A YOU KNOW, IT DIDN'T ENTER MY MIND IF HE WAS  
24 OR WASN'T.

25 Q THANK YOU. LET'S TAKE A LOOK AT A SECOND OF  
26 THE META-ANALYSES THAT YOU REVIEWED AND HAVE CONSIDERED  
27 IN DEVELOPING YOUR OPINIONS, DR. INFANTE; SPECIFICALLY,  
28 THE ZEEGERS, WHICH IS EXHIBIT 2955.

1 ALL RIGHT. NOW, FIRST, YOU CITE THE  
2 META-ANALYSIS FROM ZEEGERS FROM 2001; CORRECT? IN YOUR  
3 CHART, AT DEMONSTRATIVE 106; CORRECT?

4 A CORRECT.

5 (EXHIBIT 2955 MARKED FOR  
6 IDENTIFICATION.)

7 Q BY MR. SCHURZ: DID YOU CONSIDER, IN YOUR  
8 ANALYSIS OF THE ZEEGERS, THE SUBSEQUENT SYSTEMATIC  
9 REVIEW PUBLISHED BY ZEEGERS IN 2003? SHOWING YOU NOW  
10 WHAT IS MARKED AS EXHIBIT 2955.

11 A NO. I DON'T HAVE THAT IN MY SLIDE HERE, SO  
12 I APPARENTLY DIDN'T FIND THIS ONE.

13 Q AND DIRECTING YOUR ATTENTION TO PAGE 1 OF  
14 EXHIBIT 2955 --

15 MR. METZGER: OBJECTION --

16 Q BY MR. SCHURZ: -- THE ZEEGERS AUTHORS --

17 MR. METZGER: HOLD ON. EXCUSE ME.

18 OBJECTION, YOUR HONOR. HE HASN'T SEEN THIS  
19 BEFORE. AND THIS IS NOT A META-ANALYSIS; IT'S A REVIEW.  
20 SO --

21 THE COURT: I HAVEN'T HEARD A QUESTION YET.

22 MR. METZGER: WELL, I'D LIKE THE PREDICATE AS  
23 TO -- HE'S ALREADY SAID HE HASN'T SEEN IT.

24 THE COURT: WELL, LET'S HEAR THE QUESTION.

25 Q BY MR. SCHURZ: ARE YOU AWARE, DR. INFANTE,  
26 OF THE ZEEGERS AUTHORS' CONCLUSION IN THEIR SYSTEMATIC  
27 REVIEW, PUBLISHED TWO YEARS AFTER THEIR PRIOR SYSTEMATIC  
28 REVIEW THAT YOU'RE RELYING ON?

1 MR. METZGER: OBJECTION; LACKING IN FOUNDATION.

2 THE WITNESS: WELL, HE --

3 THE COURT: THE QUESTION IS, ARE YOU AWARE?

4 MR. METZGER: IF HE HASN'T SEEN THIS --

5 THE COURT: THE QUESTION IS, ARE YOU AWARE? IT  
6 CALLS FOR A "YES" OR "NO."

7 THE WITNESS: NO. THE ANSWER IS NO. AND I DIDN'T  
8 REVIEW THIS AS PART OF A META-ANALYSIS BECAUSE IT'S NOT  
9 A META-ANALYSIS.

10 THE COURT: OKAY. NEXT QUESTION.

11 Q BY MR. SCHURZ: AND THE 2001 WAS A  
12 SYSTEMATIC REVIEW; CORRECT -- AND A META-ANALYSIS;  
13 CORRECT?

14 A I ONLY HAVE THE DATA HERE. I DON'T KNOW THE  
15 TITLE OF IT. YOU'D HAVE TO SHOW IT TO ME.

16 Q ALL RIGHT. AND AS PART OF YOUR  
17 COMPREHENSIVE LITERATURE REVIEW, IT DID NOT INCLUDE  
18 LOOKING FOR FURTHER STATEMENTS BY THE AUTHORS OF  
19 META-ANALYSES THAT YOU REVIEWED; CORRECT?

20 A YOU MEAN FURTHER STATEMENTS OF  
21 META-ANALYSES? I'VE REVIEWED THE META-ANALYSES. IF  
22 SOMEONE HAS A STATEMENT ABOUT SOMEONE ELSE'S  
23 META-ANALYSIS, I WOULDN'T REVIEW THE STATEMENT. I  
24 WOULD -- IF I COULD FIND IT, I WOULD LOOK AT THE  
25 META-ANALYSIS.

26 Q IN 2001, THE ZEEGERS AUTHORS PUBLISHED A  
27 META-ANALYSIS AND SYSTEMATIC REVIEW; CORRECT?

28 A YES.

1 Q AND IN 2003, THE ZEEGERS AUTHORS PUBLISHED A  
2 FURTHER SYSTEMATIC REVIEW; CORRECT?

3 A BUT NOT A META-ANALYSIS, SO I DIDN'T INCLUDE  
4 IT IN MY -- THEY DON'T HAVE ANY NEW META-ANALYSES IN  
5 THE -- THAT I CAN SEE. I MEAN, I'VE NEVER LOOKED AT IT  
6 BEFORE.

7 Q ALL RIGHT. AND --

8 A I SEE THAT THERE'S A META-ANALYSIS, AND IT'S  
9 AN INTERPRETATION.

10 Q OKAY. NOW, LET'S TURN TO ANOTHER OF THE  
11 META-ANALYSES THAT YOU DID REVIEW: THE BAI ANALYSIS, AT  
12 EXHIBIT 599.

13 AND SHOWING YOU NOW WHAT'S APPEARED ON THE  
14 MONITOR. DO YOU RECOGNIZE THE BAI ANALYSIS, PUBLISHED  
15 IN 2014?

16 A YES.

17 (EXHIBIT 599 MARKED FOR IDENTIFICATION.)

18 Q BY MR. SCHURZ: DID YOU CONSIDER THIS IN  
19 DEVELOPING YOUR OPINIONS IN THIS MATTER?

20 A YES.

21 Q NOW, THIS META-ANALYSIS CONSIDERS ONLY THREE  
22 OF THE BLADDER AND COFFEE CONSUMPTION COHORT STUDIES;  
23 CORRECT?

24 A THREE OF THE WHICH? THE COHORT STUDIES, DID  
25 YOU SAY?

26 Q THIS BAI ANALYSIS CONSIDERS ONLY THREE OF  
27 THE BLADDER AND COFFEE CONSUMPTION COHORT STUDIES;  
28 CORRECT?

1           A       WELL, IN MY CHART, I HAVE 4 COHORT STUDIES  
2 AND 17 CASE-CONTROL STUDIES.

3           Q       RIGHT. AND THIS IS A FLUID CONSUMPTION  
4 STUDY; CORRECT?

5           A       YES.

6           Q       SO IT ONLY INCLUDES A SUBSET OF THE BLADDER  
7 COHORT STUDIES; CORRECT?

8           A       WELL, I'LL HAVE TO LOOK THROUGH IT NOW TO  
9 SEE WHICH COHORTS. IT SAYS IT INCLUDES FOUR COHORTS.  
10 THAT'S WHAT I HAVE, FOUR COHORT STUDIES.

11          Q       WELL, LET'S -- I THINK I CAN MAKE THIS  
12 SIMPLER. ON YOUR SLIDE, YOU IDENTIFY A TOTAL OF 11  
13 COHORT STUDIES; CORRECT?

14          A       ON BAI? NO, I HAVE FOUR COHORT STUDIES.

15          Q       I'M SORRY?

16          A       FOUR.

17          Q       SHOWING YOU DEMONSTRATIVE 105. THIS IS YOUR  
18 TABLE OF COFFEE AND BLADDER CANCER COHORT STUDIES;  
19 CORRECT?

20          A       YES.

21          Q       AND YOU IDENTIFY 11 STUDIES; CORRECT?

22          A       LET ME SEE. WHERE IS IT?

23          Q       IT'S ALSO ON YOUR MONITOR, IF THAT'S  
24 SIMPLER.

25          A       WERE ARE YOU ASKING ME TO LOOK AT BAI ON  
26 THAT?

27          Q       NO. YOU IDENTIFY 11 COHORT STUDIES  
28 EVALUATING COFFEE AND BLADDER CANCER; CORRECT?

1           A       YES.

2           Q       ALL RIGHT.  AND THE BAI ANALYSIS, THE  
3   META-ANALYSIS THAT YOU'VE INCLUDED, REVIEWED, AS YOU'VE  
4   INDICATED, WHAT YOU BELIEVE ARE FOUR OF THOSE COHORT  
5   STUDIES; CORRECT?

6           A       YES; RIGHT.

7           Q       ALL RIGHT.  SO BAI IS ONLY LOOKING AT A  
8   SMALL MINORITY OF THE STUDIES; CORRECT?

9           A       WHAT I DON'T KNOW IS IF HE DIDN'T INCLUDE  
10  OTHERS.  I'D HAVE TO LOOK BACK TO REVIEW IT NOW TO SEE  
11  WHY HE DIDN'T INCLUDE THE OTHERS.

12                   AS I MENTIONED EARLIER, THERE WERE SOME OF  
13  THEM THAT HAD PRETTY POOR METHODOLOGY THAT WERE INCLUDED  
14  IN THE PREVIOUS META-ANALYSES.  MAYBE THEY REJECTED ONES  
15  THAT THEY FELT WEREN'T OF GOOD QUALITY.

16                   BUT I CAN'T REMEMBER, AS I SIT HERE, SO I'LL  
17  HAVE TO LOOK BACK AT THIS TO ANSWER YOUR QUESTION  
18  SPECIFICALLY.

19           Q       AND DID YOU DO A METHODOLOGICAL REVIEW OF  
20  THESE 11 COHORT STUDIES THAT YOU'VE INCLUDED ON YOUR  
21  DEMONSTRATIVE, AS TO WHETHER ANY OF THEM WERE OF POOR  
22  QUALITY?

23           A       LET ME SEE.

24                   (REVIEWS DOCUMENT.)

25                   NO, I DON'T HAVE IT IN MY NOTES HERE,  
26  WHETHER I HAVE NOTES ON THE ARTICLE OR NOT.  I'D HAVE TO  
27  PULL THE ARTICLES TO LOOK AT THEM AND SEE WHAT MY  
28  MARGINAL NOTES ARE.

1 Q ALL RIGHT. SO NOW LET'S LOOK AT ANOTHER  
2 META-ANALYSIS, WHICH IS EXHIBIT 10463.

3 A WHICH ONE IS IT?

4 Q THIS IS THE HUANG 2014 META-ANALYSIS, TITLED  
5 "COFFEE CONSUMPTION AND UROLOGIC CANCER RISK: A  
6 META-ANALYSIS OF COHORT STUDIES."

7 DID YOU CONSIDER THIS STUDY IN FORMING YOUR  
8 OPINIONS IN THIS MATTER?

9 A 2014. I'M NOT SEEING IT ON MY CHART HERE IN  
10 TERMS OF META-ANALYSES, SO I DIDN'T REVIEW THIS ONE.

11 (EXHIBIT 10463 MARKED FOR  
12 IDENTIFICATION.)

13 Q BY MR. SCHURZ: IS THERE A REASON THAT YOU  
14 CHOSE THE BAI STUDY FROM 2014, WHICH REVIEWED A SMALL  
15 SUBSET, VERSUS THE HUANG ARTICLE, WHICH IS SOLELY ON  
16 COFFEE CONSUMPTION AND SHOWED NO SIGNIFICANT INCREASE?

17 MR. METZGER: WELL, OBJECTION; LACKING IN  
18 FOUNDATION AND ARGUMENTATIVE --

19 THE WITNESS: I DIDN'T THINK IT --

20 MR. METZGER: PETER, EXCUSE ME.

21 OBJECTION; LACKING IN FOUNDATION AND  
22 ARGUMENTATIVE AS PHRASED.

23 THE COURT: OVERRULED.

24 Q BY MR. SCHURZ: SO YOU DIDN'T COME ACROSS  
25 THE HUANG META-ANALYSIS AS PART OF YOUR WORK IN THIS  
26 CASE; CORRECT?

27 A CORRECT. I MEAN, IT'S 2014. I DON'T  
28 KNOW -- IT SAYS IT WAS PUBLISHED ONLINE IN MARCH. I

1 APPARENTLY MISSED IT.

2 Q OKAY. LET'S MOVE ON.

3 YOU DID CITE IN YOUR DEMONSTRATIVE THE YU  
4 META-ANALYSIS, OF EXHIBIT 10998, WHICH YOU HAVE UP THERE  
5 AMONG THE STUDIES THAT WE DISCUSSED BECAUSE IT ALSO  
6 ADDRESSES PANCREATIC CANCER.

7 AND YOU CONSIDERED THIS STUDY IN DEVELOPING  
8 YOUR OPINIONS WITH RESPECT TO BLADDER CANCER, AS WELL,  
9 DID YOU NOT?

10 A THE YU 2011?

11 Q YES.

12 A YES. AND IT SHOWS A SIGNIFICANT DECLINE.  
13 YES, I CONSIDERED IT. I REVIEWED IT.

14 Q AND THE OVERALL -- AND TURNING ATTENTION TO  
15 PAGE 0004 OF EXHIBIT 10998, AND FIGURE 2, THE --

16 A EXCUSE ME. I NEED TO FIND IT.

17 Q IF IT'S SIMPLER, YOU CAN JUST LOOK AT --  
18 WE'RE JUST GOING TO LOOK AT THE ONE FIGURE, AND THEN  
19 WE'RE FINISHED WITH THIS.

20 A ALL RIGHT.

21 Q AND THE YU INVESTIGATORS REPORT AN OVERALL  
22 RELATIVE RISK OF 0.83, WITH A CONFIDENCE INTERVAL  
23 BETWEEN 0.73 AND 0.94; CORRECT?

24 A YES. AND THAT'S WHAT I HAVE IN MY SLIDE.

25 Q RIGHT. AND SO THIS META-ANALYSIS EVALUATING  
26 BLADDER CANCER SHOWS A STATISTICALLY SIGNIFICANT  
27 DECREASED RISK OF BLADDER CANCER; CORRECT?

28 A YES.

1 Q ALL RIGHT. LET'S TAKE A LOOK NOW AT THE  
2 LAST OF THE META-ANALYSES THAT YOU EVALUATED, AND THAT'S  
3 THE ZHOU META-ANALYSIS, AT EXHIBIT 11015.

4 AND DID YOU CONSIDER THE ZHOU META-ANALYSIS  
5 IN FORMING YOUR OPINIONS WITH RESPECT TO COFFEE  
6 CONSUMPTION AND BLADDER CANCER?

7 A YES.

8 (EXHIBIT 11015 MARKED FOR  
9 IDENTIFICATION.)

10 Q BY MR. SCHURZ: NOW, ZHOU IS A META-ANALYSIS  
11 OF BOTH CASE-CONTROL AND COHORT STUDIES; CORRECT?

12 A YES.

13 Q AND YOU'VE REPORTED THE RESULTS WITH RESPECT  
14 TO BOTH: BOTH THE CASE-CONTROL, AS WELL AS THE COHORT  
15 STUDIES, IN YOUR SLIDES; CORRECT?

16 A YES.

17 Q ALL RIGHT. NOW, FOR THE COHORT STUDIES, THE  
18 ZHOU INVESTIGATORS FOUND NO STATISTICALLY SIGNIFICANT  
19 RISK OF BLADDER CANCER; CORRECT?

20 A YES.

21 Q AND THERE WAS SOME INCONSISTENCY IN THEIR  
22 FINDINGS FOR THE CASE-CONTROL STUDIES; CORRECT?

23 A WELL, I DON'T RECALL. I'D HAVE TO LOOK BACK  
24 TO REFRESH MY MEMORY. WHAT ARE YOU REFERRING TO?

25 Q OKAY. WHAT I'D LIKE TO DISCUSS IS HOW THE  
26 ZHOU INVESTIGATORS EVALUATED THE INCONSISTENCY THAT THEY  
27 FOUND IN THEIR DATA.

28 MR. METZGER: OBJECTION; LACKING FOUNDATION.

1 THE COURT: OVERRULED.

2 Q BY MR. SCHURZ: AND ADDRESSING YOUR  
3 ATTENTION TO PAGE 007 OF EXHIBIT 11015. DO YOU HAVE  
4 THAT IN FRONT OF YOU?

5 A I'M GETTING IT. YES.

6 Q AND SPECIFICALLY, I'LL DIRECT YOUR ATTENTION  
7 TO THE RIGHT-HAND SIDE, WHERE THE AUTHORS OBSERVE:

8 "THUS, CONSIDERING THE DISCREPANCY  
9 BETWEEN THE FINDINGS FROM CASE-CONTROL AND  
10 COHORT STUDIES, HOSPITAL-BASED AND POPULATION-  
11 BASED CASE-CONTROL STUDIES, CAUTION IS NEEDED  
12 IN INTERPRETING THE RESULTS FROM THE CASE-  
13 CONTROL STUDIES."

14 DO YOU SEE THAT?

15 A YES.

16 Q ALL RIGHT. AND THE ZHOU AUTHORS CONTINUE,  
17 DO THEY NOT, AND SUGGEST THAT MAYBE ONE OF THE ISSUES  
18 THAT IS INFLUENCING THE CASE-CONTROL STUDIES IS THE  
19 PRESENCE OF SELECTION BIAS AND RECALL BIAS THAT MAY BE  
20 CONTRIBUTING TO THE ASSOCIATIONS THAT ARE SEEN; CORRECT?

21 A WHERE DO YOU SEE THEM SAY -- WELL, YOU KNOW,  
22 THAT'S WHAT THEY'RE SAYING, BUT I WOULD SAY THAT THEIR  
23 DATA DON'T SUPPORT THAT, BECAUSE THEY HAVE A DOSE  
24 RESPONSE IN NONSMOKERS -- THEIR META-ANALYSIS OF 23  
25 CASES, AS I PRESENTED.

26 SO IF THEY HAVE A DOSE RESPONSE IN  
27 NONSMOKERS, I THINK THAT'S PRETTY PERSUASIVE EVIDENCE.

28 Q WELL, LET'S EVALUATE HOW THE ZHOU AUTHORS

1 INTERPRET THEIR EVIDENCE. AND IF I COULD DIRECT YOUR  
2 ATTENTION TO PAGE 006, THE PRECEDING PAGE.

3 A OKAY. LET ME GET THERE.

4 ALL RIGHT.

5 Q ALL RIGHT. AND SPECIFICALLY, I'M GOING TO  
6 FOCUS ON THE RIGHT-HAND COLUMN AND THE LAST PARAGRAPH.  
7 AND DO YOU HAVE THAT IN FRONT OF YOU?

8 A YES.

9 Q ALL RIGHT. AND IF YOU'D MOVE TO THE THIRD  
10 SENTENCE HERE ON PAGE 06, EXHIBIT 11015, THE ZHOU  
11 AUTHORS OBSERVE:

12 "THE POTENTIAL BIAS OF CASE-CONTROL  
13 STUDIES, SUCH AS SELECTION BIAS AND RECALL  
14 BIAS, MIGHT CONTRIBUTE TO THE DISCREPANCY  
15 BETWEEN CASE-CONTROL AND COHORT STUDIES."

16 DO YOU SEE THAT?

17 A YES.

18 Q ALL RIGHT. NOW, ZHOU -- THE ZHOU  
19 INVESTIGATORS LOOKED AT THE QUALITY OF THE UNDERLYING  
20 CASE-CONTROL STUDIES REGARDING BLADDER CANCER TO  
21 EVALUATE THE POTENTIAL FOR SELECTION BIAS; CORRECT?

22 A WHERE ARE YOU? I DON'T -- AS I SIT HERE,  
23 I'VE LOOKED AT A LOT OF DATA. SO LET'S LOOK AT WHAT --  
24 WHY DON'T YOU DIRECT ME TO THE SPECIFIC.

25 Q WELL, IF YOU CONTINUE ON IN THE SAME  
26 PARAGRAPH, THEY TALK ABOUT THE ANALYSIS THEY PERFORMED  
27 FOR SELECTION BIAS.

28 A (REVIEWS DOCUMENT.)

1 Q AND HAVE YOU FAMILIARIZED YOURSELF WITH THE  
2 ZHOU DISCUSSION AS IT RELATES TO RECALL BIAS AND  
3 SELECTION BIAS?

4 A YES. I MEAN, THEY'RE SPECULATING HERE THAT  
5 THEY MIGHT TEND TO RECALL -- THEY MIGHT TEND TO  
6 OVERESTIMATE AS TO COFFEE CONSUMPTION, THAN CONTROLS.  
7 THAT'S POSSIBLE, BUT I DON'T SEE THAT THEY HAVE EVIDENCE  
8 OF IT. THEY'RE JUST SPECULATING ABOUT IT.

9 Q WELL, DIDN'T THE ZHOU AUTHORS, IN FACT,  
10 PERFORM AN EVALUATION TO FIND THAT ONLY 5 OF THE 20  
11 CASE-CONTROL STUDIES SHOWED NO SIGNIFICANT DIFFERENCE IN  
12 RESPONSE RATE FOR THE CASE AND CONTROL GROUPS,  
13 SUGGESTING THAT THERE MAY BE SOME SELECTION BIAS?

14 A YES, BUT I MEAN, THAT'S ALWAYS A  
15 POSSIBILITY. I'M SAYING THEY DON'T KNOW THAT. THEY'RE  
16 SURMISING IT OR SPECULATING ABOUT IT. IT'S POSSIBLE.  
17 I'M JUST SAYING THEY DON'T HAVE EVIDENCE THAT THERE IS.

18 Q WELL, AND WHAT THEY'RE OBSERVING IS THAT,  
19 BASED ON THEIR ANALYSIS, THEY BELIEVE THAT THERE'S A  
20 PRESENCE OF SELECTION BIAS; CORRECT?

21 MR. METZGER: OBJECTION AS TO WHAT THEY BELIEVE,  
22 YOUR HONOR. THAT'S SPECULATIVE.

23 THE COURT: SUSTAINED.

24 Q BY MR. SCHURZ: SO LET'S TAKE A LOOK AT HOW  
25 THEY CONCLUDE. THE AUTHORS OBSERVED THE POTENTIAL FOR  
26 RECALL BIAS AND SELECTION BIAS AND OBSERVED THAT WITH  
27 RESPECT TO RECALL BIAS, THIS RECALL BIAS COULD ALSO  
28 AFFECT THE ASSOCIATION TOWARD A MUCH -- POSITIVE

1 ASSOCIATION BETWEEN COFFEE CONSUMPTION AND BLADDER  
2 CANCER RISK; CORRECT?

3 A YES.

4 Q AND THEN THE AUTHORS FURTHER OBSERVE:

5 "IN THIS RESPECT, COHORT STUDIES ARE  
6 PREFERABLE THAN CASE-CONTROL STUDIES."

7 CORRECT?

8 A YES.

9 Q SO THE ZHOU AUTHORS CONCLUDED THAT AS  
10 BETWEEN THOSE CASE-CONTROL STUDIES AND COHORT STUDIES  
11 EVALUATING BLADDER CANCER AND COFFEE CONSUMPTION, THE  
12 COHORT STUDIES WERE PREFERABLE, AS THEY WOULD NOT BE  
13 SUBJECT TO THE SAME SELECTION BIAS AND RECALL BIAS AS  
14 THE CASE-CONTROL STUDIES; CORRECT?

15 A FROM THAT STANDPOINT, THEY WOULD BE  
16 PREFERABLE, YES; BUT THEY DON'T KNOW THAT THERE'S THE  
17 RECALL BIAS. AND WHEN YOU EVALUATE STUDIES, YOU LOOK AT  
18 BOTH COHORT AND CASE-CONTROL STUDIES, JUST AS IARC DOES  
19 IN ITS EVALUATIONS.

20 Q AND AS BETWEEN THE TWO, THE ZHOU AUTHORS  
21 CONCLUDED THAT PREFERENCE SHOULD BE GIVEN TO COHORT  
22 STUDIES; CORRECT?

23 A THAT'S WHAT THEY CONCLUDED, YES.

24 Q OKAY. SO LET'S TALK ABOUT SOME OF THE  
25 COHORT STUDIES THAT YOU EVALUATED AS PART OF YOUR REVIEW  
26 OF BLADDER CANCER AND COFFEE CONSUMPTION.

27 AND LET'S START BY TAKING A LOOK AT THE  
28 POWERPOINT SLIDE THAT YOU HAVE OF THE COHORT STUDIES AT

1 DEMONSTRATIVE 105. AND DOES THIS INCLUDE A  
2 COMPREHENSIVE SET OF THE COHORT STUDIES YOU EVALUATED IN  
3 THIS CASE?

4 A YES.

5 Q ALL RIGHT. SHOWING YOU NOW THE ROSS STUDY,  
6 WHICH IS EXHIBIT 10798.

7 A DID YOU SAY "ROSS"?

8 Q YES.

9 A WHAT YEAR?

10 Q 2011.

11 A (REVIEWS DOCUMENT.)  
12 I DON'T SEEM TO HAVE THAT ONE IN MY REVIEW.  
13 (EXHIBIT 10798 MARKED FOR  
14 IDENTIFICATION.)

15 Q BY MR. SCHURZ: SO MY NEXT QUESTION IS: DID  
16 YOU CONSIDER THE ROSS 2011 STUDY AS PART OF YOUR  
17 COMPREHENSIVE SYSTEMATIC REVIEW OF THE BLADDER AND  
18 COFFEE LITERATURE?

19 A I MISSED THAT ONE.

20 Q OKAY.

21 A IT'S NOT IN THERE, NO.

22 Q ALL RIGHT. WE CAN PUT THAT ASIDE, THEN.  
23 I TAKE IT YOU'RE NOT FAMILIAR WITH THE  
24 CONCLUSIONS OF THE ROSS STUDY; CORRECT?

25 A I HAVEN'T READ IT.

26 Q ALL RIGHT. SO ON YOUR POWERPOINT  
27 DEMONSTRATIVE -- LET'S GO BACK TO THE DEMONSTRATIVE, AT  
28 105. WE SEE THE COHORT STATUTES THAT YOU DID IDENTIFY.

1 AND THE LAST ONE APPEARS TO HAVE BEEN PUBLISHED IN 2009;  
2 CORRECT?

3 A YES.

4 Q AND DID YOU LIMIT YOUR LITERATURE REVIEW TO  
5 THOSE STUDIES THAT WERE PUBLISHED UP THROUGH 2009?

6 A I'M LOOKING AT MY NOTES HERE. IT LOOKS LIKE  
7 I DIDN'T REVIEW ANY AFTER 2009; CORRECT.

8 Q ALL RIGHT. WELL, LET'S TAKE A LOOK AT SOME  
9 OF THE EARLIER ONES THAT YOU DID REVIEW. AND LOOKING  
10 AT -- LET'S START WITH THE SNOWDEN, AT EXHIBIT 1969.

11 AND DID YOU CONSIDER THE SNOWDEN 1984  
12 ARTICLE IN DEVELOPING YOUR OPINIONS IN THIS MATTER?

13 A YES.

14 (EXHIBIT 1969 MARKED FOR  
15 IDENTIFICATION.)

16 Q BY MR. SCHURZ: ALL RIGHT. AND IF I COULD  
17 DIRECT YOUR ATTENTION TO TABLE NO. 1, WHICH YOU CAN FIND  
18 AT PAGE NO. 2 OF THE SNOWDEN ARTICLE. LET ME KNOW WHEN  
19 YOU'RE THERE.

20 A OKAY. I'M THERE.

21 Q ALL RIGHT. AND DIRECTING YOUR ATTENTION TO  
22 THE DATA THAT IS BEING PROVIDED FOR BLADDER CANCER AND  
23 COFFEE CONSUMPTION, THIS STUDY SHOWS NO STATISTICALLY  
24 SIGNIFICANT INCREASED RISK; CORRECT?

25 A THAT'S CORRECT.

26 Q AND THE P TREND FOR THE DOSE RESPONSE WAS  
27 0.13, MEANING THAT THERE IS NO STATISTICALLY SIGNIFICANT  
28 DOSE RESPONSE; CORRECT?

1 A CORRECT.

2 Q ALL RIGHT.

3 A WELL, WAIT A SECOND.

4 Q DO YOU SEE WHERE IT PROVIDES A TREND P  
5 EQUALS 0.13?

6 A YES, BUT -- AND YOU KNOW WHAT? IN MY CHART,  
7 I HAVE "SIGNIFICANT DOSE RESPONSE." SO LET ME LOOK  
8 FURTHER IN THIS DOCUMENT, SEE IF THERE'S SOME OTHER  
9 PLACE WHERE THEY'RE MENTIONING IT. BECAUSE IF THERE  
10 ISN'T, I HAVE AN ERROR IN MY SLIDE, AND THAT'S WHAT I  
11 WANT TO FIND OUT.

12 (REVIEWS DOCUMENT.)

13 WELL, YOU KNOW, IT'S NOT SIGNIFICANT. AND  
14 THAT'S AN ERROR IN MY SLIDE, SO LET ME CORRECT THAT.

15 Q SO IN THIS RESPECT, THE SLIDE THAT WE WERE  
16 JUST LOOKING AT, DEMONSTRATIVE 105, HAS A MISTAKE WITH  
17 RESPECT TO THE DATA AS IT'S REFLECTED ON SNOWDEN;  
18 CORRECT?

19 A THE DOSE RESPONSE ISN'T SIGNIFICANT.

20 Q OKAY.

21 A SO AGAIN, YOU ASKED ME ABOUT AUTHORS'  
22 CONCLUSIONS. THEY DO CONCLUDE THERE'S A POSITIVE  
23 ASSOCIATION BETWEEN COFFEE CONSUMPTION AND BLADDER  
24 CANCER, EVEN THOUGH THE RESULT ISN'T -- THE RESULT OF  
25 THE TREND ANALYSIS WASN'T SIGNIFICANT AT THE 05 LEVEL.

26 Q ALL RIGHT. SO WITH RESPECT TO SNOWDEN, AT  
27 LEAST, YOUR STATEMENT AT 105, THAT IT REFLECTS A  
28 SIGNIFICANT DOSE RESPONSE TREND, IS INCORRECT; CORRECT?

1 STRIKE THAT.

2 A THAT'S CORRECT.

3 Q ALL RIGHT. LET'S TURN TO THE ZEEGERS 2001  
4 STUDY, WHICH IS EXHIBIT 2254; ALSO REFERENCED IN YOUR  
5 MATERIALS AT DEMONSTRATIVE 105.

6 A ZEEGERS -- WHICH YEAR DID YOU SAY?

7 Q WE'RE DELIVERING IT TO YOU. THIS IS A  
8 DIFFERENT REPORT, EXHIBIT 2254.

9 AND DR. INFANTE, DID YOU CONSIDER THE  
10 ZEEGERS 2001 COHORT STUDY AS PART OF YOUR ANALYSIS IN  
11 THIS CASE?

12 A YES.

13 (EXHIBIT 2254 MARKED FOR  
14 IDENTIFICATION.)

15 Q BY MR. SCHURZ: SO TAKING A LOOK AT PAGE 004  
16 OF EXHIBIT 2254, I DIRECT YOUR ATTENTION TO TABLE NO. 2.  
17 AND DO YOU HAVE THAT IN FRONT OF YOU?

18 A YES, I DO.

19 Q NOW, YOU'VE IDENTIFIED VALUES OFF OF THIS  
20 TABLE THAT ARE TAKEN FROM THE SECOND COLUMN, THAT  
21 INCLUDES THE RELATIVE RISK RATIOS, IN WHAT APPEARS AS  
22 THE MIDDLE COLUMN. DO YOU SEE THAT?

23 A YES.

24 Q AND IF YOU LOOK AT THE LAST COLUMN, WHICH IS  
25 THE FULLY ADJUSTED COLUMN FOR AGE, SMOKING, AND TEA  
26 CONSUMPTION AND OTHER VARIABLES, DO YOU SEE THAT  
27 ANALYSIS?

28 A YES.

1 Q AND FOR WOMEN, THERE IS NO STATISTICALLY  
2 SIGNIFICANT -- STRIKE THAT.

3 FOR WOMEN, AS REPORTED IN THE ZEEGERS  
4 ANALYSIS, EXHIBIT 2254, THERE IS A STATISTICALLY  
5 SIGNIFICANT DECREASE IN CANCER RISK, IS THERE NOT?

6 A YES. AND I INDICATE THAT IN MY SLIDE.

7 Q AND IT REFLECTS A DOSE-RESPONSE TREND THAT  
8 IS ALSO STATISTICALLY SIGNIFICANT; CORRECT?

9 A YES.

10 Q AND FOR MEN -- AGAIN, STAYING IN THE COLUMN  
11 FOR THE FULLY ADJUSTED VALUES -- THERE IS NO  
12 STATISTICALLY SIGNIFICANT INCREASE IN CANCER RISK WHEN  
13 CONSIDERING THE FULLY ADJUSTED VALUES THAT APPEAR HERE  
14 IN THE FAR RIGHT-HAND COLUMN; CORRECT?

15 A THAT'S -- THE P VALUE IS .06; CORRECT.

16 Q ALL RIGHT.

17 A I TOOK MY DATA FROM THE MIDDLE COLUMN, WHICH  
18 IS ADJUSTED FOR CIGARETTE SMOKING AND YEARS OF SMOKING.

19 Q RIGHT.

20 A AND THAT'S WHAT -- THAT SHOWS A SIGNIFICANT  
21 TREND --

22 Q AND SO --

23 A -- FOR MEN; FOR MEN. AND IT SHOWS A  
24 SIGNIFICANT TREND IN THE OPPOSITE DIRECTION FOR WOMEN.

25 Q RIGHT. ALL RIGHT.

26 BUT WITH RESPECT TO THE FULLY ADJUSTED  
27 VALUE, AS REPORTED BY ZEEGERS, WHAT THEY REFLECT IS A  
28 NOT STATISTICALLY SIGNIFICANT RISK OF 1.03; CORRECT?

1           A       YES, BUT MY POINT IS, THAT'S ALSO INCLUDING  
2 ADJUSTMENT FOR TEA CONSUMPTION. AND I HAVEN'T SEEN DATA  
3 WHICH INDICATES THAT BLADDER CANCER IS ASSOCIATED WITH  
4 CONSUMPTION OF TEA.

5           Q       ALL RIGHT. NOW --

6           A       SO THEY'RE OVER-ADJUSTING, IN MY OPINION, IN  
7 THAT ANALYSIS.

8           Q       OKAY. SO YOU WOULD DISAGREE WITH THE  
9 ADJUSTMENTS THAT THE ZEEGERS AUTHORS HAVE MADE WITH  
10 RESPECT TO THE STUDY; CORRECT?

11          A       NO, I'M NOT DISAGREEING WITH THE ADJUSTMENTS  
12 THEY'VE MADE. I'M SAYING IT'S NOT NECESSARILY MORE  
13 MEANINGFUL THAN THE ADJUSTMENT FOR CIGARETTE SMOKING AND  
14 NUMBER OF YEARS SMOKED.

15          Q       OKAY.

16          A       BECAUSE THEY MAY BE -- SOMETIMES AUTHORS  
17 OVER-ADJUST. AND I'M SAYING THAT I THINK THIS IS A  
18 REFLECTION OF OVERADJUSTMENT BECAUSE THERE'S NO EVIDENCE  
19 ASSOCIATING, THAT I'M AWARE OF, TEA CONSUMPTION WITH  
20 BLADDER CANCER.

21                   IT'S LIKE ADJUSTING FOR, I SUPPOSE, MEN THAT  
22 HAVE GRAY HAIR. IF IT ADJUSTS FOR IT, THAT MIGHT SHOW  
23 THAT OLDER MEN, THAT HAVE AN OLDER AGE, THAT WOULD  
24 INCREASE THEIR RISK. IF YOU MAKE THAT ADJUSTMENT, THE  
25 RISK WOULD GO AWAY.

26                   SO THEY'RE ADJUSTING FOR A FACTOR THAT'S NOT  
27 RELATED TO IT, IN MY OPINION.

28          Q       OKAY. THANK YOU.

1           A       YOU'RE WELCOME.

2           Q       LET'S TALK A LITTLE BIT ABOUT THE CASE-  
3 CONTROL STUDIES THAT YOU'VE RELIED ON WITH RESPECT TO  
4 BLADDER CANCER.

5                   NOW, FIRST, BY WAY OF BACKGROUND, DR.  
6 INFANTE, WHEN YOU WORKED WITH THE FEDERAL GOVERNMENT FOR  
7 OSHA AND NIOSH, YOUR DUTIES AS AN EMPLOYEE DID NOT  
8 INVOLVE EPIDEMIOLOGY OF DIETARY EXPOSURES; CORRECT?

9           A       CORRECT.

10          Q       AND FOLLOWING YOUR GOVERNMENT SERVICE, YOUR  
11 WORK AS AN ADJUNCT PROFESSOR AT GEORGE WASHINGTON  
12 UNIVERSITY DID NOT ADDRESS ISSUES OF DIETARY EXPOSURE OR  
13 NUTRITIONAL EPIDEMIOLOGY; CORRECT?

14          A       CORRECT.

15          Q       AND NONE OF YOUR CONSULTING WORK AND WORK IN  
16 THE CONTEXT AS AN EXPERT WITNESS, PRIOR TO YOUR WORKING  
17 WITH MR. METZGER IN 2007, ADDRESSED ISSUES WITH RESPECT  
18 TO DIETARY EXPOSURES OR NUTRITIONAL EPIDEMIOLOGY;  
19 CORRECT?

20          A       CORRECT.

21          Q       NOW, YOU'VE NEVER AUTHORED ANY PEER-REVIEWED  
22 ARTICLES RELATING TO NUTRITIONAL EPIDEMIOLOGY; CORRECT?

23          A       NO. I DON'T THINK THAT'S CORRECT, NO.  
24 BECAUSE I THINK SOME OF THE EARLY PUBLICATION I HAD,  
25 THERE ARE TWO THAT HAD TO DO WITH DIETARY INTAKE OF  
26 FORMALDEHYDE -- I'M SORRY. DIETARY INTAKE OF FLUORIDE  
27 AND ITS EFFECT ON ENAMEL FLUOROSIS.

28                   AND THEN THERE WAS ANOTHER ONE ON NUTRITION

1 AND DIET AND A TYPE OF LESION TO TEETH THAT ARE SEEN IN  
2 THE DEVELOPING COUNTRIES, WHERE THEY HAVE PROTEIN  
3 CALORIE MALNUTRITION.

4 SO I HAVE PUBLISHED SOME EARLY STUFF THAT  
5 HAS TO DO WITH DIET AND NUTRITION.

6 Q AND SPECIFICALLY WITH RESPECT TO DENTISTRY;  
7 CORRECT?

8 A WELL, THE FIRST ONE WAS WITH RESPECT TO  
9 DENTISTRY, THE FLUORIDE STUDY. THE SECOND WAS IN  
10 RELATION TO GROWTH AND DEVELOPMENT, AND LIKE LINEAR  
11 HYPOPLASIA IN CHILDREN IN THE DEVELOPING COUNTRIES; AND  
12 ALSO, THE APACHE INDIANS IN ARIZONA.

13 Q ALL RIGHT. NOW, YOU'RE AWARE THAT  
14 NUTRITIONAL EPIDEMIOLOGY IS A DISTINCT FIELD, JUST AS  
15 OCCUPATIONAL EPIDEMIOLOGY IS A DISTINCT FIELD; CORRECT?

16 A WELL, THEY'RE SUBDIVISIONS OF EPIDEMIOLOGY.

17 Q AND IARC HAS SEPARATE WORKING GROUPS FOR  
18 NUTRITIONAL EPIDEMIOLOGY; CORRECT?

19 A I'M NOT SURE. WHAT DO YOU MEAN, "SEPARATE  
20 WORKING GROUPS"? THEY HAVE SEPARATE WORKING GROUPS FOR  
21 EVERY MONOGRAPH THAT THEY DEVELOP, REGARDLESS OF WHAT IT  
22 IS: IF IT'S CHEMICAL EXPOSURES OR IN THE OCCUPATIONAL  
23 SETTING OR WHATEVER.

24 Q ARE YOU AWARE --

25 A EACH WORKING GROUP, THEY SELECT A NEW GROUP  
26 OF WORKING GROUP MEMBERS.

27 Q AND ARE YOU AWARE THAT IARC HAS A SEPARATE  
28 GROUP FOR NUTRITIONAL EPIDEMIOLOGY?

1           A           SEPARATE FROM WHAT?

2           Q           SEPARATE AND DISTINCT FROM ITS OCCUPATIONAL  
3 OR ENVIRONMENTAL EPIDEMIOLOGY GROUPS.

4           MR. METZGER:   OBJECTION; LACKING IN FOUNDATION.

5           THE WITNESS:   NO, I DON'T -- I DON'T KNOW THAT.   I  
6 WOULD HAVE TO REVIEW WHO WAS ON THE REVIEW COMMITTEES  
7 AND SEE IF SOME OF THEM WERE ALSO ON SOME OF THE OTHER  
8 COMMITTEES, TO ANSWER YOUR QUESTION.

9           Q           BY MR. SCHURZ:   ALL RIGHT.   ARE YOU FAMILIAR  
10 WITH --

11          THE COURT:   JUST A SECOND.   MR. SCHURZ, HOW MUCH  
12 LONGER ARE GOING TO BE WITH THIS WITNESS?

13          MR. SCHURZ:   I WOULD SUSPECT ALL AFTERNOON, YOUR  
14 HONOR.

15          THE COURT:   OKAY.   I HAVE TO ATTEND A MEETING THIS  
16 AFTERNOON.   SO I'LL BE BACK -- WE'LL RESUME AT 1:45.  
17 AND YOU'LL BE ABLE TO COMPLETE BY WHAT TIME THIS  
18 AFTERNOON?

19          MR. SCHURZ:   WELL, I CAN TELL YOUR HONOR, WE'RE  
20 WORKING THROUGH SIX SUBSTANTIVE AREAS --

21          THE COURT:   JUST GIVE ME A TIME.

22          MR. SCHURZ:   I THINK, 4:00 O'CLOCK; I THINK, 4:30.  
23 I THINK WE'RE --

24          THE COURT:   WELL, I HAVE ANOTHER HEARING THAT'S  
25 GOING TO TAKE SOME TIME THIS AFTERNOON.   SO SEE IF YOU  
26 CAN EXPEDITE THAT.   I HAVE ANOTHER MEETING SCHEDULED AT  
27 3:00.   I'LL SEE WHETHER --

28                        AND TOMORROW -- WHAT'S THE SCHEDULE

1 TOMORROW?

2 MR. SCHURZ: WE UNDERSTAND THAT DR. HUFF IS  
3 AVAILABLE. WE HAVE ONE ISSUE THAT WE WANTED TO RAISE  
4 WITH YOUR HONOR, IS WE HAVE -- OKAY.

5 SO WE UNDERSTAND DR. HUFF WILL BE APPEARING  
6 TOMORROW.

7 THE COURT: OKAY. AND HOW LONG IS DR. HUFF'S  
8 TESTIMONY GOING TO TAKE?

9 MR. METZGER: I THINK HIS TESTIMONY WILL PROBABLY  
10 TAKE ONE DAY.

11 THE COURT: ONE DAY?

12 MR. METZGER: AND THAT WOULD PROBABLY INCLUDE -- I  
13 THINK WE COULD PROBABLY -- I THINK WE'LL PROBABLY  
14 COMPLETE HIM, IF WE HAVE A FULL DAY. I MEAN, I'M SAYING  
15 BOTH SIDES. MR. SCHURZ HAS ADVISED THAT HE DOES NOT  
16 HAVE MUCH CROSS FOR HIM, SO I THINK WE SHOULD BE ABLE TO  
17 GET HIM DONE IN A DAY.

18 THE COURT: ALL RIGHT. I HAVE A SCHEDULING ISSUE  
19 TOMORROW TOO.

20 WHAT WERE YOU GOING TO RAISE?

21 MR. SCHURZ: THAT WAS IT, YOUR HONOR.

22 THE COURT: OKAY. I HAVE A MEETING DURING THE  
23 NOON HOUR TOMORROW TOO. SO WE'LL PROBABLY GO IN THE  
24 MORNING UNTIL AROUND -- PROBABLY TILL AROUND 12:15, AND  
25 WE'LL RESUME AT ABOUT 2:30. SO JUST AS A HEADS-UP, YOU  
26 SHOULD BE ABLE TO COMPLETE HUFF, NEVERTHELESS.

27 MR. METZGER: YOUR HONOR, I DON'T THINK WE HAVE TO  
28 REALLY HURRY HERE BECAUSE DR. BAYARD, WHO IS OUR LAST

1 WITNESS, IS NOT AVAILABLE TILL MONDAY. SO WE WILL  
2 FINISH DR. INFANTE AND DR. HUFF THIS WEEK WITHOUT ANY  
3 PROBLEM.

4 THE COURT: AS LONG AS THEY'RE NOT RUSHING OUT OF  
5 TOWN. IF DR. HUFF DOESN'T FINISH TOMORROW, HE'LL BE  
6 AVAILABLE --

7 MR. METZGER: OH, NO, NO. HE'S AVAILABLE; HE'S  
8 AVAILABLE. I BROUGHT HIM IN FROM THE EAST COAST, AND  
9 HE'LL STAY HERE TILL HE'S DONE. AND DR. INFANTE IS ALSO  
10 AVAILABLE TOMORROW IF HE SPILLS OVER INTO TOMORROW.

11 THE COURT: ALL RIGHT. WE'LL BE IN RECESS, THEN,  
12 AT THIS TIME TILL 1:45.

13 (AT 11:51 A.M., A LUNCH RECESS WAS TAKEN  
14 UNTIL 1:45 P.M. OF THE SAME DAY.)

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# **EXHIBIT “F”**

**CURRICULUM VITAE**

**Name:** Peter Francis Infante

**Business Address:** Managing Member  
Peter F. Infante Consulting, L.L.C.  
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**Home Address:** [REDACTED]  
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(703) [REDACTED]

**Date of Birth:** February 23, 1941  
**Place of Birth:** Lima, Ohio

**Marital Status:** Married  
**Children:** Two

**Education:**

<b>Year:</b>	<b>Degree:</b>	<b>Institution:</b>
1971-73	Dr.P.H.	Department of Epidemiology School of Public Health University of Michigan
1970-71	M.P.H.	School of Public Health University of Michigan
1968 (6 months)		Graduate Studies Pediatrics & Nutrition College of Medicine Ohio State University
1967-68	Certificate of Residency	Pediatric Dentistry Children's Hospital Ohio State University
1966-67	Certificate of Internship	Pediatric Dentistry Children's Hospital Ohio State University
1962-66	D.D.S.	College of Dentistry Ohio State University
1959-62		St. Joseph's College Rensselaer, Indiana

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**Present Positions:**

June 1, 2002 to present: Managing Member, Peter F. Infante Consulting, L.L.C. Consulting in occupational and environmental health.

**Past Positions:**

August 1, 2002 to January 1, 2011: Adjunct Professor and Professorial Lecturer of Environmental and Occupational Health, The George Washington University, School of Public Health and Health Services, Washington, D.C.

1983 to May 2002: Director, Office of Standards Review, Health Standards Program, Occupational Safety and Health Administration, U.S. Department of Labor, Washington, D.C.

Work description: Primary Agency responsibility for reviewing existing OSHA health standards and making recommendations for modifications based on risk assessments and epidemiologic, toxicologic and industrial hygiene data. Office responsible for regulation of toxic substances in the workplace.

**Past Positions:**

1978-83: Director, Office of Carcinogen Identification and Classification, Health Standards Programs, OSHA, Department of Labor, Washington, D.C.

Work description: Responsibility for identification and classification of carcinogenic substances and establishing priority for their regulation.

1975-78 -- Epidemiologist, Biometry Section, Industry-wide Studies Branch, Division of Surveillance, Hazard Evaluations and Field Studies, National Institute for Occupational Safety and Health, Center for Disease Control, Cincinnati, Ohio

Work description: Conducted epidemiological investigations to determine associations between exposure to toxic substances and cancer, pregnancy outcome and other chronic disabling conditions.

1976-77 -- Acting Chief, Biometry Section, Industry-wide Studies Branch, National Institute for Occupational Safety and Health, Center for Disease Control, Cincinnati, Ohio

Work description: Responsibility for the conduct of all occupational epidemiological studies being carried out by the Biometry Section

1974-75 -- Epidemiologist, Division of Chronic Disease, Ohio Department of Health, Columbus, Ohio

Work description: Responsibility for establishing a central data base for the occurrence of cancer in Ohio children and also for investigating secular trends in cancer mortality. I also worked with members of other State and Federal Institutions investigating possible relations between polyvinyl chloride manufacture, other industrial factors and increased risk of congenital malformations and cancer. I also advised the Division in methodology and statistical analyses for the selection of population groups for health screening and for follow-up evaluation of treatment.

1973 -- (April-December) -- Epidemiologic Consultant for World Health Organization, Pan American Health Organization, Washington, D.C.

Work description: Scientific responsibility for determining the dental epidemiologic aspects of multi-disciplinary field research to investigate fluoride metabolism for the individual child and its relation to eventual caries experience in children of rural Guatemala. This included evaluation of field procedures and statistical analyses of data available. During this period, I also examined several hundred children to obtain baseline data for oral conditions. Analyses and reports pertaining to this investigation were submitted to Pan American Health Organization, World Health Organization and to the National Institute of Dental Research.

1973 -- Research Associate, Center for Human Growth and Development, University of Michigan

Work description: Analyses of data from the National Preschool Nutritional Survey of 1969 and 1970.

1972-73 -- Research in Child Growth and Dental Development

Work Description: Conducted an epidemiologic study of dental development in relation to growth in black and white preschool children of the lower socioeconomic level from southeastern Michigan. This investigation was completed in partial fulfillment for the degree of Doctor of Public Health from the Department of Epidemiology, School of Public Health, University of Michigan.

1969-70 -- Dental Epidemiologist for the National Preschool Nutritional Survey, 1968-70

Work description: Conducted the dental aspects of this survey, which was supported by Maternal and Child Health Services, Department of Health, Education and Welfare. This included the examination of preschool children in approximately 36 states, plus children of the White Mountain Apache Indian Reservation. Some of these findings were reported in "A Study of Nutritional Status of Preschool Children in the United States, 1968-70," Suppl., Pediat., 53:597-646, 1974. Several others have been reported elsewhere.

**Consultant or Advisory Positions:**

Ohio Department of Health, Columbus, Ohio

\* Consultant to Division of Chronic Diseases, 1974-75

American Public Health Association.

\* Health Hazards Project, 1975

Department of Health, Education and Welfare Subcommittee on Environmental Mutagenesis.

\* NIOSH representative, 1975-78

\* OSHA representative, 1978-85

World Health Organization, International Agency for Research on Cancer, Lyon, France.

\* Member of the Expert Committee on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, 1977-79

International Workshop/Conference on the Toxicology of Metals, 1980

\* Member of Epidemiology Workgroup

Consensus Workshop on Formaldehyde, 1983

\* Member of Epidemiology Panel

Federal Asbestos Taskforce

\* Chairman, Epidemiology Panel, 1982-87

National Academy of Sciences, National Research Council

\* Subcommittee to revise Emergency Exposure Guidance Levels for Benzene and Ethylene Oxide, 1985

National Cancer Institute

\* Advisory Panel for Occupational Mortality Study of Workers Exposed to Methylene Chloride, OSHA representative, 1987-90

National Cancer Institute

- \* Advisory Panel for Occupational Mortality Study of Workers Exposed to Acrylonitrile, OSHA representative, 1988-90

World Health Organization, International Program on Chemical Safety

- \* Member of Task Group on Environmental Health Criteria, 1989-1990

National Academy of Sciences, National Research Council

- \* Committee on Environmental Epidemiology, Federal liaison member, 1990-1992

National Academy of Sciences, National Research Council

- \* Committee on Risk Assessment Methodology, Federal liaison member, 1990-1993

Teratogenesis, Carcinogenesis, and Mutagenesis

- \* Associate Editor, 1989-90

National Safety Council

- \* Planning Committee for Conference on Risk, 1990-91

World Health Organization, International Agency for Research on Cancer, Lyon, France.

- \* Expert Committee on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, February, 1993--participant

World Health Organization, International Agency for Research on Cancer, Lyon, France.

- \* IARC Meeting of European Investigators on Cancer Risk Among Service Station Attendants and Related Occupations, December, 1993--participant

National Institute of Environmental Health Sciences

- \* ad hoc Interagency Coordinating Committee on the Validation of Alternative Methods (e.g., evaluation of alternate toxicologic testing methods that can be used for regulatory purposes)

--principal OSHA representative, 1994-2002

Department of Health and Human Services, Office of Women's Health,

- \* Interagency Working Group on the Environment and Women's Health--OSHA representative, 1994-2002

World Trade Organization (WTO) 2000;

- \* Selected as one of only four experts world-wide to provide opinions to a panel of judges at the WTO in Geneva, Switzerland regarding the relative toxicity of chrysotile asbestos in relation

to other forms of asbestos and asbestos substitutes for a case on whether the WTO should allow the European Community countries to ban the importation of chrysotile asbestos from Canada.

New York State Department of Health, Center for Environmental Health, Bureau of Toxic Substance Assessment--Trichloroethylene Air Criteria Document 2006;

\* Member of Review Panel--Purpose of document is to determine the atmospheric concentration to be used as a guide for decisions about the nature of the efforts to manage and reduce TCE exposure in the general environment in the State of New York.

National Toxicology Program 2008;

\*Served on Styrene Expert Panel; evaluated epidemiological and toxicological data to make recommendation for listing of styrene in the 12<sup>th</sup> Report on Carcinogens

World Health Organization, International Agency for Research on Cancer, Lyon, France 2009;

\* Member of the Monograph Working Group on IARC Monographs on the Evaluation of the Carcinogenic Risks Humans; Arsenic, Metals, Fibers, and Dusts. Volume 100 C; A Review of Human Carcinogens 2012

Environmental Protection Agency (EPA) 2014;

\* Appointed to the EPA Science Advisory Board (SAB) Chemical Assessment Augmented for Ethylene Oxide. The document develops an estimate of cancer risk to humans exposed to ethylene oxide.

**Awards:**

U.S. Public Health Service Traineeship, 1970-73

\* Award to study Public Health and Epidemiology at University of Michigan, School of Public Health

U.S. Department of Health, Education, and Welfare, Public Health Service, Center for Disease Control, National Institute for Occupational Safety and Health

\* Special Commendation for Research Contributions Toward Understanding the Toxicology of Benzene and Beryllium, 1978

U.S. Department of Labor, Secretary's Exceptional Achievement Award, 1993

U.S. Department of Labor, Special Achievement Award, 1993

**Past Clinical Activities:**

The Children's Hospital, Columbus, Ohio, July 1966 to June 1968.  
Children and Youth clinical practice while completing Internship  
and Residency in Pediatric Dentistry

Martin Memorial Hospital, Mt. Vernon, Ohio, summer of 1968.  
Outpatient clinical practice while attending graduate school.

Children and Youth Program, Columbus, Ohio. Clinical Pediatric  
Dental Practice, 1974.

**Dental License:**

Ohio, 1966  
District of Columbia, 1981  
Northeast Regional Dental Boards, 1980

**Professional Organizations:**

American College of Epidemiology (Fellow)  
American Conference of Governmental Industrial Hygienists  
American Public Health Association (Occupational Health and  
Safety)  
Collegium Ramazzini (Fellow)

**Publications:**

Infante, P.F. Epidemiologic studies of the relation between  
deciduous tooth eruption and child growth. Ann Arbor, University  
of Michigan, School of Public Health, 1973. VIII + 100 p.  
typed dissertation.

Infante, P.F. and Owen, G.M. Relation of the chronology of  
deciduous tooth emergence to height, weight and head  
circumference in children. Arch. Oral Biol., 18:1411-1417,  
November, 1973.

Infante, P.F. Sex differences in the chronology of deciduous  
tooth emergence in white and black children. J. Dent. Res.,  
53:418-421, March-April, 1974.

Infante, P.F. and Russell, A.L. An epidemiologic study of dental  
caries in preschool children in the United States by race and  
socioeconomic level. J. Dent. Res., 53:393-396, March-April,  
1974.

- Infante, P.F. Enamel hypoplasia in Apache Indian children. *Ecology of Food and Nutrition*, 3:155-156, No. 2, 1974.
- Infante, P.F. and Gillespie, G.M. An epidemiologic study of linear enamel hypoplasia of deciduous anterior teeth in Guatemalan children. *Arch. Oral Biol.*, 19:1055-1061, November, 1974.
- Infante, P.F. An epidemiologic study of deciduous tooth emergence and growth in white and black children of southeastern Michigan. *Ecology of Food and Nutrition*, 4:117-124, 1975.
- Infante, P.F. Estimates of dietary fluoride intake from supplements and communal water supplies. *Am. J. Dis. Child.*, 129:835-837, 1975.
- Infante, P.F., Owen, G.M. and Russell, A.L. Dental caries in preschool Apache Indian children. *J. Dent. Res.*, 54:915, 1975.
- Infante, P.F. Malocclusion in the deciduous dentition in white, black and Apache Indian children. *Angle Orthodont.*, 45:213-218, 1975.
- Infante, P.F. and Owen, G.M. Dental caries and levels of treatment for preschool children by geographical region, social class, race and size of community. *Pub. Health Dent.*, 35:19-27, Winter, 1975.
- Infante, P.F. An epidemiologic study of deciduous molar relations in preschool children. *J. Dent. Res.*, 54:723-272, July-August, 1975.
- Infante, P.F., Ackerman, J.A. and MacKenzie, A.L. Secular trends in leukaemia mortality. *Lancet*, ii, 720-721, September 21, 1974.
- Infante, P.F. Oncogenic and mutagenic risks in communities with polyvinyl chloride production facilities. *Ann. N.Y. Acad. Sci.*, 271:49-57, 1976.
- Infante, P.F. and Gillespie, G.M. Dental caries experience in the deciduous dentition in rural Guatemalan children, ages six months to seven years. *J. Dent. Res.*, 55:951-952, November-December, 1976.
- Infante, P.F. An epidemiologic study of finger habits in preschool children as related to malocclusion, socioeconomic

status, race, sex and size of community. *J. Dent. Child.*, 43:33-38, January-February, 1976.

Infante, P.F. and Gillespie, G.M. Enamel hypoplasia in relation to caries in Guatemalan children. *J. Dent. Res.*, 56:493-498, May-June, 1977.

Infante, P.F. and Newton, Jr., W.A. Prenatal chlordane exposure and neuroblastoma. *New Engl. J. Med.*, 293:308, August 7, 1975.

Infante, P.F., Wagoner, J.K. and Waxweiler, R.J. Carcinogenic, mutagenic and teratogenic risks associated with vinyl chloride. *Mutation Res.*, 41:(1) 131-142, November, 1976.

Infante, P.F., and Wagoner, J.K. Evidence for the carcinogenicity of beryllium. *International Conference on Heavy Metals in the Environment, Toronto, Canada, October 27-31, 1975.* (Proceedings from Conference, pp. 329-338).

Infante, P.F. and Lemen, R.A. Hazards of asbestos in dentistry. *Am. Dent. Assoc. J.*, 93:221-222, August, 1976.

Infante, P.F., Wagoner, J.K., McMichael, A.J., Waxweiler, R.J. and Falk, H. Genetic risks of vinyl chloride. *Lancet*, i:734-735, April 3, 1976.

Infante, P.F., Wagoner, J.K., McMichael, A.J., Waxweiler, R.J. and Falk, H. Genetic risks of vinyl chloride. *Lancet*, i:1289-1290, June 12, 1976.

Wagoner, J.K., Infante, P.F., and Saracci, R. Vinyl chloride and mortality? *Lancet*, ii:194-195, July 24, 1976.

Infante, P.F. and Epstein, S.S. Blood disease, childhood tumors and exposure to chlorinated hydrocarbon pesticides. *Conference on Women in the Workplace, Society for Occupational and Environmental Health, Washington, D.C., (p. 51-69) April, 1977.*

Infante, P.F. and Wagoner, J.K. The effect of lead on reproduction. *Conference on Women and the Workplace. Society for Occupational and Environmental Health, Washington, D.C., (p. 232-242) April, 1977.*

Wagoner, J.K., Infante, P.F. and Brown, D.P. Genetic effects associated with industrial chemicals. *Conference on Women and the Workplace, Society for Occupational and Environmental Health, Washington, D.C., (p. 100-113) April, 1977.*

Infante, P.F. and Wagoner, J.K. Chloroprene: Observations of carcinogenesis and mutagenesis. In Hiatt, H.H., Watson, J.D. and Winsten, J.A., eds., *Origins of Human Cancer*, Cold Spring Harbor Laboratories, Cold Springs, New York, 1977.

Wagoner, J.K. and Infante, P.F. Vinyl chloride: A case for the use of laboratory bioassay in the regulatory control procedure. ( In Hiatt H.H., Watson, J.D. and Winsten J.A., eds., *Origins of Human Cancer*, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, c1977 ) pp. 755-758

Infante, P.F., Rinsky, R., Wagoner, J.K. and Young, R.J. Leukemia in benzene workers. *Lancet*, ii:76-78, July 9, 1977.

Infante, P.F., Rinsky, R., Wagoner, J.K. and Young, R.J. Leukemia in benzene workers. *J. Environ. Path. Toxicol.*, 2:251-251, 1978.

Infante, P.F. Carcinogenic and mutagenic risks associated with halogenated olefins. *Env. Health Perspect.* 21:251-254, 1977.

Infante, P.F. Health hazards to working women - The plastics and rubber industries. *Women in the Workplace, A Symposium*, N. Calif. Am. Ind. Hyg. Assoc., 1977, pp. 65-69.

Infante, P.F. Epidemiologic approaches for surveillance of genetic hazards with particular reference to anesthetic gases. *Expert Conference on Genetic Damage in Man Caused by Environmental Agents*, Academic Press, c1979, pp. 289-300.

Bahlman, J., Alexander, V., Infante, P.F., Wagoner, J.K., Lane, M. and Bingham, E. Vinyl halides: Carcinogenicity -- Vinyl bromide, Vinyl chloride, and Vinylidene chloride. *Am. Ind. Hyg. Assoc. J.*, 40:A30-A40, 1979.

Infante, P.F., Rinsky, R.A., Wagoner, J.K. and Young, R.J. Benzene and leukemia. *Lancet*, ii:867-868, October 22, 1977.

Infante, P.F., Leukemia among workers exposed to benzene. *Environmental Cancer: A report to the public*, Texas Reports on Biology and Medicine, 37:153-161, 1978.

Young, R.J., Rinsky, R.A. and Infante, P.F. Benzene in consumer products. *Science*, 199:248, 1978.

Wagoner, J.K. and Infante, P.F., Beryllium: Carcinogenicity studies. *Science*, 201:298-303, 1978.

Infante, P.F., Epstein, S.S., and Newton, W.A. Blood dyscrasias and childhood tumors and exposure to chlordane and heptachlor. *Scand. J. Work Environ. Health*, 4:137-150, 1978.

Infante, P.F., Wagoner, J.K. and Sprince, N.L. Mortality patterns from lung cancer and non-neoplastic respiratory disease among white males in the Beryllium Case Registry. *Env. Res.*, 21:35-43, 1980.

Wagoner, J.K., Infante, P.F. and Bayliss, D.L. Beryllium: An etiologic agent in the induction of lung cancer, non-neoplastic respiratory disease and heart disease among industrially exposed workers. *Env. Res.*, 21:15-34, 1980.

Infante, P.F. and Legator, M. Workshop on Methodology for Assessing Reproductive Hazards in the Workplace: Recommendations for Future Research. *Env. Res.*, 20:217-223, 1979.

Infante, P.F. and Legator, M. Eds. Proceedings of a Workshop on Methodology for Assessing Reproductive Hazards in the Workplace. DHHS (NIOSH) Pub. No. 81-100, U.S. Gov. Printing Office, 1980, XIV + 423 p.

Infante, P.F. Chloroprene: Adverse effects on reproduction. ( In Infante, P.F. and Legator, M. Eds. Proceedings of a Workshop on Methodology for Assessing Reproductive Hazards in the Workplace. DHHS (NIOSH) Pub. No. 81-100, U.S. Gov. Printing Office, 1980 ) pp. 87-100.

Wagoner, J.K. and Infante, P.F. A review of the methodologic approaches in the assessment of an association between vinyl chloride exposure and reproductive hazards. ( In Infante, P.F. and Legator, M. Eds. Proceedings of a Workshop on Methodology for Assessing Reproductive Hazards in the Workplace. DHHS (NIOSH) Pub. No. 81-100, U.S. Gov. Printing Office, 1980 ) pp. 43-52.

Kang, H.K., Infante, P.F. and Carra, J.S. Occupational lead exposure and cancer. *Science*, 207:935-936, 1980.

Braver, E.R. and Infante, P.F. Probability window analysis and lung cancer in chromate workers. *J. Occup. Med.*, 22:302-304, 1980.

Infante, P.F. Panel Discussion: Role of high risk groups in standard derivation. *Env. Health Perspect.*, 29:168-170, 1979.

Infante, P.F., Wagoner, J.K. and Sprince, N.L. Bronchogenic cancer and non-neoplastic respiratory disease associated with beryllium exposure. ( In Lemen, R. and Dement, J.M. Eds. Dusts and Disease. Pathotox Pub. c1979 ) pp. 473-482.

Infante, P.F. and Marlow, P.B. Evidence for the carcinogenicity of selected halogenated hydrocarbons including ethylene dichloride. (In Ames, B., Infante, P.F. and Reitz, R. Eds. Ethylene dichloride: A potential health risk? Banbury Report 5, Cold Spring Harbor Lab., c1980 ) pp. 287-308.

Ames, B., Infante, P.F. and Reitz, R. Eds. Ethylene dichloride: A potential health risk? Banbury Report 5, Cold Spring Harbor Lab. 1980, XI + 350 p.

Wagoner, J.K., Infante, P.F. and Apfeldorf, R.B. Toxicity of vinyl chloride and polyvinyl chloride as seen through epidemiologic observations. J. Tox. Env. Health, 6:1101-1107, 1980.

White, M.C., Infante, P.F. and Walker, B. Occupational exposure to benzene: A review of carcinogenic and related health effects following the U.S. Supreme Court Decision. Am. J. Ind. Med., 1:233-243, 1980.

Young, R.J., and Infante, P.F. Consumer's benzene exposure during a furniture stripping operation. ( In M. McCann and G. Barazani, Eds. Health Hazards in the Arts and Crafts. Society for Occupational and Environmental Health, Wash, D.C., 1980 ) pp. 75-79.

Beall JR, Alexander V, Bien CT, Infante P., et al. Health Hazard Alert-2-Nitropropane (2-NP). DHHS (NIOSH) Pub. No. 80-142, 1980.

Apfeldorf, R. and Infante, P.F. Review of epidemiologic study results of vinyl chloride related compounds. Env. Health Perspect., 41:221-226. 1981.

Infante, P.F. Observations of the site specific carcinogenicity of vinyl chloride to humans. Env. Health Perspect., 41:89-94, 1981.

Blackwell, M, Kang, H., Thomas, A. and Infante, P. Formaldehyde: Evidence of Carcinogenicity. NIOSH Current Intelligence Bulletin #34. Am. Ind. Hyg. Assoc. J., A34-A45, 1981.

Infante, P.F., Ulsamer, A.G., Groth, D., Chu, K., and Ward, J. Health hazards of formaldehyde. Lancet, ii:980-981, 1981.

Infante, P.F., and Tsongas, T.A. Mutagenic and oncogenic effects of chloromethanes, chloroethanes and halogenated analogues of vinyl chloride. (In Tice, R.R., Costa, D. and Schaich, K.M., Eds. Genotoxic Effects of Airborne Agents, Plenum Press, New York, 1982), pp. 301-327.

White, M.C., Infante, P.F. and Chu, K.C. A quantitative estimate of leukemia mortality associated with occupational exposure to benzene. Risk Analysis, 2:199-203, 1982.

Kang, H.K., Infante, P.F. and Carra, J.S. Determination of blood lead elimination patterns of primary lead smelter workers. J. Tox. Env Health, 11:199-210, 1983.

Infante, P.F. and White, M.C. Benzene: Epidemiologic observations of leukemia by cell type, related blood abnormalities and adverse effects from low-level exposure. Env. Health Perspect. 52:75-82, 1983.

Infante, P.F. and Tsongas, T.A. Occupational reproductive hazards: Necessary steps to prevention. Am. J. Ind. Med., 4:383-390, 1983.

Tsongas, T.A. and Infante, P.F. Occupational reproductive hazards: Regulatory concerns.. In Lockey, J.E., Lemasters, G.K. and Keye, W.R. Eds. Reproduction: The New Frontier in Occupational and Environmental Health Research, Alan R. Liss, Inc New York, 1984, pp. 533-539.

Infante, P.F., White, M.C. and Chu, K.C, Assessment of leukemia mortality associated with occupational exposure to benzene. Risk Analysis, 4:9-13, 1984.

Infante, P.F. and White, M.C. Projections of leukemia risk associated with occupational exposure to benzene. Am. J. Ind. Med, 7:403-413, 1985.

Braver, E.R., Infante, P. and Chu, K. An analysis of lung cancer risk from exposure to hexavalent chromium. Terat. Carc. Muta., 5:365-378, 1985.

Infante, P.F. and Tsongas, T.A. Anesthetic gases and pregnancy: A review of evidence for an occupational hazard. ( In K. Hemminki, M. Sorsa and H. Vainio, Eds. Occupational Hazards and Reproduction, Hemisphere Pub, c 1985 ) Ch. 24, pp. 287-294, 1985.

Infante, P.F. Vinyl chloride: A case history of regulatory action in relation to scientific knowledge of cancer-causing

effects. (In Stich, H.F. ed. Carcinogens and Mutagens in the Environment. Volume IV, The Workplace: Monitoring and Prevention of Occupational Hazards. CRC Press, Boca Raton c 1985.) Ch. 9, pp. 75-81.

Infante, P.F. and Schneiderman, M.A. Formaldehyde, lung cancer, and bronchitis. Lancet i:436-437, 1986.

Infante, P.F. Benzene Toxicity: Studying a subject to death. Am. J. Ind. Med. 11:599-604, 1987.

Infante, P.F. and Freeman, C. Cancer mortality among workers exposed to chlordane. J. Occup. Med., 29:908-909, 1987.

Infante, P.F. and DiStasio, M.V. Occupational benzene exposure: Preventable deaths. Lancet i:1399-1400, 1988.

Infante, P.F. Recent laboratory studies in chemical carcinogenesis: Benzene. (In Maltoni, C. and Selikoff, I.J. eds. Occupational and Environmental Significance of Industrial Carcinogens.) Ann. N.Y. Acad. Sci., 534:486-489, 1988.

Infante, P.F. and Pohl, G.K. Living in a chemical world: Actions and reactions to industrial carcinogens. Terat, Mutagen and Carcino, 8:225-249, 1988.

Infante, P.F. Exposure assessment and dose response in the evaluation of occupational cancer mortality studies. ( In Hogstedt, C. and Reuterwall, C. eds. Progress in Occupational Epidemiology, Proceedings from Sixth International Symposium on Epidemiology in Occupational Health, Stockholm, Sweden, 16-19 August 1988. Excerpta Medica, Amsterdam, c 1988 ) pp. 383-386.

Sandler, B.H., Harwood, S.E., Thurber, C.H. and Infante, P.F. Development of the Occupational Safety and Health Administration's proposed standard to protect workers from contracting bloodborne diseases in the workplace. J Pub Health Dent, 49:87-89, 1989.

Infante, P.F., Schwartz, E. and Cahill, R. Benzene in petrol: A continuing hazard. Lancet, 336:814-815, 1990.

Infante, P.F. Commentary--Influence of genetic toxicology data on OSHA regulations. Environmental Mutagen Society Newsletter, Aug. 1990.

Infante, P.F. Viewpoint--Prevention versus chemophobia: a defence of rodent carcinogenicity tests. *Lancet*, 337:538-540, 1991.

Infante, P.F. Carcinogenicity tests and public health. *Lancet*, 337:1408-1409, 1991.

Infante, P.F. Benzene and leukemia: The 0.1 ppm ACGIH proposed TLV for benzene. *Appl. Occup. Environ. Hyg.*, 7:253-262, 1992.

Infante, P.F. and Book, S.A. Chemicals and human cancer. *Lancet* 340:1408-1409, 1992.

Infante, P.F. Use of rodent carcinogenicity tests for determining potential cancer risk to humans. *Environ. Health Perspect.*, 101(Suppl 5):143-148, 1993.

Infante, P.F. The implications of using alternative methods of assessing exposures for risk assessment. *Risk Analysis* (In press)

Infante, P.F. State of the science on the carcinogenicity of gasoline with particular reference to recent cohort mortality study results. *Environ. Health Perspect.*, 101(Suppl 6):105-109, 1993.

Infante, P.F. OMB interference in Federal agency risk assessments and health study design protocols. *Risk Analysis*, 13:491-492, 1993.

Schuman, L.D. and Infante, P.F. Synthetic mineral fibers. *J. Occup Med.*, 35:1173-1174, 1993.

Waalkes, M.P., Infante, P. and Huff, J. Commentary: The scientific fallacy of route specificity of carcinogenesis with particular reference to cadmium. *Reg. Tox. Pharm.*, 20:119-121, 1994.

Infante, P.F. and Pesak, J. A historical perspective of some occupationally related diseases of women. *J Occup Med.*, 36:826-31, 1994.

Infante, P.F., Schuman, L.D. Dement, J. and Huff, J. Fibrous glass and cancer. *Am. J. Industr. Med.* 26:559-584, 1994.

Infante, P.F. Cancer and blue collar workers: Who cares? *New Solutions*, 5:52-57, 1995.

Infante, P.F. Benzene and leukemia: Cell types, latency and amount of exposure associated with leukemia. (In, Update on Benzene, Advances in Occupational Medicine and Rehabilitation. Imbriani, M., Ghittori, S., Pezzagno, G., Capodaglio, E., Eds. Fondazione Salvatore Maugeri Edizioni, Pavia, Italy, 1995.) pp. 107-120.

Infante, P.F., Schuman, and Huff, J. Fibrous glass insulation and cancer: Response and rebuttal. Am. J. Industr. Med. 30:113-120, 1996.

Infante, P. Quantitative risk of leukemia/lymphoma from occupational benzene exposure. The Toxicology Forum 22nd Annual Winter Meeting, February 24-27, 1997; pp485-488, c. Toxicology Forum, Washington, D.C. 1997.

Infante, P.F. Benzene: An historical perspective on the American and European occupational setting; Chapter 4, pp 38-51. (In, Late Lessons from Early Warnings: the Precautionary Principle 1896-2000, Environmental Issue Report No. 22, Harremoes, P. et al. eds), European Environmental Agency, c EEA, Copenhagen, 2001.

Alexson O, et al. Correspondence about publication ethics and Regulatory Toxicology and Pharmacology. Int J Occup Environ Health 9: 386-389, 2003.

Infante P.F. and Newman L.S. Commentary: Beryllium exposure and chronic beryllium disease. The Lancet 363: 415-416, 2004.

Infante, P.F. Cancer risks in a UK benzene exposed cohort. Occup. Env. Med. 62: 231-235, 2005.

Infante P.F. Safeguarding scientific evaluations of governmental agencies: Case study of OSHA and the 1,3-butadiene classification. Int J Occup Environ Health 11: 372-377, 2005.

Infante P.F., Tomatis L. Commentary to the paper by P. Bernardini et al "Malattie mieloproliferative da uso di benzina come solvente: descrizione di tre casi" Med Lav 96: 119-125, 2005.

Infante P.F. The past suppression of Industry knowledge of the toxicity of benzene to humans and potential bias in future benzene research. Int J Occup Env Health 12: 268-272, 2006.

Infante P.F. Benzene exposure and multiple myeloma: a detailed meta-analysis of benzene cohort studies. Ann New York Acad Sci 1076: 90-109, 2006.

Bailar III JC, et al. FIOH-sponsored newsletter misrepresents asbestos hazards in Zimbabwe. *Int J Occup Env Health* 112: 254-258, 2006.

Huff J, Lunn RM, Waalkes MP, Tomatis L, Infante PF. Cadmium-induced cancer in animals and in humans. *Int J Occup Env Health* 13: 202-212, 2007.

Lunn R, Jameson CW, Jahnke G, Garner S, Atwood S, Carter G, Ewens A, Greenwood D, Ratcliffe J, Kolstad H, Vodicka P, Haseman J, Rickert D, Darden E, Saunders T, Jeter S, Brown J, Dakin S, Phillips D, Eustis S, Infante P, Matanoski G, Que Hee SS, Smith TJ, Snedeker S, Stone MP, Ward EM, Yost GS, Zeise L. (2008) Final Report on Carcinogens Background Document for Styrene. National Toxicology Program, Rep Carcinogens Background Doc. 2008 Sep;(8-5978):i-462.

Phillips, D., S. Snedeker, S. Eustis, M. Stone, P. Infante, E.M. Ward, G., Matanoski, G.S. Yost, S.S. Que Hee, L. Zeise, and T.J. Smith. 2008. Part A - Peer Review of the Draft Background Document on Styrene. Styrene Expert Panel Report [online]. Available: [http://ntp.niehs.nih.gov/NTP/roc/twelfth/2008/ExpertPanelMtgs/Styrene\\_PanelReportPartA\\_508.pdf](http://ntp.niehs.nih.gov/NTP/roc/twelfth/2008/ExpertPanelMtgs/Styrene_PanelReportPartA_508.pdf)

Phillips, D., S. Snedeker, S. Eustis, M. Stone, P. Infante, E.M. Ward, G. Matanoski, G.S. Yost, S.S. Que Hee, L. Zeise, and T.J. Smith. 2008. Part B - Recommendation for Listing Status for Styrene and Scientific Justification for the Recommendation. Styrene Expert Panel Report [online]. Available: [http://ntp.niehs.nih.gov/NTP/roc/twelfth/2008/ExpertPanelMtgs/Styrene\\_PanelReportPartB\\_508.pdf](http://ntp.niehs.nih.gov/NTP/roc/twelfth/2008/ExpertPanelMtgs/Styrene_PanelReportPartB_508.pdf)

Huff J, Infante PF. Identifying cancer sites for human carcinogens in the IARC monographs. *Occup Environ Med* 66: 140, 2009.

Infante, PF, Petty SE, Groth DH, Markowitz G and Rosner D. Vinyl chloride propellant in hair spray and angiosarcoma of the liver among hairdressers and barbers: Case reports. *Int J Occup Env Health* 15: 36-42, 2009

Infante, PF and Bingham E. Aromatic Hydrocarbons-Benzene and Other Alkylbenzenes. (In, Bingham, E and Cohrssen, B. Eds. *Patty's Toxicology*, 6<sup>th</sup> edition) Chapter 29, pp 153-210) John Wiley and Sons, Inc., New Jersey, 2009.

Infante PF. The IARC October 2009 evaluation of benzene carcinogenicity was incomplete and needs to be reconsidered. *Am J Indust Med* 54, 157-164, 2011.

Infante PF, Huff J. (2011) Cancer incidence among petrochemical workers in the Porto Torres industrial area. *Med Lav* 102, 4: 382-383.

Huff J, Infante PF. (2011) Commentary: Styrene exposure and risk of cancer. *Mutagenesis* 26: 583-584.

Infante PF, Bingham E. (2012) Aromatic Hydrocarbons-Benzene and Other Alkylbenzenes. (In Bingham E and Cohrsson B, eds., *Patty's Toxicology, Sixth Edition*, © Wiley and Sons, Inc. Hoboken, NJ, (pages 153-220).

Infante, PF. (2013) Benzene and gasoline: Greater risks of adult and childhood cancers. Late lessons from early warnings: science, precaution, innovation. Annex 3 - Update of case studies from Late lessons from early warnings: the precautionary principle 1896-2000 vol. 1, European Environmental Agency, 2013.

Infante, PF. (2013) Benzene and leukemia, Pliofilm revisited: I. An historical review of the leukemia deaths among Akron Goodyear Tire and Rubber Company employees. *Int J Occup Env Health* 19: 215-222.

Infante, PF. (2013) Benzene and leukemia, Pliofilm revisited: II. Take-home leukemia. *Int J Occup Env Health* 19: 245-247.

Infante PF. (2016) The continuing struggle between career civil servants and political appointees in the development of government public health standards. *Int J Occup Env Health* 22: 269-273.

Infante, PF. (2017) Residential proximity to gasoline stations and risk of childhood leukemia. *AM J Epid* 185: 1-4.

### **Abstracts:**

Infante, P.F. Deciduous tooth emergence and growth in white and black children. *Abstr. Internat. A. Dent. Res. Abstr.*, 53:236, February, 1974.

Infante, P.F. Deciduous molar relations in U.S. preschool children. *Abstr. Internat. A. Dent. Res. Abstr.*, 54:469, February, 1975.

Infante, P.F. Emergence of deciduous teeth. *Abstr. Dent. Abstr.*, 19:603-604, October, 1974.

Infante, P.F. and Russell, A.L. Prevalence of caries in preschool children. Abstr. Dent. Abstr., 19:598, October, 1974.

Infante, P.F. and Owen, G.M. Tooth emergence and somatic growth. Abstr. Dent. Abstr., 19:331-332, June, 1974.

Wolf, L. and Infante, P.F. Interrelations of distocclusion and general somatic growth. Abstr. Internat. Assoc. Dent. Res. Abstr. 55:548, February, 1976.

Infante, P.F. and Wagoner, J.K. Genetic effects of vinyl chloride and other industrial chemicals. Abstr. Sixth Annual Meeting of the European Environmental Mutagen Society, Gernrode, German Democratic Republic, pp. 31-32, September 27-October 2, 1976.

Infante, P.F. The role of occupational factors in oral and pharyngeal cancers. Abstr. Internat. Assoc. Dent. Res. Abstr. 56:524, June, 1977.

Infante, P.F. and Wagoner, J.K. Chloroprene: Observations of carcinogenesis and mutagenesis. Abstr. Origins of Human Cancer, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, September, 1976. (p.77)

Wagoner, J.K. and Infante, P.F. Vinyl Chloride: The use of laboratory assay for regulatory control. Abstr. Origins of Human Cancer, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, September, 1976. (p. 109)

Infante, P.F. Genetic hazards of anesthetic gases, epidemiologic study, prevention and extrapolation from experimental test systems. Abstr.: 48, European Society of Human Genetics, Oslo Symposium: Clinical Genetics, Oslo, Norway, 1977.

Wagoner, J.K. and Infante, P.F. Qualitative extrapolation from laboratory assay to humans as seen through the carcinogenicity, mutagenicity or teratogenicity of vinyl chloride, and anesthetic gases. Env. Health Perspect. 22:184, Feb. 1978.

Infante, P.F. Benzene and multiple myeloma. Abstr. #16, Collegium Ramazzini 3<sup>rd</sup> International Scientific Conference, Framing the Future in Light of the Past: Living in a Chemical World, Bologna, Italy, Sept. 18-21, 2005.

Goldstein BD, Infante PF. Benzene as a cause of hematological cancers: a recurring example of the importance of mechanistic understanding and animal studies. Poster session, IARC 50th

Anniversary Meeting, "Global Cancer, Occurrence, Causes and Avenues to Prevention." June 7-10, 2016, Lyon, France.

**Papers Presented:**

Fluoride and general aspects of nutrition in relation to dental health. Harvard School of Dental Medicine, Nov. 20, 1973.

Deciduous tooth emergence and growth in white and black children. International Association for Dental Research, 52nd General Session, Atlanta, March 21-24, 1974.

Oncogenic and mutagenic risks in communities with polyvinyl chloride reduction facilities. Conference on Occupational Carcinogenesis, New York Academy of Sciences, March 24-27, New York, 1975.

Deciduous molar relations in U.S. preschool children. International Association for Dental Research, 53rd General Session, New York, April 5-8, 1975.

Evaluation of nutritional practices on dental development. Bi-annual Staff Development Program, Ohio Department of Health, June 18, 1975.

Carcinogenic, mutagenic and teratogenic risks associated with vinyl chloride. Symposium on New Developments in Mutagenicity Testing of Environmental Chemicals, Zinkovy Castle, Czechoslovakia, October 13-17, 1975.

Evidence for the carcinogenicity of beryllium. International Conference on Heavy Metals in the Environment, Toronto, October 27-31, 1975.

Childhood tumors and blood dyscrasias associated with exposure to chlordane. Conference on Perinatal Carcinogenesis, Tampa, January 19-21, 1976.

Qualitative extrapolation from laboratory assay to humans as seen through the carcinogenicity, mutagenicity or teratogenicity of vinyl chloride and anesthetic gases. Conference on Problems of Extrapolating the Results of Laboratory Animal Data to Man and Extrapolating Results From High Dose Level Experiments to Low Dose Level Exposures, Pinehurst, North Carolina, March 10-12, 1976.

Interrelations of distocclusion and general somatic growth. International Association for Dental Research 54th General

Session, Miami, March 25-28, 1976.

Epidemiologic approaches and assessments for determining carcinogenic and mutagenic hazards to humans. Workshop on Basic Practical Approaches to Environmental Mutagenesis and Carcinogenesis, Dushenbe, Soviet Union, April 6-8, 1976.

Blood Disease, childhood tumors and exposure to chlorinated hydrocarbon pesticides. Conference on Women and the Workplace, Washington, D.C., June 17-19, 1976.

Reproductive effects associated with lead exposure. Conference on Women and the Workplace, Washington, D.C., June 17-19, 1976.

Mutagenic, cytogenetic and reproductive effects of lead. Workshop on Lead Metabolism and Toxicity, Environmental Sciences Laboratory, Mount Sinai School of Medicine, New York, August 5, 1976.

Clinical diagnosis and causes of death for subjects with beryllium disease. International Conference on Health Hazards in Metal-working Industries, Oslo, Norway, Aug. 16-19, 1976.

Chloroprene: Observations of carcinogenesis and mutagenesis. Meeting on the Origins of Human Cancer, Cold Spring Harbor, New York, Sept. 1-14, 1976.

Vinyl chloride and anesthetics. Special case study. Course on Genetic Toxicology, University of Texas Medical Branch, Galveston, Texas, Sept. 20-24, 1976.

Occupational hazards: Do they extend beyond plant boundaries? Air Pollution Control Association Meeting on Toxic Substances in the Air Environment, Cambridge, Mass., Nov. 8 and 9, 1976.

Mutagenic effects of certain industrial chemicals. Stockholm University, Stockholm, Sweden, Nov. 18, 1976.

Carcinogenic, mutagenic and teratogenic risks associated with exposure to vinyl chloride. Graduate Seminars on the Environment, U.S. Environmental Protection Agency, Cincinnati, Ohio, Jan. 21, 1977.

Women and the plastics and rubber industries. Conference on Women in the Workplace, Oakland, Calif., March 24 and 25, 1977.

Exposure to vinyl chloride and pregnancy outcome. Expert Conference on Genetic Damage in Man Caused by Environmental

Agents, Oslo, Norway, May 11-13, 1977.

Epidemiologic approaches for surveillance of genetic hazards with particular reference to anesthetic gases. Expert Conference on Genetic Damage in Man Caused by Environmental Agents, Oslo, Norway, May 11-13, 1977.

Health risks associated with halogenated olefins besides vinyl chloride. Conference on Metabolism and Toxicity of Vinyl Chloride Related Compounds, National Institutes of Health, Bethesda, Maryland, May 2-4, 1977.

The role of occupational factors in oral and pharyngeal cancers. International association for Dental Research 55th General Session, Las Vegas, Nevada, June 23-26, 1977. Extrapolation from experimental test systems for evaluation of genetic risks in man. Second International Conference on Environmental Mutagens, Edinburgh, Scotland, July 11-15, 1977.

Embryotoxic and teratogenic effects of industrial chemicals with particular reference to anesthetic gases. Second International Course in Industrial Toxicology, Helsinki, Finland, August 8-13, 1977.

Epidemiologic approaches for surveillance of genetic or reproductive hazards associated with the occupational setting. Second International Course in Industrial Toxicology, Helsinki, Finland, August 8-13, 1977.

The use of laboratory bioassay for regulatory control of carcinogens and mutagens. Second International Course in Industrial Toxicology, Helsinki, Finland, August 8-13, 1977.

Genetic Hazards of anesthetic gases, epidemiologic study, prevention and extrapolation from experimental test systems. European Society of Human Genetics, Oslo Symposium: Clinical Genetics, May 14-15, 1977.

Case studies of occupationally related reproductive hazards. Workshop on Occupationally Induced Reproductive Toxicology, October 3-5, 1977, Washington, D.C.

Benzene, Government Overview. Environmental Cancer--Report to the Public, Houston, Texas, October 12-13, 1977.

Special case studies of mutagenic chemicals associated with adverse reproductive function. Second Annual Course in the Principles of Practice of Genetic Toxicology, University of

Texas, Galveston, Texas, October 24-28, 1977.

Cancer and respiratory disease risk among individuals in the Beryllium Case Registry. Conference on Occupational Exposures to Fibrous and Particulate Dust and Their Extension into the Environment, Society for Occupational and Environmental Health, December 4-7, 1977, Washington, D.C.

Case studies of agents associated with adverse effects on reproduction: Chloroprene. Workshop on Methodology for Assessing Reproductive Hazards in the Workplace, National Institute for Occupational Safety and Health and Society for Occupational and Environmental Health, April 9-22, 1978, Washington, D.C.

Principles and methods for detecting chemical mutagens -- Epidemiologic approaches. First Industrial Workshop in Chemical Mutagens, Environmental Mutagen Society, May 22-25, Hunt Valley, Maryland, 1978.

Occupational health standards for high risk groups.. Conference on Pollutants and High Risk Groups, University of Massachusetts, Amherst, Massachusetts, June 5-6, 1978.

OSHA's responsibility in cancer prevention: An update on the cancer hearings. New York Committee for Occupational Safety and Health, New York, June 24, 1978.

Occupational factors in embryotoxicity and teratogenicity. Current problems in the toxicology of beryllium. Extrapolation of experimental test results to man. Hygienic standards for occupational exposure to chemical agents: OSHA's new carcinogen policy. Above papers presented at Third Advanced Course in Industrial Toxicology, Institute of Occupational Health, Helsinki, Finland, August 7-12, 1978.

Special case studies of agents that cause genetic damage. Course on Principles and Practices of Genetic Toxicology, University of Texas Medical Branch, Galveston, Texas, October 27, 1978.

Risk estimates and regulatory aspects of mutagenicity study. Course on Principles and Practices of Genetic Toxicology, University of Texas Medical Branch, Galveston, Texas, October 27, 1978.

Genetic risk assessment, Second Annual Industrial Workshop in Chemical Mutagens: Principles and Methods of Detection.

University of Texas Medical Branch, Hunt Valley Inn, Maryland, May 7, 1979.

Toxic substances and risks to future generations. Management of Toxic Substances in the Workplace Symposium, Rutgers Medical School, Piscataway, New Jersey, May 9, 1979.

Chemicals and the unborn. Kanawha Valley Occupational and Environmental Health Conference, West Virginia State College, June 1-2, 1979.

The scientific case and social need for the establishment of a generic cancer policy. American Society of Safety Engineers, San Francisco, June 11-12, 1979.

Future generations: Reproductive health. "Lost in the Workplace: Is there an Occupational Disease Epidemic? Chicago, Sept. 13-14, 1979.

Evidence for the carcinogenicity of selected halogenated hydrocarbons including ethylene dichloride. Cold Spring Harbor Laboratory, New York, November 14-17, 1979.

Observations of the site specific carcinogenicity of vinyl chloride to humans. Conference to reevaluate the toxicity of vinyl chloride, polyvinyl chloride and structural analogues. National Institutes of Health, March 20-21, 1980.

OSHA's Cancer Policy. Ford UAW Health and Safety Meeting, Detroit, November 11, 1980.

Benzene: Epidemiologic observations of leukemia by cell type, related blood abnormalities and adverse effects from low level exposure. Second Annual Symposium on Environmental Epidemiology, University of Pittsburgh, School of Public Health, April 27-29, 1981.

Epidemiologic methods for the identification of cancer risk in the industrial setting.

Carcinogenic risks of polyvinyl chloride.

Benzene and Cancer.

The Carcinogenesis of beryllium: A case study.

Extrapolation from experimental studies to humans.

OSHA's Cancer Policy.

All of the above papers presented at International Course on Occupational Cancer, Helsinki, Finland, August 6-15, 1979.

Epidemiological aspects of environmental mutagenesis and

carcinogenesis. City University, Puebla, Mexico, June 9-11, 1980.

Experimental and epidemiologic evidence of the carcinogenicity of chloromethanes and chloroethanes. Conference on The Genotoxic Effects of Airborne Agents, Brookhaven National Laboratory, Feb. 9-11, 1981.

Anesthetic gases and pregnancy.

Environmental causes in reproductive problems: Clues to prevention. Above papers presented at International Course on Occupational Hazards and Reproduction, Helsinki, Finland, August, 1981.

Science in health policy and decision making. University of California at Berkeley, June 5, 1981.

Risk assessment of reproductive hazards. Interagency Regulatory Liaison Group Workshop on Reproductive Toxicity Risk Assessment. NIH, Sept. 21-23, 1981.

A case history of the evidence for carcinogenicity of vinyl chloride. Canadian Cancer Society Workshop on Carcinogens in the Workplace. Toronto, Oct. 26-27, 1981.

Testimony at U.S. Consumer Product Safety Commission Hearing on Proposed Regulation for Urea Formaldehyde Foam Insulation. Washington, D.C. March 20, 1981.

Testimony Before the Hazardous Products Board of Review Concerning the Nature and Characteristics of Urea Formaldehyde Based Thermal Insulation, Foamed in Place, Used to Insulate Buildings. Hull, Quebec, Nov. 12, 1981.

The contribution of occupation to environmental cancer. American Public Health Association 110th Annual Meeting, November 14-18, 1982, Montreal.

Policy implications of occupational reproductive studies. American Public Health Association 110th Annual Meeting, November 14-18, 1982, Montreal.

Case study: Benzene. NIH Graduate School, December 12, 1982, Bethesda, Md.

Future procedures for human monitoring: Non-traditional end points. Environmental Mutagen Society Satellite Meeting, March

1-2, 1983, San Antonio, Texas.

Benzene and leukemia: An evaluation of epidemiologic studies. Course on Environmental Epidemiology, Columbia University, April 13, 1983.

Vinyl chloride. Canadian Cancer Society International Conference on Cancer in the Workplace, May 16-18, 1983, Vancouver, B.C.

Carcinogenic effects of industrial exposures to benzene. Subcommittee on Environmental Mutagenesis, DHHS meeting on Review of the Genetic Toxicology and General Toxicology of Benzene, NIH, May 6, 1983.

Projections of leukemia risk associated with occupational exposure to benzene. Collegium Ramazzini International Conference on Benzene, New York, November 3-4, 1983.

An evaluation of the epidemiologic studies related to beryllium exposures. Course on Environmental Epidemiology, Columbia University, March 28, 1984.

Regulation of benzene. Course on Toxic Substances Policy, NIH Graduate School, December 18, 1984.

Adverse health effects of some toxic air pollutants at chemical plants in the Kanawha Valley. Testimony before the Committee on Energy and Commerce, Subcommittee on Health and the Environment, United States Congress. Institute, W.Va., December 14, 1984.

Risk assessment on benzene. Collegium Ramazzini meeting on Risk Assessment of Benzene, New York, March 12-13, 1985.

Toxic effects of poison gases and other hazardous air pollutants from chemical plants. Testimony at joint hearing: Subcommittee on Health and the Environment and Subcommittee on Commerce, Transportation and Tourism. United States Congress, Washington, D.C. March 26, 1985.

Assessment of Risk Associated with Occupational Exposure to Benzene. Medical College of Virginia, Richmond, November 20, 1985.

Recent Laboratory Studies in Chemical Carcinogenesis: Benzene. Collegium Ramazzini Meeting on Living in a Chemical World, Bologna, Italy, October, 1985.

Risk Assessment in the Federal Government (OSHA), 7th Annual

Meeting of the American College of Toxicology, "Frontiers in Toxicology" Philadelphia, Pa., November 16-19, 1986.

Occupational Cancer. Uniformed Services University of the Health Sciences, Naval Medical Command, Bethesda, Md., December 8, 1986.

Occupational Cancer and Regulation. Department of Epidemiology, Johns Hopkins University, March 16, 1987.

Living in a Chemical World. Plenary Session: Pathology in a Changing World; 25th Anniversary, The Royal College of Pathologists, London, England, Sept., 8-11, 1987.

Dose Response in Occupational Mortality Studies. American Public Health Association Meeting, New Orleans, La., Oct. 18-22, 1987.

Testimony on OSHA Standard Setting. Committee on Labor and Human Resources, United States Senate, April 19, 1988.

Occupational Exposure to Benzene: Some Aspects of the OSHA Final Rule. American Industrial Hygiene Conference, San Francisco, Calif., May 15-21, 1988.

Exposure Assessment and Dose Response in the Evaluation of Occupational Mortality Studies. 6th International Symposium on Epidemiology in Occupational Health, Stockholm, Sweden, Aug. 15-18, 1988.

The Policy/Politics of the OSHA Benzene Standard. Johns Hopkins University, School of Public Health, Baltimore, Md., November 21, 1988.

Benzene Risk Assessment. Uniformed Services University of the Health Sciences, Naval Medical Command, Bethesda, Md. Jan. 9, 1989.

Dose Response in the Evaluation of Occupational Cancer Mortality Studies. American Industrial Hygiene Conference, St. Louis, Mo. May 22-26, 1989.

A Data Source Related to Occupational Exposure. American Industrial Hygiene Conference, St. Louis, Mo., May 22-26, 1989.

Benzene and Cancer: Epidemiology, Risk Assessment and Public Policy. University of Pennsylvania, School of Medicine, June 22, 1989.

Testimony at hearing on the Re-authorization of the Paperwork

Reduction Act. Legislation and National Security Subcommittee, Committee on Government Operations, U.S. Congress. July 27, 1989.

OSHA Health Standards. Martin Marietta Safety and Health Management Conference, Cocoa Beach, Fla., Sept., 19, 1989.

The OSHA Regulatory Agenda for Health and Safety Standards. American Public Health Association Meeting, Chicago, Ill., Oct. 22, 1989.

Advantages and Disadvantages in Risk Assessment Methodologies. Johns Hopkins University, School of Public Health, Baltimore, Md., July 3, 1990.

Health Effects of Gasoline Vapors: Benzene. Risk Assessment Forum Colloquium on Exposure to Gasoline Vapor from Underground Storage Tanks, Environmental Protection Agency, Washington, D.C., September 13, 1990.

Animal Cancer Testing. The Diane Rehm Show on 88.5 FM, The American University, September 28, 1990.

Exposure Assessment and Dose Response in Occupational Epidemiology Studies: The Correct Interpretation?, Division of Occupational and Environmental Medicine, George Washington University, Washington, D.C., September 25, 1990.

The 0.1 ppm ACGIH proposed TLV for benzene. Presented before the ACGIH Committee, Cincinnati, Ohio, March 21, 1991.

Prevention versus chemophobia: Testing for carcinogens with rodents. American Industrial Hygiene Conference and Exposition, Salt Lake City, May 21, 1991.

Risk assessment and regulation, Johns Hopkins University, School of Public Health, Baltimore, Md., June 27, 1991.

Panel on state of the science on epidemiologic studies related to workers exposed to gasoline vapors. At International Symposium on the Health Effects of Gasoline, Miami, Fla., November 5-8, 1991.

Prevention or chemophobia: Use of rodent studies for identifying carcinogens and estimating cancer risk. American Public Health Association Annual Meeting, Atlanta, Ga., November 10-14, 1991.

Use of cell proliferation data in cancer risk assessment: U.S regulatory views: OSHA. Presented at An International Symposium

on Cell Proliferation and Chemical Carcinogenesis, National Institutes of Environmental Health Sciences, Research Triangle Park, N. Carolina, January 14-16, 1992,

Panel discussion on implications of using alternative methods of assessing exposures for risk assessments, Committee on Risk Assessment Methodology, Workshop on Single Scenario and Population Distribution Estimates of Exposure: Applications and Implications in Risk Assessments, National Academy of Sciences, Washington, D.C., February 10-11, 1992.

Seminar on scientific basis for occupational regulations, University of Lowell, Lowell Massachusetts, May 8, 1992.

How does exposure information in epidemiologic studies contribute to the process of regulation or risk assessment? Workshop on Retrospective Exposure Assessment in Occupational Epidemiology. National Institute for Occupational Safety and Health, Cincinnati, Ohio, September 22, 1992.

Seminar on the development of OSHA standards for toxic substances in the workplace. Harvard University, Boston, January 22, 1993.

Estimates of cancer risk related to occupational cadmium exposure. American Industrial Hygiene Conference & Exposition, New Orleans, Louisiana, May 15-21, 1993.

OSHA evaluation of carcinogenic risk among workers exposed to formaldehyde. Eighth Annual Toxicology Symposium, Ashville, NC, August 3, 1993.

A historical perspective of some occupationally related diseases of women. Women's Health:Occupation and Cancer Conference sponsored by the National Cancer Institute, Baltimore, Maryland, November 1, 1993.

Issues related to lung cancer and other cancers among industrially exposed workers. Presented before the President's Cancer Panel, Tysons Corner, Virginia, October 5, 1994.

Evaluation of carcinogenicity studies of workers exposed to beryllium. Conference on beryllium related diseases. National Institute of Environmental Health Sciences, Research Triangle Park, N.C., November 8-10, 1994.

Medical and ethical issues related to chronic beryllium disease--OSHA's view of genetic screening. National Institute of Environmental Health Sciences, Research Triangle Park, N.C.,

November 8-10, 1994.

Need for study of occupation and cancer through Cancer Registries. National Program of Cancer Registries Meeting on Occupation, Industry and Cancer Registration, Miami, Fla., June 18, 1995.

Fire Fighters' Occupational Health: Who does care? Presented at 13th Symposium on the Occupational Health and Hazards of the Fire Service, San Francisco, Calif., August 31, 1995.

OSHA's Regulatory Agenda. Harvard School of Public Health, Boston, January 5, 1996.

Benzene exposure and the real risk of leukemia: An American overview. Meeting of the Association of Brazilian Industrial Hygienists, Sao Paulo, Brazil, September 2-5, 1996.

Exposure assessment and dose response for industrial carcinogens. Meeting of the Association of Brazilian Industrial Hygienists, Sao Paulo, Brazil, September 2-5, 1996.

Cancer risk to blue collar workers. Meeting of the Association of Brazilian Industrial Hygienists, Sao Paulo, Brazil, September 2-5, 1996.

Quantitative risk of leukemia/lymphoma from occupational benzene exposure. The Toxicology Forum 22nd Annual Meeting, Washington, D.C., February 24-27, 1997.

Benzene and multiple myeloma. Collegium Ramazzini 3<sup>rd</sup> International Scientific Conference, Framing the Future in Light of the Past: Living in a Chemical World, Bologna, Italy, Sept. 18-21, 2005.

Childhood leukemia and low level atmospheric exposure to benzene and other aromatic hydrocarbons. Presented at meeting on Benzene, Childhood Leukemias and Hematopoietic and Lymphoreticular Cancers sponsored by the Collegium Ramazzini and Mount Sinai School of Medicine, New York, NY, June 28, 2012.